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Technical Guidance on the Requirements of the *Hazardous Products Act* and the *Hazardous Products Regulations*

WHMIS 2015 Supplier Requirements

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Section A

Introduction

WHMIS Overview

The Workplace Hazardous Materials Information System (WHMIS) is a national information system designed to protect Canadian workers by providing safety and health information about hazardous workplace materials. The key elements of the system are hazard classification, hazard communication through cautionary labelling of containers and the provision of safety data sheets (SDSs), and worker education and training programs.

WHMIS is implemented through coordinated federal, provincial, and territorial (FPT) legislation. Federal legislation related to WHMIS supplier requirements consists of the:

- *Hazardous Products Act* (HPA)
- *Hazardous Products Regulations* (HPR)
- *Hazardous Materials Information Review Act* (HMIRA)
- *Hazardous Materials Information Review Regulations* (HMIRR)

The purpose of this technical document is to provide guidance on the requirements of the HPA and the HPR to suppliers of hazardous products destined for Canadian workplaces. A supplier is defined in the HPA as "…a person who, in the course of business, sells or imports a hazardous product." This guidance also provides suppliers with information on the HMIRA and its regulations and the mechanism to protect confidential business information (CBI) while still disclosing critical hazard information to workers.

The HPA provides Health Canada with the authority to regulate the sale and importation of hazardous products intended for use, handling or storage in Canadian workplaces. The HPR sets out the hazard classification and hazard communication requirements. The HMIRA and its associated regulations allow CBI to be protected and set out the process for filing a claim for exemption. Additional information on the HMIRA and CBI can be found in Appendix A of this document.

The Workplace Hazardous Materials Bureau (WHMB) in Health Canada administers the HPA and HMIRA. Health Canada's responsibilities under WHMIS are to:

- Administer and provide guidance to suppliers on the requirements of the HPA, HMIRA and their associated regulations
- Collaborate with FPT occupational health and safety (OHS) agencies on WHMIS implementation
- Represent Canada in international meetings, such as meetings of the United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS)
- Collaborate with the United States Occupational Safety and Health Administration (U.S. OSHA) on the development and implementation of hazard classification and hazard communication requirements

The employer and worker requirements of WHMIS are not the focus of this document. Each of the thirteen provincial and territorial agencies responsible for occupational health and safety has established employer WHMIS requirements within their respective jurisdictions. The Labour Program at Employment and Social Development Canada is responsible for workplaces under federal jurisdiction. For further information on employer WHMIS requirements, contact the occupational health and safety agency in your jurisdiction. Specific WHMIS requirements for any jurisdiction can also be found at WHMIS.org. This site is Canada's portal to WHMIS information for all WHMIS stakeholders, including suppliers, employers, workers and trainers.

Further Information

NOTES: In case of discrepancy between this document and the Acts or Regulations, the official versions of the Acts or Regulations will prevail.

This document contains references to legislation and guidance pertaining to other Competent Authorities e.g., U.S. OSHA's Hazard Communication Standard 2012 (U.S. OSHA HCS 2012). These references are often made for comparative purposes and, in that context, are based on Health Canada's understanding of the legislation and guidance. For compliance purposes and additional information regarding the legislation and guidance from other Competent Authorities referred to in this document, readers should consult the relevant Competent Authority. Specific questions or comments regarding this guidance, including WHMIS and implementation of the GHS for workplace chemicals in Canada can be directed to Health Canada: WHMIS_SIMDUT@hc-sc.gc.ca

Additional information can be found online:

- Health Canada http://www.whmis.gc.ca/
- *Hazardous Products Act* (HPA), *Hazardous Products Regulations* (HPR), *Hazardous Materials Information Review Act* (HMIRA), and *Hazardous Materials Information Review Regulations* (HMIRR)

Structure of the Technical Guidance on the Requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR) – WHMIS 2015 Supplier Requirements

The Technical Guidance on the Requirements of the HPA and HPR – WHMIS 2015 Supplier Requirements includes the following sections:

Section A: Introduction

Section B: Requirements of the *Hazardous Products Act*

Outlines the statutory requirements for suppliers under the amended HPA and HMIRA

Section C: Regulatory Requirements

Provides comprehensive information concerning the supplier requirements for WHMIS 2015. Section C is divided into eight distinct parts, which are identical to the Parts of the HPR:

Part 1 - Interpretation
Part 2 – Classification of a Product, Mixture, Material or Substance
Part 3 - Labelling
Part 4 - Safety Data Sheet
Part 5 - Exceptions
Part 6 - Additional Requirements
Part 7 - Physical Hazard Classes (includes chapters for each of the physical hazard classes in the HPR)
Part 8 - Health Hazard Classes (includes chapters for each of the health hazard classes in the HPR)

Appendix A: Confidential Business Information

Provides comprehensive information on the claim for exemption process, which protects certain information from disclosure, pursuant to the HMIRA and HMIRR.

Generally, the structure of the Technical Guidance includes each statutory or regulatory requirement followed by a discussion of the particular requirement, including examples where appropriate. The requirements for the HPA and HMIRA are highlighted in green boxes while the HPR requirements are highlighted in blue boxes. Variances between Canada and the U.S. are highlighted in orange boxes. These key variances are necessary in order to maintain the current level of protection for workers or due to the requirements of the respective legislative frameworks.

GHS Implementation in Canada and WHMIS 2015

On February 11, 2015, the Government of Canada published the HPR, which, in addition to the amendments made to the HPA, modified WHMIS 1988 to incorporate the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This modified WHMIS is referred to as WHMIS 2015. The HPR is based on the building blocks of the fifth revised edition of the GHS. With the incorporation of the GHS, the hazard classification and communication requirements of WHMIS are aligned with the workplace hazard classification and communication requirements of the U.S. and other Canadian trading partners. It is possible to meet both Canadian and U.S. hazard communication requirements for a hazardous product using a single label and SDS.

Suppliers need to be aware of the new requirements and changes to previous requirements when selling or distributing products in Canada. The purpose of this document is to inform suppliers of these requirements. The following is a summary of the key changes to WHMIS:

- Principles used to classify a substance or mixture as a hazardous product
- Physical and health hazard classes and classification criteria

- Format and content requirements for labels and SDS
- Labelling and SDS exemptions for suppliers

As an integrated hazard communication system, the key objectives of the GHS are:

- To increase worker protections through the adoption of an improved, globally recognized standard for communicating the hazards associated with workplace hazardous chemicals;
- To facilitate trade through common labelling and other hazard communication requirements; and
- To lower costs for businesses and consumers by reducing the need for retesting and reclassifying workplace hazardous chemicals from, or for, different markets.

The GHS covers all hazardous substances and mixtures and applies to all potential exposures to all hazardous chemicals in all types of situations, including production, storage, transport, workplace use, consumer use and in the environment. The GHS (commonly referred to as "The Purple Book") standardizes the criteria for classifying chemicals according to their health, environmental and physical hazards, and standardizes the hazard communication requirements for labelling and SDSs. The GHS guidance is updated and revised every two years.

The GHS includes three groups of hazards:

- Physical Hazards (which represent hazards relating to physical and chemical properties): All GHS physical hazard classes except the Explosives hazard class have been adopted in Canada through the HPR. In addition, the following new physical hazard classes have been introduced through the HPR to enhance protections for workers: Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, and Physical Hazards Not Otherwise Classified.
- Health Hazards (which represent hazards to health arising from exposure to a substance or mixture): All GHS health hazard classes have been adopted in Canada in the HPR. The Biohazardous Infectious Materials hazard class (which is not a GHS health hazard class) from WHMIS 1988 has been retained in the HPR in order to maintain worker protection, and a new Health Hazards Not Otherwise Classified hazard class has been introduced.
- Environmental Hazards (which represent hazards to the environment): The GHS environmental hazard classes have not been adopted in the HPR.

While WHMIS 2015 includes new harmonized criteria for hazard classification and communication requirements for labels and SDSs, the roles and responsibilities for suppliers, employers and workers have not changed. Employers and workers should consult their occupational health and safety jurisdiction for information on their obligations and WHMIS requirements.

Supplier Obligations

Canadian suppliers of hazardous products must comply with the requirements of the HPA and the HPR, as administered by Health Canada. Importers of hazardous products used directly in their own workplace are also governed by this legislation.

Canadian suppliers of hazardous products are required to:

- Identify whether their products are hazardous products;
- Prepare or obtain bilingual labels and SDSs ;
- Affix a label to a hazardous product and provide the SDS to the purchaser of a hazardous product;
- Prepare and maintain documents, including copies of labels and SDSs, as well as sales and purchasing information, and provide these documents to the Minister or an inspector on request;
- Update SDSs and labels within 90 and 180 days, respectively, of a supplier becoming aware of "significant new data" (i.e., information which changes the classification of the hazardous product or ways to protect against the hazards presented by the product); and
- Disclose any information required to appear on an SDS to a safety or health professional, in an emergency.

With the exception of CBI claims administered under the HMIRA, there is no pre-market approval mechanism or registration requirement under the HPA.

Exclusions

The WHMIS supplier hazard communication requirements do not apply to certain products sold or imported for use, handling or storage in Canadian workplaces.

The exclusions to supplier requirements under the HPA and HPR are:

- Explosives as defined in the *Explosives Act*
- Cosmetics, devices, drugs or foods, as defined in the *Food and Drugs Act*
- Pest control products as defined in the *Pest Control Products Act*
- Consumer products as defined in the *Canada Consumer Product Safety Act*
- Wood or products made of wood
- Nuclear substances within the meaning of the *Nuclear Safety and Control Act*, that are radioactive
- Hazardous waste being a hazardous product that is sold for recycling or recovery and is intended for disposal
- Tobacco and tobacco products as defined in the *Tobacco Act*
- Manufactured articles

Comparison to Transportation of Dangerous Goods

The federal *Transportation of Dangerous Goods Act* (TDG Act) is not the same as the WHMIS legislation. The TDG Act protects the general public from hazards associated with transporting dangerous materials on public roads, in the air, by rail, or on waterways. In contrast, WHMIS protects the health and safety of workers at workplaces by requiring that product hazard

information be provided to employers and workers to promote the safe handling and use of these products in the workplace. The two systems often deal with the same chemicals, but the TDG Act addresses their transport and WHMIS addresses their use, handling, and storage in workplaces.

Canada-U.S. Cooperation under the Regulatory Cooperation Council

Adopting the GHS fulfills the Canada-U.S. Regulatory Cooperation Council (RCC) commitment to align and synchronize implementation of common classification and labelling requirements for workplace hazardous chemicals. Consistent with the overall objectives of the RCC and as part of the Canada-U.S. RCC Joint Forward Plan, Health Canada continues to collaborate with U.S. OSHA to promote ongoing alignment of hazard classification and communication requirements for workplace chemicals, without reducing the level of safety or of protection to workers.

Through adoption of the GHS, it is possible to meet both Canadian and U.S. requirements for a hazardous product using a single label and SDS. Health Canada and U.S. OSHA collaborated to keep the variances between the two countries to a minimum. However, there are some regulatory variances between the two countries that are necessary in order to maintain the previous level of protection for workers or due to the requirements of the respective legislative frameworks.

Variances between the HPR and U.S. OSHA's HCS 2012 are discussed throughout this document and are highlighted in orange boxes . Some of the key variances include the Canadian requirements for:

- Bilingual labels and SDSs
- Updating information on labels and SDSs when suppliers becomes aware of significant new data
- A Canadian supplier identifier on the label and SDS
- Label elements for a mixture containing a Category 2 carcinogen at a concentration between 0.1% - 1.0%
- Label elements for Physical Hazards Not Otherwise Classified and Health Hazards Not Otherwise Classified
- Including the Biohazardous Infectious Materials hazard class from WHMIS 1988
- Label elements for Water Activated Toxicants
- Labels on multi-container shipments and kit outer containers
- Labels for Combustible Dusts

Canada and the U.S. have each agreed to accept the additional information required by the other. It is therefore possible to meet both Canadian and U.S. requirements for a hazardous product using a single label and SDS. Such labels and SDSs would have to meet the requirements for each country. It is important to note, however, that an SDS and label that are compliant with the HCS 2012 may not be sufficient for compliance in Canada; suppliers selling or importing hazardous products to Canadian workplaces must be compliant with the Canadian requirements.

Transition Timelines to WHMIS 2015

To give suppliers, employers and workers time to adjust to the requirements under WHMIS 2015, the implementation of WHMIS 2015 will take place over a three-stage transition period that is synchronized nationally across federal, provincial and territorial jurisdictions. This transition approach is similar to the approach adopted by U.S. OSHA to implement the HCS 2012.

Phase 1: From February 11, 2015 until May 31, 2017, suppliers (manufacturers and importers) can use WHMIS 1988 or WHMIS 2015 to classify and communicate the hazards of their products. Suppliers must use a label and (material) safety data sheet ((M)SDS) for each hazardous product that either fully comply with the requirements of WHMIS 1988 or WHMIS 2015, but not a combination of the two.

Phase 2: Beginning June 1, 2017 and continuing until May 31, 2018, distributors can continue to sell, and suppliers importing for their own use, can continue to import hazardous products with labels and (M)SDSs that are compliant with WHMIS 1988 or WHMIS 2015. During this phase, all other suppliers are required to comply with WHMIS 2015 requirements.

Phase 3: Beginning June 1, 2018 and onward, manufacturers, importers and distributors are required to sell or import only those hazardous products that are compliant with WHMIS 2015. At this point, transition to WHMIS 2015 is complete for manufacturers, importers and distributors. Beginning June 1, 2018 and continuing until November 30, 2018, employers may use controlled products or hazardous products that comply with either WHMIS 1988 or WHMIS 2015. Beginning December 1, 2018 (FPT OHS jurisdictions may have variations to the end of transition date), all hazardous products in the workplace must comply with WHMIS 2015. Employer requirements fall under FPT OHS jurisdiction. Requirements may vary – consult your local jurisdiction for their WHMIS requirements and transition timelines.

Phase	Timing	Suppliers		
		Manufacturers and Importers	**Distributors**	**Employer***
Phase 1	From February 11, 2015 to May 31, 2017	WHMIS 1988 or WHMIS 2015	WHMIS 1988 or WHMIS 2015	WHMIS 1988 or WHMIS 2015*
Phase 2	From June 1, 2017 to May 31, 2018	WHMIS 2015	WHMIS 1988 or WHMIS 2015	WHMIS 1988 or WHMIS 2015*
Phase 3	From June 1, 2018 to November 30, 2018	WHMIS 2015	WHMIS 2015	WHMIS 1988 or WHMIS 2015*
Completion	December 1, 2018	WHMIS 2015	WHMIS 2015	WHMIS 2015*

*Requirements may vary - consult your local jurisdiction for their WHMIS requirements and transition timing. Specific WHMIS requirements for any jurisdiction can be found at WHMIS.org.

Section B

Hazardous Products Act

Interpretation

The *Hazardous Products Act* (HPA) is divided into Parts I, II, and III. Part I of the HPA was repealed in 2010 with the enactment of the *Canada Consumer Product Safety Act*. The definitions in section 2 of the HPA apply to Parts II and III. In addition, the terms defined by the HPA retain that meaning in the *Hazardous Products Regulations* (HPR).

Discussion of the *Hazardous Products Act*
Section 2

> **"analyst"** means an individual designated as an analyst under subsection 21(1);

As specified in subsection 21(1) of the HPA, the Minister of Health may designate an "analyst" for the purposes of any provision of the HPA or of the HPR. An analyst can be any individual or class of individuals who, in the Minister's opinion, is qualified to be so designated. However, if the individual is employed by a provincial government, or a public body established under an Act of the legislature of a province, the Minister may make the designation only after obtaining the approval of that government or public body.

> **"container"** includes a bag, barrel, bottle, box, can, cylinder, drum or similar package or receptacle but does not include a storage tank;

Although the definition of "container" specifically excludes storage tanks, it is an inclusive definition. Therefore, a "container" under the HPA is not limited to the items specifically listed in the definition. Dictionary definitions of the term "container" refer to:

- "an object (such as a box or can) that can hold something",
- "a receptacle for holding goods",
- "anything that contains or can contain something such as a carton, box, crate or can" or
- "an object used for or capable of holding, especially for transport or storage, such as a carton, box, etc."

Therefore, almost any type of packaging could be considered as a container, including shrink wrap. "Storage tank" is not a defined term in the HPA. However, based on dictionary definitions, this term refers to large containers, vessels or reservoirs that can hold and store liquids or gases. They are usually permanently installed on a work place premises, sometimes underground. Safety requirements pertaining to work place storage tanks fall under the federal, provincial and territorial authority to make occupational safety and health legislation. Storage tanks are not subject to requirements under the HPA. However, if a storage tank is mounted on a truck, it is no longer excluded from the definition of container since it is considered as a portable tank.

Comparison to the U.S. Occupational Safety and Health Administration (OSHA) Hazard Communication Standard 2012 (HCS 2012)

In the HCS 2012, the definition of "container" includes storage tanks. It must be recalled, however, that the U.S. Occupational Safety and Health Administration has responsibility for all aspects of occupational health and safety, so this is analogous to the coverage provided by the federal, provincial and territorial occupational health and safety regulations in Canada.

> **"document"** means anything on which information that is capable of being understood by an individual or being read by a computer or other device is recorded or marked;

The term "document" refers to anything on which information that is recorded or marked can be understood by a human being or can be read by a machine such as letters, numbers and images (symbols) on a paper document or on a microfilm as well as in electronic documents such as an emails, Word, Excel or PDF documents. Electronic documents could be provided on storage devices such as compact discs, USB flash drives or portable hard drives. Under the HPA a "safety data sheet" (SDS) is, by definition, a document.

> **"hazardous product"** means any product, mixture, material or substance that is classified in accordance with the regulations made under subsection 15(1) in a category or subcategory of a hazard class listed in Schedule 2;

Under the HPA, a "hazardous product" is a product, mixture, material or substance that is classified according to the criteria set out in the HPR in at least one category or subcategory of the health hazard or physical hazard classes that are listed in Schedule 2 of the HPA. The HPR are currently the only regulations made under subsection 15(1) of the HPA.

There are four important terms used in this definition: product, mixture, material and substance (also referred to as PMMS).

- The terms "mixture" and "substance" are defined in the HPA (see below).
- The term "material" is not defined in the HPA, but under the HPR, it is generally used in the context of Biohazardous Infectious Materials.
- The term "product" is not defined, but is used in the HPR in sections relating to physical hazard classes such as Flammable Aerosols and Gases Under Pressure, where the packaging of the mixture, material or substance, as well as the contents of the packaging, must be considered for the purpose of classification. That is, a mixture, material or substance in its package is considered to form a product and it is the overall product that is classified.

> **"import"** means to import into Canada;

To "import" means to bring into a country from another country. This definition is specific to importation into Canada. A person, who, in the course of business, brings into Canada a hazardous product intended for use, handling or storage in a work place, from a foreign source (i.e., from another country), is importing. The importer, therefore, is a "supplier" under the HPA.

"inspector" means an individual designated as an inspector under subsection 21(1);

As specified in subsection 21(1) of the HPA, the Minister of Health may designate an "inspector" for the purposes of any provision of the HPA or of the HPR. An inspector can be any individual or class of individuals who, in the Minister's opinion, is qualified to be so designated. However, if the individual is employed by a provincial government, or a public body established under an Act of the legislature of a province, the Minister may make the designation only after obtaining the approval of that government or public body.

"label" means a group of written, printed or graphic information elements that relate to a hazardous product, which group is designed to be affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged;

The definition of "label" includes the different means of providing labelling for a hazardous product and different types of characters including letters, numbers and pictograms. The group of required information elements that constitute the label of a hazardous product may be printed directly on the hazardous product i.e., printed on the unpackaged hazardous product or printed directly on the container in which the hazardous product is packaged. The group of required information elements may also be printed on a support, such as self-adhesive paper or a plastic sleeve which are respectively affixed or attached to the container.

Specific details on label requirements can be found in Part 3 of the Technical Guidance. As required by sections 3.4 and 3.5 of the HPR, the required information elements of the label of a hazardous product must be clearly and prominently displayed on a surface that is visible under normal conditions of use, and easily legible without the aid of any device other than corrective lenses.

"manufactured article" means any article that is formed to a specific shape or design during manufacture, the intended use of which when in that form is dependent in whole or in part on its shape or design, and that, when being installed, if the intended use of the article requires it to be installed, and under normal conditions of use, will not release or otherwise cause an individual to be exposed to a hazardous product;

The definition of "manufactured article" is linked to an exclusion found in paragraph 12(i) of the HPA. If an article meets this definition, it is not subject to any requirements under the HPA.

"Normal conditions of use" means the normally expected conditions under which the article is employed for its intended purpose, and excludes the maintenance or repair of the article as well as the mishandling or misuse of the article. To be exposed to a hazardous product means to be exposed to amounts or levels of the hazardous product in a sufficient quantity to pose a hazard. It does not include acute or chronic exposure to minute or trace amounts that do not pose a physical or health risk to workers.

Examples:

An industrial mercury thermometer is a manufactured article. Although it contains a hazardous product, under normal conditions of use, mercury is not expected to be released and a worker would not be exposed to that substance. An industrial mercury thermometer is, therefore, excluded from the requirements of the HPA.

An industrial refrigerator is a manufactured article made up of various components including a system for containing gases under pressure, which are hazardous products. During installation and under normal conditions of use, the gases are not expected to be released and a worker would not be exposed to these gases. An industrial refrigerator is, therefore, excluded from the requirements of the HPA.

An industrial welding rod is **not** a manufactured article, because, although formed to a specific design, during normal conditions of use, it will release hazardous products contained in the rod. Welding rods are, therefore, not manufactured articles, and cannot be excluded from the requirements of the HPA on that basis.

"Minister" means the Minister of Health;

In the HPA and throughout this document, the term "Minister" means the Minister of Health.

"mixture" means a combination of, or a solution that is composed of, two or more ingredients that, when they are combined, do not react with each other, but excludes any such combination or solution that is a substance;

A "mixture" is the result of the combination of at least two different ingredients that do not react with each other. Each ingredient in the mixture must remain present in the same proportion as when it was initially introduced to create the mixture. The ingredients could be liquids, solids or gases.

It is important to clearly identify if the hazardous product that is to be classified is a substance or a mixture. The classification rules in the HPR may be different for a substance versus a mixture. It is important to note that a "complex mixture" is a term defined in subsection 5.6(1) of the HPR.

"person" means an individual or an organization as defined in section 2 of the *Criminal Code*;

As indicated in this definition a "person" can be an "individual", or an organization as defined in section 2 of the *Criminal Code.*

As defined in section 2 of the *Criminal Code*, "organization" means:

(a) a public body, body corporate, society, company, firm, partnership, trade union or municipality, or

(b) an association of persons that

(i) is created for a common purpose,
(ii) has an operational structure, and
(iii) holds itself out to the public as an association of persons;

"prescribed", for the purposes of Part II, means prescribed by regulations made under subsection 15(1), and, for the purposes of Part III, means prescribed by regulations made under section 27;

To date, the only Regulations made under subsection 15(1) of the HPA are the HPR. No regulations have been made under section 27 of the Act. The expression "prescribed by the regulations", should be understood as meaning the same as "as required by the regulations".

Note: The definition of the term "prescribed" appears only in the English version of the HPA. The French version of the HPA uses a different drafting technique to express the same concept.

"review officer" means an individual designated as a review officer under section 26.2;

As specified in section 26.2 of the HPA, the Minister of Health may designate as a "review officer" any individual or class of individuals who, in the Minister's opinion, is qualified to be so designated, for the purposes of reviewing, under section 26.3 of the HPA, ministerial orders made under section 26.1 of that Act.

"safety data sheet" means a document that contains, under the headings that, by virtue of the regulations made under subsection 15(1), are required to appear in the document, information about a hazardous product, including information related to the hazards associated with any use, handling or storage of the hazardous product in a work place;

The HPR set out the requirements for information elements to appear on a safety data sheet (SDS), including headings. These SDS content requirements are designed to provide information on the hazards presented by a hazardous product, as well as precautionary measures that apply to the use, handling and storage of the product. The SDS provides more detailed information about a hazardous product than the label. The requirements for the provision of information on SDSs are set out in Part 4 and Schedule 1 and Schedule 2 of the HPR. As specified in subsection 6.2(1) of the HPR, the information elements provided on an SDS must always be in both official languages of Canada (English and French).

"sell" includes

(a) offer for sale or distribution, expose for sale or distribution, have in possession for sale or distribution or distribute — whether for consideration or not — to one or more recipients, and

(b) make any transfer of possession that creates a bailment or, in Quebec, make any transfer of possession of a movable, for a specific purpose, without transferring ownership, and with the obligation to deliver the movable to a specified person or to return it, such as a transfer by means of a deposit, a lease, a pledge, a loan for use or a contract of carriage;

The definition of "sell" begins with the word "includes", which means that the meaning attributed to the term "sell" by paragraphs (a) and (b) should be understood as being additional to the ordinary meaning of "sell". In paragraph (a) of this definition, in addition to "offer for sale", "expose for sale" and "distribute", the term includes the following: offering, exposing or having in possession a hazardous product for distribution; and having in possession a hazardous product for sale. As a result, the definition of "sell" in section 2 of the HPA captures nine distinct actions, namely:

1. selling – according to the regular meaning of sell;
2. distributing, whether for consideration or not;
3. making any transfer of possession that creates a bailment;
4. offering for sale;
5. offering for distribution;
6. exposing for sale;
7. exposing for distribution;
8. having in possession for sale; and
9. having in possession for distribution.

The definition also specifies that distribution is a form of sale whether the distribution is for consideration or not. Based on this definition, a distribution or give-away of the hazardous product as a sample, prize or a "free" item is, therefore, included in the definition of "sell".

In the context of the HPA, the term "distribute" does not include internal movement of a product within an organization, but does include transfers of a product between independent organizations as well as between separate subsidiaries of a parent corporation, or between a subsidiary and its parent corporation.

The term "consideration" includes money as well as services or goods for exchange without using money (i.e., bartering). The term "recipients" refers to individuals (i.e. human beings), organizations (which includes companies), and governments that receive a hazardous product upon sale or distribution.

Where a hazardous product, such as a laboratory sample, is supplied to a work place by the same entity that operates the work place, the supply of that hazardous product is not governed by the HPA. However, in such circumstances, the provision of safety information to workers falls under federal, provincial and territorial occupational safety and health legislation. On the other hand, where a hazardous product is supplied to a work place by a different entity than the operator of the work place, then the supplier of the hazardous product is "distributing" the said product under the HPA. Consequently, the supplier, in this case, is required to comply with the requirements of the HPA and the HPR.

Paragraph (b) of the definition of "sell" specifies that any transfer of possession that creates a bailment is included in the Act's definition of "sell". A bailed product is a product in relation to which there is a transfer of possession but not ownership (e.g., a laboratory sample sent for analysis or a product provided to a third party for packaging, whereby the third party does not have ownership of the sample or product). It is important to note that when a hazardous product is moved between departments within the same work place of an employer, it is not considered to be a bailment since possession and ownership of the hazardous product remain with the employer.

The scope of the HPR is limited to hazardous products sold or imported in Canada by a supplier. The term "bailment" is a common law concept. However, in civil law, which is a legal system in Canada that prevails only in the province of Quebec, the term "bailment" is not used, but an equivalent concept exists in that province. Therefore, as part of the definition of "sell", it was necessary to describe the equivalent of "bailment" under civil law, i.e., "*in Quebec, make any transfer of possession of a movable, for a specific purpose, without transferring ownership, and with the obligation to deliver the movable to a specified person or to return it, such as a transfer by means of a deposit, a lease, a pledge, a loan for use or a contract of carriage*;".

Paragraph 13(1)(b) of the HPA specifies that no supplier shall sell a hazardous product that is intended for use, handling or storage in a work place in Canada unless the hazardous product or the container in which the hazardous product is packaged has an HPR compliant label affixed to it, printed on it or attached to it in a manner that meets the requirements of the HPR. This requirement applies in each of the nine situations that are encompassed by the definition of "sell" in section 2 of the HPA. Thus, for example, when a supplier sells a hazardous product (according to the regular meaning of sell), or exposes for sale or has in possession for sale a hazardous product that is intended for use, handling or storage in a work place in Canada, the labelling requirement set out in paragraph 13(1)(b) of the HPA must be met.

"substance" means any chemical element or chemical compound — that is in its natural state or that is obtained by a production process — whether alone or together with

(a) any additive that is necessary to preserve the stability of the chemical element or chemical compound,

(b) any solvent that is necessary to preserve the stability or composition of the chemical element or chemical compound, or

(c) any impurity that is derived from the production process;

All naturally occurring and synthetic chemical elements can be found in the Mendeleev periodic table. Examples of naturally occurring chemical elements are calcium (Ca), titanium (Ti), carbon (C), or helium (He). A chemical compound consists of two or more different chemical elements that are associated via chemical bonds e.g., water (H_2O), propane (C_3H_8), acetone ($(CH_3)_2CO$), zinc chloride ($ZnCl_2$), sodium hydroxide (NaOH) or toluene (C_7H_8).

The term "substance" refers, in principle, to a single entity (e.g., toluene, silver nitrate, ammonia). However, the definition of "substance" in the HPA considers that a substance may have small amounts of stabilizing additives, impurities and stabilizing solvents. Impurities, stabilizing solvents, or stabilizing additives may have their own unique hazards and/or may contribute to the hazards of the substance.

Therefore, for the purposes of hazard classification under the HPR, impurities, stabilizing solvents, or stabilizing additives that are, by themselves, classified in a category or subcategory of a health hazard class and that are present in a substance at a concentration above the corresponding concentration limit must be considered for the classification of the substance. Further information can be found in Part 2 of the Technical Guidance.

"supplier" means a person who, in the course of business, sells or imports a hazardous product;

Under the HPA, manufacturers, importers or distributors of a hazardous product, are all considered "suppliers".

The term "manufacturer" is defined in subsection 1(1) of the HPR as follows: "manufacturer" means a supplier who, in the course of business in Canada, manufactures, produces, processes, packages or labels a hazardous product and sells it. For more information about this definition, refer to section C (Part 1) of the Technical Guidance. A manufacturer is different from an importer. An importer is a supplier who brings a hazardous product into Canada, but does not sell the product. If an importer does modify a hazardous product that they imported (for example, by repackaging or relabeling it) and subsequently sells the modified hazardous product, then the importer meets the definition of a "manufacturer" under the HPR.

A manufacturer is also different from a distributor. A distributor is a Canadian supplier to whom a hazardous product was sold, who resells the hazardous product without modifying it in any way. If a distributor does modify a hazardous product that they purchased (for example, by repackaging or relabeling it) and subsequently sells it, then the distributor meets the definition of a "manufacturer" under the HPR.

The HPR includes definitions for the terms "initial supplier identifier" (subsection 1(1)), "first supplier" and "subsequent supplier" (subsection 5.7(1)). Further guidance on these terms can be found in Parts 1 and 5 of this Technical Guidance.

"work place" has the meaning assigned by regulations made under subsection 15(1).

To date, the only Regulations made under subsection 15(1) of the HPA are the HPR. Under the HPR, "work place" is defined in subsection 1 (1) as follows: "means a place where a person works for remuneration." For more information about this definition, refer to section C (Part 1) of the Technical Guidance.

PART II
Hazardous Products

Discussion of the *Hazardous Products Act*
Section 12

Restrictions on Application

12 This Part does not apply in respect of the sale or importation of any

(a) to (c) [Repealed, 2014, c. 20, s. 113]

(d) nuclear substance, within the meaning of the *Nuclear Safety and Control Act*, that is radioactive;

(e) hazardous waste, being a hazardous product that is sold for recycling or recovery or is intended for disposal;

(f) and (g) [Repealed, 2014, c. 20, s. 113]

(h) tobacco or a tobacco product as defined in section 2 of the *Tobacco Act*;

(i) manufactured article; or

(j) anything listed in Schedule 1.

Application

There are certain products that do not fall under the scope of the HPA. The products listed in paragraphs 12(d) through (i) are not subject to requirements under the HPA and HPR.

In addition, the amendments to the HPA in 2014 included the introduction of Schedule 1 to the Act, which is referred to in paragraph 12(j). This Schedule lists excluded items that were previously mentioned in former paragraphs 12 (a), (b), (c), (f) and (g), respectively:

1. Any pest control product as defined in subsection 2(1) of the *Pest Control Products Act*
2. Any explosive as defined in section 2 of the *Explosives Act*
3. Any cosmetic, device, drug or food, as defined in section 2 of the *Food and Drugs Act*
4. Any consumer product as defined in section 2 of the *Canada Consumer Product Safety Act*
5. Any wood or product made of wood

These products do not fall under the scope of the HPA and therefore are not subject to the requirements under the HPA and the HPR. In the future, the products listed in Schedule 1 to the HPA may be considered for inclusion under the HPA following the regular regulatory process.

Paragraph 12(d)
The definition of "nuclear substance" is found under the *Nuclear Safety and Control Act* (NSCA), and includes only the radioactive components of radioactive nuclide mixtures. As a result, non-radioactive hazardous product carrier materials in radioactive nuclide mixtures are subject to the requirements of the HPA. However, there are labelling and SDS exemptions for mixtures of radioactive nuclides and non-radioactive carriers under subsections 5.1(1), 5.1(2) and 5.1(3) of the HPR. Refer to Part 5 of this Technical Guidance for additional information on these exemptions. Note that the HPA labelling requirements for non-radioactive carrier materials for radioactive nuclides are in addition to, and separate from, any labelling requirements for radioactive nuclides under the NSCA.

Comparison to HCS 2012

"Ionizing and nonionizing radiation" are not covered in the HCS 2012.

Paragraph 12(e)
By virtue of paragraph 12(e) of the HPA, hazardous waste is exempt from the requirements of the HPA. While hazardous waste is not a defined term in section 2 of the Act, paragraph 12(e) provides the meaning of this term as follows:

"... being a hazardous product that is sold for recycling or recovery or is intended for disposal."

Some hazardous products are recovered and then either re-used or recycled and then sold as a recycled product with or without further processing. Paragraph 12(e) does not establish an exemption for hazardous products that are recycled and then sold to another work place. Only hazardous waste that is "intended for disposal" or is "sold for recycling or recovery" falls within the definition of hazardous waste and is thereby exempt from the requirements of the HPA.

Comparison to HCS 2012

The HCS 2012 does not cover "hazardous waste" as defined by the *Solid Waste Disposal Act,* as amended by the *Resource Conservation and Recovery Act of 1976*, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

Paragraph 12(h)
The definition of "tobacco product" is found in section 2 of the *Tobacco Act*.

Comparison to HCS 2012

The HCS 2012 does not cover "tobacco or tobacco products".

Paragraph 12(i)
The definition of "manufactured article" in section 2 of the HPA is discussed earlier in this chapter.

A "manufactured article" is excluded from the requirements of the HPA if it meets the conditions stated in the definition. The manufactured article definition refers to the release of or exposure to a hazardous product "under normal conditions of use". "Normal conditions of use" means the normally expected conditions under which the article is employed for its intended purpose, and excludes the maintenance or repair of the article as well as the mishandling or misuse of the article. Furthermore, if under normal conditions of use, hazardous products are released from the manufactured article only in trace amounts that would not pose a health risk to workers the article still falls under the "manufactured article" exemption.

If a hazardous product is an article but is not exempt from the application of the HPA under the manufactured article exemption because, under normal conditions of use, it releases a hazardous product, the supplier must provide the required hazard information in the appropriate section(s) of the SDS in relation to those substances or mixtures that are hazardous products and that are released under normal conditions of use. In addition, hazard information related to hazardous decomposition products and hazardous combustion products (which are hazardous products) released during normal use of articles which are known to the supplier must also be disclosed on the SDS. Finally, paragraph 4(1)(c) of the HPR requires that the supplier provide on the SDS all additional hazard information that is available with respect to the hazardous product or a product, mixture, material or substance that has similar properties.

The words "to be exposed to a hazardous product" at the end of the manufactured article definition do not necessarily refer only to a hazardous product which is present in the manufactured article that is sold or imported. These words also refer to hazardous products that are released as a result of thermal or chemical degradation. Where a hazardous product that is present in the manufactured article is released during normal use but in an altered form that is also a hazardous product (e.g., an oxide), the manufactured article exclusion cannot be used. Note that if a product does not contain a hazardous product when it is sold or imported, it is not subject to the HPA, even if a hazardous product is formed and released when the article is used under normal conditions.

Comparison to HCS 2012

The HCS 2012 does not cover "articles".

Under the HCS 2012 "article" is defined as a manufactured item other than a fluid or particle:

> (i) which is formed to a specific shape or design during manufacture;
> (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
> (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical . . . and does not pose a physical hazard or health risk to employees.

Paragraph 12(j) / Schedule 1

Section 1 of Schedule 1

The definition of "pest control products" is defined in subsection 2(1) of the *Pest Control Products Act* (PCPA)

Comparison to HCS 2012

Under the HCS 2012, an SDS is required for pesticides as defined in the *Federal Insecticide, Fungicide, and Rodenticide Act* (7 U.S.C. 136 et seq.), when subject to the labelling requirements of that Act and labelling regulations issued under that Act by the US Environmental Protection Agency. However HCS 2012 does not require any labelling for these pesticides.

Section 2 of Schedule 1

The definition of "explosive" is found in section 2 of the *Explosives Act*. The Explosives hazard class from the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was not adopted in the HPR as a result of this exclusion.

Comparison to HCS 2012

The HCS 2012 includes "explosives".

Section 3 of Schedule 1

The definitions of "cosmetic", "device", "drug" and "food" are found in section 2 of the *Food and Drugs Act* (FDA).

Comparison to HCS 2012

The HCS 2012 does not cover:

> Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the work place;
>
> Any drug, as that term is defined in the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the work place (e.g., first-aid supplies);
>
> Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the work place;

The following require an SDS but do not have labelling requirements under the HCS 2012:

> Any **food, food additive, color additive**, **drug, cosmetic, or medical or veterinary device** or product, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), as such terms are defined in the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 301 et seq.) or the *Virus-Serum-Toxin Act of 1913* (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labelling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;
>
> Any **distilled spirits (beverage alcohols), wine, or malt beverage** intended for nonindustrial use, as such terms are defined in the *Federal Alcohol Administration Act* (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labelling requirements of that Act and labelling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;

Section 4 of Schedule 1

The definition of "consumer product" is found in section 2 of the *Canada Consumer Product Safety Act* (CCPSA).

Comparison to HCS 2012

The HCS 2012 does not apply to consumer products, as defined in the *Consumer Product Safety Act*, when the employer can show that the product is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended. Furthermore, the HCS 2012 does not require labelling of consumer products as defined in the *Consumer Product Safety Act*, when subject to a consumer product safety standard or labelling requirement of the Act or its Regulations. An SDS and training still need to be provided for such products.

Section 5 of Schedule 1

There is no regulatory definition of "any wood or product made of wood". Examples of wood and products made of wood include:

Wood board, beam or plank, fuel wood, wood in chips or particles, sawdust/wood waste and scrap, bark, fire logs, wood shavings, logs, wood wool/wood flour, lumber, wood pellets, veneer sheets, particleboard, fiberboard, plywood, parallam wood, oriented strandboard, waferboard, laminated beams, and densified wood.

Comparison to HCS 2012

The following "wood or wood products" are not covered by the HCS 2012:

> Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

Prohibitions

Discussion of the *Hazardous Products Act*
Subsection 13(1)

Prohibitions re sale

13(1) Subject to the *Hazardous Materials Information Review Act*, no supplier shall sell a hazardous product that is intended for use, handling or storage in a work place in Canada unless

(a) the supplier has in their possession a safety data sheet for the hazardous product that meets the requirements set out in the regulations made under subsection 15(1);

(a.1) on the sale of the hazardous product to any person or government, the supplier provides to the person or government the safety data sheet referred to in paragraph (a), or causes it to be provided, if on that sale the person or government acquires possession or ownership of that hazardous product; and

(b) the hazardous product or the container in which the hazardous product is packaged has a label that meets the requirements set out in the regulations made under subsection 15(1) affixed to it, printed on it or attached to it in a manner that meets the requirements set out in the regulations made under that subsection.

Paragraphs 13(1)(a), (a.1) and (b) of the HPA refer to SDS and labelling requirements.

Guidance on labelling and SDS requirements can be found in Parts 3 and 4 of this Technical Guidance.

Based on the definition of "sell" in section 2 of the HPA, the term "sell" captures nine distinct actions. Three of them (numbers 1 -3 in the list below) involve a transfer of ownership or possession, and six of them do not (numbers 4 – 9 in the list below):

1. selling – according to the regular meaning of sell;
2. distributing, whether for consideration or not;
3. making any transfer of possession that creates a bailment;
4. offering for sale;

5. offering for distribution;
6. exposing for sale;
7. exposing for distribution;
8. having in possession for sale; and
9. having in possession for distribution.

Paragraph 13(1)(a) of the HPA specifies that suppliers who sell (i.e., who undertake any of the actions above) a hazardous product that is intended for use, handling or storage in a work place in Canada are required to have in their possession an SDS for the hazardous product that meets the requirements of the HPR.

Upon sale of a hazardous product in Canada, a supplier must provide the SDS to the person or government who received the hazardous product, as per paragraph 13(1)(a.1) of the HPA. This paragraph specifies that the requirement to provide the SDS on the sale of a hazardous product to a person or government applies only in circumstances where "*the person or government acquires possession or ownership of that hazardous product".* Therefore, paragraph 13(1)(a.1) only applies to actions that include selling (according to the regular meaning of sell), distributing and making any transfer of possession that creates a bailment - items 1, 2 and 3 in the list above. When the supplier undertakes any of those three actions, he has the obligation to provide (or cause to be provided) an SDS (that is compliant with the requirements of the HPR) to the person or government who acquires possession or ownership of the hazardous product. It must be noted that subsection 13(1) is a prohibition; it is prohibited for a supplier to accomplish any of the above three actions if he does not provide (or cause to be provided) an SDS that is compliant with the requirements of the HPR.

The obligation to provide an SDS occurs on the sale of the hazardous product when the person or government obtains the possession **or** ownership of the product. As a result, the obligation to provide an SDS exists even in situations where the transfer of the ownership occurs before the transfer of possession (e.g. a sale contract regarding a hazardous product that is agreed by the parties prior to delivery of the product). Since the sale always occurs before workers begin any use, handling or storage of the hazardous product in the work place, this requirement helps to ensure that the SDS will be in possession of the person or government who acquires possession or ownership of the hazardous product before any potential exposure to the hazardous product could occur.

Discussion of the *Hazardous Products Act*
Subsection 13(2)

Definition of "government"

13(2) In this section, "government" means any of the following or their institutions:

(a) the federal government;

(b) a corporation named in Schedule III to the *Financial Administration Act*;

(c) a provincial government or a public body established under an Act of the legislature of a province; and

(d) an aboriginal government as defined in subsection 13(3) of the *Access to Information Act*.

The term "government" is used in the context of paragraph 13(1)(a.1) of the Act, which refers to "the sale of a hazardous product to any person or government …".

The term "province", used in paragraph 13(2)(c) of the Act, means a province of Canada, and includes Yukon, the Northwest Territories and Nunavut.

According to subsection 13(3) of the *Access to Information Act* the term "aboriginal government" means

(a) Nisga'a Government, as defined in the Nisga'a Final Agreement given effect by the *Nisga'a Final Agreement Act*;

(b) the council, as defined in the Westbank First Nation Self-Government Agreement given effect by the *Westbank First Nation Self-Government Act*;

(c) the Tlicho Government, as defined in section 2 of the *Tlicho Land Claims and Self-Government Act*;

(d) the Nunatsiavut Government, as defined in section 2 of the *Labrador Inuit Land Claims Agreement Act*;

(e) the council of a participating First Nation as defined in subsection 2(1) of the *First Nations Jurisdiction over Education in British Columbia Act*;

(e.1) the Tla'amin Government, as defined in subsection 2(2) of the *Tla'amin Final Agreement Act*;

(f) the Tsawwassen Government, as defined in subsection 2(2) of the *Tsawwassen First Nation Final Agreement Act*;

(g) a Maanulth Government, within the meaning of subsection 2(2) of the *Maanulth First Nations Final Agreement Act*; or

(h) Sioux Valley Dakota Oyate Government, within the meaning of subsection 2(2) of the *Sioux Valley Dakota Nation Governance Act*.

Discussion of the *Hazardous Products Act*
Section 14

Prohibition re importation

14 Subject to the *Hazardous Materials Information Review Act*, no supplier shall import a hazardous product that is intended for use, handling or storage in a work place in Canada unless

(a) the supplier obtains or prepares, on or before the importation of the hazardous product, a safety data sheet for the hazardous product that meets the requirements set out in the regulations made under subsection 15(1); and

(b) the hazardous product or the container in which the hazardous product is packaged has a label that meets the requirements set out in the regulations made under subsection 15(1) affixed to it, printed on it or attached to it in a manner that meets the requirements set out in the regulations made under that subsection.

Under section 14 of the HPA, a Canadian supplier who imports a hazardous product intended for use, handling or storage in a work place in Canada must obtain or prepare, on or before the importation, an SDS. In addition, they must ensure that a label that meets the requirements of the HPR has been affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged.

Guidance on labelling and SDS requirements can be found in Parts 3 and 4 of this Technical Guidance.

It must be noted that, under the HPA, there is no obligation for a foreign supplier of a hazardous product to provide an SDS and/or labels. The HPA applies only to sales and importation of hazardous products in Canada. Where a foreign supplier sells and ships a hazardous product directly to a Canadian customer, that Canadian customer is the Canadian importer and becomes the regulated party who is subject to the requirements of the HPA, provided that the importation is made in the context of the importer's course of business. The Canadian importer – not the foreign supplier – is responsible for ensuring that the label and SDS of the hazardous product are in compliance with the requirements of the HPA and the HPR.

A Canadian importer of the hazardous product who does not obtain an SDS that is compliant from his foreign supplier on or before importation must prepare a compliant SDS on or before the importation of the hazardous product, in order to comply with section 14 of the HPA.

In addition, paragraph 14(b) requires that the imported hazardous product or its container be labelled according to the applicable requirements of the HPR on or before the importation. However, an importer may use the exemption provided in subsection 5.15(1) of the HPR which allows the Canadian importer to import hazardous products that are not labelled according to the HPR if the hazardous products are imported for the purpose of being brought into compliance with the labelling requirements of the HPR before they are used or sold.

Discussion of the *Hazardous Products Act* Section 14.1

Prohibition re sale

14.1(1) Despite section 13, no supplier shall sell a hazardous product that contains asbestos and is intended for use, handling or storage in a work place in Canada unless, subject to the *Hazardous Materials Information Review Act*, the supplier complies with the requirements set out in paragraphs 13(1)(a) to (b) and the hazardous product meets the requirements set out in the regulations made under subsection 15(2).

Prohibition re importation

14.1(2) Despite section 14, no supplier shall import a hazardous product that contains asbestos and is intended for use, handling or storage in a work place in Canada unless, subject to the *Hazardous Materials Information Review Act*, the supplier complies with the requirements set out in paragraphs 14(a) and (b) and the hazardous product meets the requirements set out in the regulations made under subsection 15(2).

Subsections 14.1(1) and (2) of the HPA prohibit the sale and importation of hazardous products that contain asbestos and are intended for use, handling or storage in a work place in Canada, unless:

- the supplier meets the SDS and label requirements that apply to hazardous products under the HPA and HPR; and,
- hazardous products meet the requirements of any asbestos-specific regulations made under subsection 15(2) of the HPA.

Subsection 15(2) of the HPA provides authorities for the Governor in Council to make regulations respecting the sale or importation of hazardous products containing asbestos and that are intended for use, handling or storage in a work place in Canada.

Since there are currently no asbestos regulations made under subsection 15(2), hazardous products that contain asbestos that are intended for use, handling or storage in a work place in Canada have to meet the applicable labelling and SDS requirements of the HPR to be sold or imported in Canada.

Discussion of the *Hazardous Products Act*
Section 14.2

False information – hazardous product or container

14.2(1) No supplier shall sell or import a hazardous product that is intended for use, handling or storage in a work place in Canada if the hazardous product or the container in which the hazardous product is packaged has affixed to, printed on or attached to it information about the hazardous product that is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included in a label or safety data sheet for that hazardous product in order for the supplier to comply with the requirements set out in paragraphs 13(1)(a) to (b) or 14(a) and (b), as the case may be.

Safety data sheet – sale

14.2(2) No supplier shall sell a hazardous product that is intended for use, handling or storage in a work place in Canada if the safety data sheet for the hazardous product that is in their possession in order to comply with the requirement set out in paragraph 13(1)(a), or that they provide or cause to be provided in order to comply with the requirement set out in paragraph 13(1)(a.1), is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included in a label or safety data sheet for that hazardous product in order for the supplier to meet the requirements set out in paragraphs 13(1)(a) to (b).

Safety data sheet – importation

14.2(3) No supplier shall import a hazardous product that is intended for use, handling or storage in a work place in Canada if the safety data sheet for the hazardous product that the supplier obtains or prepares in order to comply with the requirement set out in paragraph 14(a) is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included in a label or safety data sheet for that hazardous product in order for the supplier to comply with the requirements set out in paragraphs 14(a) and (b).

Course of sale

14.2(4) No supplier who sells a hazardous product that is intended for use, handling or storage in a work place in Canada shall, in the course of selling the hazardous product, communicate by any means any information about the hazardous product that is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included in a label or safety data sheet for that hazardous product in order for the supplier to comply with the requirements set out in paragraphs 13(1)(a) to (b).

Subsections 14.2(1), (2) and (3) of the HPA prohibit suppliers from selling or importing a hazardous product that is intended for use handling or storage in a work place in Canada, if the label or SDS for the hazardous product contains information that is false, misleading or likely to create an erroneous impression with respect to the information required to be included in a label or SDS for a hazardous product.

Subsection 14.2(4) of the HPA prohibits a supplier who sells a hazardous product intended for use, handling or storage in a work place in Canada from communicating, by any means, in the course of selling the hazardous product, any information about the hazardous product that is false, misleading or likely to create an erroneous impression with respect to the information required to be included in a label or SDS for a hazardous product. This prohibition includes information on a supplier website or in technical documents made available or communicated to the public.

An example of false or misleading information would be a label of a hazardous product that bears the required precautionary statement "*Wear protective gloves/protective clothing/eye protection/face protection*", and also depicts a worker having direct contact (with bare hands) with a hazardous product classified in Skin Corrosion – Category 1C. This image is misleading and creates an erroneous impression with regard to the manner of handling the hazardous product. Furthermore, it contradicts the precautionary statement provided on the label.

Additional information beyond what is required under the HPR may be included on the label and the SDS as long as the information is not false, misleading, or likely to create an erroneous impression with respect to information that is required under the HPR. For example, a supplier may include information languages other than English and French on the label and SDS, as long as the information conveyed in these additional languages is not false, misleading or likely to create an erroneous impression.

Preparing and Maintaining Documents

Discussion of the *Hazardous Products Act* Section 14.3

Requirements

14.3(1) Every supplier who sells or imports a hazardous product that is intended for use, handling or storage in a work place in Canada shall prepare and maintain

(a) a document containing a true copy of a label that represents the label that is affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged in order to meet the requirement set out in paragraph 13(1)(b) or 14(b), as the case may be, when they sell or import the hazardous product;

(b) a document containing a true copy of a safety data sheet for the hazardous product that represents the safety data sheet that is in their possession in order to meet the requirement set out in paragraph 13(1)(a) or that they obtain or prepare in order to meet the requirement set out in paragraph 14(a), as the case may be, when they sell or import the hazardous product;

(c) if the supplier obtained the hazardous product from another person, a document that indicates the person's name and address, the quantity of the hazardous product obtained by the supplier and the month and year in which they obtained it;

(d) a document that indicates, for any sales of the hazardous product that result in a transfer of ownership or possession, the locations at which those sales took place, the period during which they took place, and, for each month in that period, the quantity sold during the month; and

(e) the prescribed documents.

Period for keeping document

14.3(2) The supplier shall keep the documents for six years after the end of the year to which they relate or for any other period that may be prescribed.

Keeping and providing documents

14.3(3) The supplier shall keep the documents at the supplier's place of business in Canada or at any prescribed place and shall, on written request, within the time and in the manner specified in the request, provide them to the Minister or an inspector.

Exemption - outside Canada

14.3(4) The Minister may, subject to any terms and conditions that he or she may specify, exempt a supplier from the requirement to keep documents in Canada if the Minister considers it unnecessary or impractical for the supplier to keep them in Canada.

Section 14.3 of the HPA requires suppliers of hazardous product to prepare and maintain documents, including true copies of labels and SDSs, as well as sales and purchasing

information. These documents must be provided to the Minister or an inspector on written request. Section 14.3 also addresses the period for keeping documents and the location where they must be kept.

Documents that must be prepared and maintained may be similar to those that businesses already retain as part of their normal bookkeeping practices. Under section 14.3, suppliers must prepare and maintain:

- A document containing a true copy of the label in both official languages, unless the label is not required as a result of an exemption under the HPR (e.g., sale or importation of a bulk shipment or a hazardous product without packaging of any sort);
- A document containing a true copy of the SDS in both official languages;
- A document indicating the name and address of the person from whom the supplier obtained the hazardous product, the quantity of the hazardous product obtained, and the month and year in which the supplier obtained it; and,
- For any sales of the product that resulted in a transfer of ownership or possession, a document indicating the locations at which sales took place (i.e., address of the place of business of the supplier), the period during which sales took place (e.g., from June 1, 2015 to May 23, 2016), and, for each month in that period, the quantity sold during the month (e.g., June 2016 = 60 units; July 2016 = 234 tons; August 2016 = 6234 L).

The specific information concerning the names and addresses of customers who purchased the hazardous product is not required to be maintained under subsection 14.3(1). However, if available, this information may be obtained by an inspector using powers granted under subsection 22(1) of the HPA.

In addition to the most up-to-date version of the label and SDS of the hazardous product, older versions of the label and SDS must also be maintained for the prescribed period of time.

A “true copy” means that the copy must accurately reflect (shape, size color, etc.) the actual label and safety data sheet.

These documents must be maintained for six years after the end of the year to which they relate, unless regulations specify another time period. To date, no other period has been prescribed in regulations. This time period aligns with existing document retention requirements that suppliers may already be required to meet, such as those under the federal *Income Tax Act*.

Documents can be maintained in paper or electronic format, but they must be kept at a supplier’s place of business in Canada. Suppliers may determine the business location of those records, at their discretion. Regardless of where those documents are kept, it is important that they be accessible and that suppliers be able to provide them to the Minister or an inspector upon written request and within the specified time period.

Section 14.3(4) of the HPA allows the Minister to grant an exemption if the Minister considers that keeping documents in Canada is unnecessary or impractical. Requests for an exemption from

this requirement will be reviewed on a case-by-case basis and should be submitted in writing to Health Canada.

The documents provided to the Minister or an inspector upon written request must be legible and must clearly identify the required information.

As specified in subsection 6.2(1) of the HPR, the information elements provided on an SDS and label must always be in both official languages of Canada (English and French). Therefore, the true copy of the label and SDS to be maintained as per paragraphs 14.3(1)(a) and (b) of the HPA must be in bilingual (i.e., English and French). As a result, the Minister or an inspector could require the true copy of the English or French portion of the label or SDS, or the true copy of the bilingual SDS or label. However, with regard to the documents to be maintained under paragraphs 14.3(1)(c) and (d) of the HPA and that may be required by the Minister or an inspector, the supplier can provide the document written in English or French.

Subsection 14.3(3) also stipulates that suppliers shall, on written request, provide documents to the Minister of Health within the time and in the manner (e.g., printed on paper or in an electronic format) specified in the request. Suppliers must provide the required records within the timelines set out in the written request.

Furthermore, as part of an inspection, an inspector may request, in writing, access to documents that are required to be maintained pursuant to subsection 14.3(1) of the HPA. Suppliers must provide the required documents to an inspector within the time and in the manner specified in the request.

Section C

Regulatory Requirements

PART 1

Interpretation

Part 1 of the *Hazardous Products Regulations* (HPR) provides the definitions for terms that are used in the regulations. This Part of the Technical Guidance provides additional information and some examples of the application and use of these definitions. It is important to note that some terms are not defined in Part 1. Definitions for these terms can instead be found in the specific Part or Subpart of the HPR where the terms are used, and further information is found in the Technical Guidance chapter corresponding to that Part or Subpart. In some cases, more information regarding the meaning of a specific term defined in this Part may be found in the specific Part or Subpart of the HPR where the defined term is used. Information regarding the terms defined in the *Hazardous Products Act* can be found in the Statutory Requirements chapter of the Technical Guidance.

Discussion of the *Hazardous Products Regulations*
Subsection 1(1)

1(1) The following definitions apply in these Regulations.

"Act" means the *Hazardous Products Act.*

"Act" refers to the *Hazardous Products Act* which was amended by the Economic Action Plan 2014 Act, No. 1, which received Royal Assent on June 19, 2014. The amendments to the *Hazardous Products Act* came into force on February 11, 2015.

"aerosol dispenser" means a non-refillable receptacle made of metal, glass or plastic and containing a gas that is compressed, liquefied or dissolved under pressure, with or without a liquid, foam, mousse, paste, gel or powder, and fitted with a release device allowing the contents to be ejected in the form of solid or liquid particles in suspension in a gas, as a foam, mousse, paste, gel or powder or in a liquid or gaseous state.

"Aerosol dispenser" is a term used in subsection 2.3(8) (Aerosols bridging principle) and in Subpart 3 of Part 7 (Flammable Aerosols) of the HPR. In this hazard class there are three defined types of aerosols:

(1) flammable aerosol;

(2) spray aerosol; and

(3) foam aerosol.

Aerosol dispensers that are classified in the Flammable Aerosols hazard class are not required to be classified in the Flammable Gases, Flammable Liquids or Flammable Solids hazard classes (Subpart 2, 6 or 7 of Part 7, respectively). However, they may also be classified in the Gases Under Pressure hazard class (Subpart 5 of Part 7), if they meet the criteria for any of the categories of this hazard class.

Comparison to the U.S. Occupational Safety and Health Administration Hazard Communication Standard 2012 (HCS 2012)

The term "aerosol" is defined in the HCS 2012, paragraph B.3.1, as meaning "any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas". The HCS 2012 definition of "aerosol" is essentially the same as that under the HPR. The HPR definition includes the terms "mousse" and "gel" to align with the terminology used in Subpart 3 of Part 7 (Flammable Aerosols).

"ATE" means an acute toxicity estimate, and includes the LD_{50} and the LC_{50}, and the acute toxicity point estimate determined in accordance with the table to section 8.1.7.

"ATE" is an acronym that is used in Subpart 1 of Part 8 (Acute Toxicity) and in paragraph 11(d) of Schedule 1. The term "acute toxicity estimate" could apply to:

(i) a hazardous product that is a substance;

(ii) a hazardous product that is a mixture; or

(iii) an ingredient in a hazardous product that is a mixture.

An ATE could be any of the following:

- an LD_{50} value;
- an LC_{50} value;
- an acute toxicity point estimate; or
- a calculated value, for a mixture, that is determined using either the mathematical formula in section 8.1.5 of the HPR or the mathematical formula in section 8.1.6 of the HPR.

An acute toxicity point estimate (ATPE) is a numerical value that must be determined in accordance with the table to section 8.1.7 of the HPR. The ATPE is an estimate of the lethal dose or lethal concentration of an ingredient in a mixture. It is established when the supplier does not know the LD_{50} or LC_{50} value of the ingredient, but knows either:

(1) the range of values within which the LD_{50} or LC_{50} of the ingredient falls, or

(2) the acute toxicity hazard category into which the ingredient falls.

Where there is no specific LD_{50} or LC_{50} value available for an ingredient in a mixture, determining the ATPE allows an acute toxicity value (i.e., the ATPE value) for this ingredient to be used in the calculation of the ATE of the mixture, in accordance with section 8.1.5 or 8.1.6 of the HPR.

Note: the terms "LD_{50}" and "LC_{50}", mentioned in the definition of "ATE", are also defined in subsection 1(1) of the HPR.

More information with regard to ATE and ATPE, including a discussion on how to calculate these values, is found in the Technical Guidance chapter corresponding to Subpart 1 of Part 8 (Acute Toxicity).

"CAS registry number" means the identification number assigned to a chemical by the Chemical Abstracts Service, a division of the American Chemical Society.

"CAS registry number", also known as "CAS number", is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS), a division of the American Chemical Society, to a chemical substance. For example, the CAS registry number of acetone is 67-64-1.

"chemical name" means a scientific designation of a material or substance that is made in accordance with the rules of nomenclature of either the Chemical Abstracts Service, a division of the American Chemical Society, or the International Union of Pure and Applied Chemistry, or a scientific designation of a material or substance that is internationally recognized and that clearly identifies the material or substance.

"Chemical name": The use of a chemical name along with a CAS registry number, helps in the precise identification of a material or substance. Some examples of chemical names that would meet the definition include "1,4-dimethylbenzene" and "para-xylene". Although both chemical names refer to the same substance, both are internationally recognized and they clearly identify the substance, as required by the definition. The chemical name of a material or substance could also be used as the "product identifier", which is required to be provided on the label and SDS.

The definition of chemical name includes not only the identity of a chemical substance, but also the identity of biohazardous infectious materials, even though these materials are not traditionally regarded as chemicals. A "chemical name" of a biohazardous infectious material could be, for example: *Streptococcus pneumonia* or measles virus.

The chemical name and/or the CAS registry number of a material or substance may be used to locate more information regarding the material or substance using sources such as the following:

- SDSs, technical data sheets, and product safety bulletins;
- OSHA Chemical Sampling Information pages;
- The Merck Index; and
- ChemID

"flash point" means the lowest temperature, corrected to the standard pressure of 101.3 kPa, at which the application of an ignition source causes the vapours of a liquid to ignite.

"Flash point" is only used in Subpart 6 of Part 7 (Flammable Liquids) and in paragraph 9(g) of Schedule 1 of the HPR. As specified in subsection 7.6.1(3), the flash point of a liquid that is a substance must be obtained using an "appropriate closed-cup method" listed in paragraph 2.6.4.2.5 of the GHS, as amended from time to time. For a liquid that is a mixture, the flash point must be determined either by tests using an appropriate closed-cup method (paragraph 7.6.1(4)(a)) or by the use of an applicable calculation method (paragraph 7.6.1(4)(b)). It would be a good practice to state on the SDS the method used to obtain a flash point value, as different methods can yield different results.

"gas" means a mixture or substance that

(*a*) at 50°C has an absolute vapour pressure of greater than 300 kPa; or

(*b*) is completely gaseous at 20°C and at the standard pressure of 101.3 kPa

"Gas" is defined as a mixture or substance that meets the above criteria. Hazard definitions and classification criteria in the physical and health hazard classes frequently refer to a physical state, either solid, liquid or gas. This definition of "gas" allows the supplier to determine if their product is a "gas" within the meaning of the HPR, whenever this term is used. If the hazardous product is not a "gas" as per this definition, then the definitions of "liquid" and "solid" should be reviewed to determine the physical state of the product for HPR classification purposes. In the definitions and classification criteria for the hazard classes, set out in Parts 7 and 8, where no mention is made with regard to physical state, it must be understood that the hazard class applies to all physical states.

"GHS" means the United Nations document entitled *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Fifth Revised Edition.

The **"GHS"** is a document that is updated by the United Nations from time to time. Where the HPR refer to the GHS, they are referring to the 5th revised edition published in 2013 (GHS). There are notable exceptions, which can be identified by the words "the GHS, as amended from time to time". While there are several instances where the acronym "GHS" is used in the HPR, it is most often used to refer to section 3 of Annex 3 of the GHS that lists the prescribed hazard communication elements (symbol, signal word, hazard statement and precautionary statements) for each category and subcategory of each GHS hazard class.

"hazardous ingredient" means an ingredient in a mixture that, when evaluated as an individual substance, is classified in a category or subcategory of a health hazard class.

"Hazardous ingredient" is an ingredient in a mixture which, when evaluated as an individual substance against the criteria of all health hazard classes of the HPR, is classified in at least one category or subcategory of a health hazard class.

It is important to note that hazardous ingredients that contribute to the classification of a mixture in at least one category or subcategory of a health hazard class are required to be disclosed under item 3 of the SDS.

The following definitions from the *Hazardous Products Act* (HPA) apply in this Part.

Definitions from the HPA (Section 2)

"mixture" means a combination of, or a solution that is composed of, two or more ingredients that, when they are combined, do not react with each other, but excludes any such combination or solution that is a substance.

"substance" means any chemical element or chemical compound — that is in its natural state or that is obtained by a production process — whether alone or together with

(a) any additive that is necessary to preserve the stability of the chemical element or chemical compound

(b) any solvent that is necessary to preserve the stability or composition of the chemical element or chemical compound, or

(c) any impurity that is derived from the production process;

"hazard statement" means a phrase assigned to a category or subcategory of a hazard class or, in the case of column 5 of Parts 4 to 6 of Schedule 5, the required statement that describes the nature of the hazard presented by a hazardous product.

"Hazard statement" includes a phrase assigned to a category or subcategory of a hazard class by section 3 of Annex 3 of the GHS or in column 5 of Parts 1 to 3 of Schedule 5 of the HPR. For example, the hazard statement for Acute Toxicity - Oral - Category 1 is "Fatal if swallowed" and the hazard statement for Acute Toxicity – Oral - Category 4 is "Harmful if swallowed."

The hazard statements for the hazard classes that are not covered by the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, Physical Hazards Not Otherwise Classified (PHNOC), Biohazardous Infectious Materials and Health Hazards Not Otherwise Classified (HHNOC)) are either prescribed or referred to in Schedule 5 of the HPR. There are assigned hazard statements for Combustible Dusts, Simple Asphyxiants and Pyrophoric Gases (found in column 5 of Parts 1 to 3 of Schedule 5).

Parts 4 to 6 of Schedule 5 (PHNOC, Biohazardous Infectious Materials and HHNOC) require a hazard statement but do not prescribe the wording for the statement. The supplier must provide an appropriate hazard statement that describes the nature of the hazard.

As permitted by subsection 3.2(3) of the HPR, hazard statements may be combined where appropriate, if the combination conveys the same information as would have been conveyed by each of the individual statements.

Except in the case of certain exemptions, the HPR does not allow the omission of hazard statements.

Comparison to HCS 2012

The hazard statements assigned by the HPR to Combustible Dusts, Simple Asphyxiants and Pyrophoric Gases are the same as the hazard statements assigned by HCS 2012 (section C.4.30) for these hazard classes.

The HCS 2012 (paragraph (f)(1)) does not require the disclosure of hazards not otherwise classified on the label and does not address biohazardous infectious materials.

The HCS 2012 (paragraph C.2.2.1) allows the manufacturer or importer to combine hazard statements as long as all the required hazard information is conveyed.

The HCS 2012 (paragraph C.2.2.2) allows for the omission of hazard statements if the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture.

"initial boiling point" means the temperature of a liquid at which its vapour pressure is equal to the standard pressure of 101.3 kPa, i.e., the temperature at which the first gas bubble appears.

"**Initial boiling point**" is only used in Subpart 6 of Part 7 (Flammable Liquids) and in paragraph 9(f) of Schedule 1. In addition to the flash point, the initial boiling point is required to classify a substance or mixture in Category 1 or 2 of this hazard class. A flammable substance or mixture with a low boiling point is more likely to catch fire upon exposure to an ignition source, since it may emit vapours at temperatures that may be close to or within the ranges that may be encountered in work places.

"initial supplier identifier" means the name, address and telephone number of

(*a*) the manufacturer; or

(*b*) the importer of the hazardous product who operates in Canada.

"initial supplier identifier" means the name, address and telephone number of either the Canadian manufacturer or the Canadian importer of a hazardous product.

Definitions of "manufacturer", "importer", "distributor" and "supplier"

The term "manufacturer" is defined, in subsection 1(1) of the HPR, as "a supplier who, in the course of business in Canada, manufactures, produces, processes, packages or labels a hazardous product and sells it". A manufacturer is different from an importer. An importer is a supplier who brings a hazardous product into Canada, but does not sell the product. If an importer does modify a hazardous product that they imported (for example, by repackaging or relabeling it) and subsequently sells the modified hazardous product, then the importer meets the definition of a "manufacturer" under the HPR.

A manufacturer is also different from a distributor. A distributor is a Canadian supplier to whom a hazardous product was sold, who resells the hazardous product without modifying it in any way. If a distributor does modify a hazardous product that they purchased (for example, by repackaging or relabeling it) and subsequently sells it, then the distributor meets the definition of a "manufacturer" under the HPR.

The term "supplier" is defined, in section 2 of the HPA, as "a person who, in the course of business, sells or imports a hazardous product". Therefore, all of the above-mentioned parties (i.e., a manufacturer, an importer or a distributor of a hazardous product) are considered as "suppliers" under the HPA.

Requirement to provide the initial supplier identifier on the SDS and label of a hazardous product and exceptions to this requirement

As specified in paragraphs 3(1)(b) and 4(1)(b) and Schedule 1 of the HPR, the initial supplier identifier (the name, address and telephone number of either the Canadian manufacturer or the Canadian importer) must be provided on the label and SDS of a hazardous product that is sold in or imported into Canada and intended for use, handling or storage in a Canadian work place.

However, as specified in section 5.8 of the HPR, where a hazardous product is being sold by a Canadian distributor, the distributor may provide his own name, address and telephone number on the label and SDS in lieu of the name, address and telephone number of the Canadian manufacturer or Canadian importer. It is important to note that, since this exemption only applies in a situation where a hazardous product is being sold by a Canadian distributor (including a downstream Canadian distributor), the use of this exemption still requires the disclosure of the contact information of a Canadian party on the label and SDS.

In situations where a hazardous product is being imported only for use in the importer's own work place, the Canadian importer may retain the name, address and telephone number of the foreign supplier on the label and SDS instead of replacing it with his own name, address and telephone number (section 5.9 of the HPR).

Providing the initial supplier identifier on the SDS and label of a hazardous product that is imported into Canada

Where a foreign supplier sells and ships a hazardous product directly to a Canadian customer, that Canadian customer is the Canadian importer. The Canadian importer is responsible for ensuring that the label and SDS of the hazardous product are in compliance with the requirements of the HPA and the HPR.

If the hazardous product is only being used in the Canadian importer's own work place, then the name, address and telephone number of the Canadian importer is not required to be provided on the label and SDS, as long as the name, address and telephone number of the foreign supplier is retained on the label and SDS (section 5.9 of the HPR). If the Canadian importer is reselling the hazardous product, then the Canadian importer's name, address and telephone number must be provided on the label and SDS. It would be acceptable to include the contact information of both the Canadian importer and the foreign supplier.

It is important to note that the concept of a "foreign-based importer" or "non-resident importer" is not relevant in the context of the HPA and the HPR, because a "foreign-based importer" or "non-resident importer" does not fall within the definition of a "supplier" as set out in section 2 of the HPA. Therefore, with regard to the requirement in paragraphs 3(1)(b) and 4(1)(b) and Schedule 1 of the HPR to provide the initial supplier identifier (the name, address and telephone number of either the Canadian manufacturer or the Canadian importer), the name, address and telephone number of a "foreign-based importer" or "non-resident importer" cannot be used.

Further information regarding initial supplier identifier and the exceptions to the requirement to provide the initial supplier identifier on the label and SDS of a hazardous product is found in Part 5 of the Technical Guidance.

"LC_{50}" means the concentration of a mixture or substance in air that causes the death of 50.0% of a group of test animals.

"LC_{50}": The acronym LC stands for the term "Lethal Concentration". The number 50 in the subscript of LC_{50} means that, in an animal study, 50% of the exposed animal population died, or was expected to have died, at the specified concentration. The LC_{50} is one way of measuring the short-term poisoning potential (acute toxicity) of a mixture or substance.

LC_{50} values typically relate to a 4-hour experimental exposure period via inhalation. Where LC_{50} values have been obtained in studies using an exposure duration of 1 hour, these values must be converted to 4-hour equivalents using the calculation method set out in subsection 8.1.1(4) of the HPR. Where LC_{50} values have been obtained in studies using an exposure duration other

than 4 hours or 1 hour, these values need to be converted to 4-hour equivalents in order to compare the LC_{50} values to the criteria set out in Table 3 to subsection 8.1.1(3) of the HPR. A calculation method that may be used for such a conversion is found in the Acute Toxicity chapter of the Technical Guidance (discussion of subsection 8.1.1(4) of the HPR). There are three sets of LC_{50} classification criteria which deal separately with gases, vapours, and collectively, dusts and mists. The LC_{50} value is expressed as weight of test substance per standard volume of air (mg/l) for vapours and for dusts and mists, or as volume parts per million (ppmV) for gases.

Further information is provided in the Technical Guidance chapter corresponding to Subpart 1 of Part 8 (Acute Toxicity).

"LD_{50}" means the single dose of a mixture or substance that, when administered by a particular exposure route in an animal study, is expected to cause the death of 50.0% of a given animal population.

"LD_{50}": The acronym LD stands for the term "Lethal Dose". The number 50 in the subscript of LD_{50} means that, in an animal study, 50% of the tested animal population died, or was expected to have died, at the specified dose administered. LD_{50} values are expressed in terms of the amount of a mixture or substance administered per unit weight of test animal (mg/kg of body weight). The LD_{50} is one way of measuring the short-term poisoning potential (acute toxicity) of a mixture or substance.

LD_{50}s and LC_{50}s can be found from a variety of sources, including databases such as the Registry of Toxic Effects of Chemical Substances (RTECS®), CHEMINFO and the Hazardous Substances Data Bank (HSDB®) in the Canadian Centre for Occupational Health and Safety (CCOHS) CHEMpendium™ collection, in chemical reviews such as the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles, the World Health Organization (WHO) Environmental Health Criteria (EHC) series, the International Program on Chemical Safety (IPCS) Concise International Chemical Assessment Documents (CICADs), the OECD Screening Information DataSet (SIDS), and in the published scientific literature.

"liquid" means a mixture or substance that

(*a*) at 50°C has a vapour pressure of 300 kPa or less;

(*b*) is not completely gaseous at 20°C and at the standard pressure of 101.3 kPa; and

(*c*) has a melting point or initial melting point of 20°C or less at the standard pressure of 101.3 kPa or, in the case of a mixture or substance for which neither can be determined, is shown

(i) to be a liquid as a result of the ASTM International method ASTM D4359-90, entitled *Standard Test Method for Determining Whether a Material Is a Liquid or a Solid*, as amended from time to time, or

(ii) to not be pasty as a result of the test for determining fluidity (penetrometer test), referred to in section 4 of chapter 3 of Part 2, numbered 2.3.4, of Annex A of the *European Agreement Concerning the International Carriage of Dangerous Goods by Road*, as amended from time to time.

"Liquid" is defined as a mixture or substance that meets the above criteria. Hazard definitions and classification criteria in the physical and health hazard classes frequently refer to a physical state, either solid, liquid or gas. This definition of "liquid" allows the supplier to determine if their product is a "liquid" within the meaning of the HPR, whenever this term is used.

In some cases, for example, viscous mixtures or substances, a specific melting point cannot be determined. Such a mixture or substance must be regarded as a "liquid" if it meets the criteria set out in (a) and (b) above, and either:

(1) the result of the ASTM D 4359-90 test (*Standard Test Method for Determining Whether a Material Is a Liquid or a Solid*) indicates that the material is a liquid; or

(2) the result of the test for determining fluidity (penetrometer test), prescribed in Section 2.3.4 of Annex A of the *European Agreement Concerning the International Carriage of Dangerous Goods by Road*, indicates that the mixture or substance is "not pasty".

It is important to note that the test for determining fluidity (penetrometer test), which measures the rate of penetration of a mixture or substance using a penetrometer, does not actually determine whether the mixture or substance is a liquid. Rather, it determines whether the mixture or substance is "pasty". If a mixture or substance is not "pasty", according to this test method, and if it meets the criteria set out in (a) and (b) above, then it is a "liquid" within the meaning of the HPR.

If a mixture or substance is not a "liquid" as per this definition, then the definitions of "gas" and "solid" should be reviewed to determine the physical state of the mixture or substance for HPR classification purposes. In the definitions and classification criteria for the hazard classes set out in Parts 7 and 8, where no mention is made with regard to physical state, it must be understood that the hazard class applies to all physical states.

"Manual of Tests and Criteria" means the United Nations document entitled *Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria*, as amended from time to time.

The **"Manual of Tests and Criteria"** is a manual that contains criteria, test methods and procedures to be used for the classification of dangerous goods according to the provisions of Parts 2 and 3 of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, as well as the classification of chemicals presenting physical hazards according to the GHS. Test procedures found in the Manual of Tests and Criteria are referred to in the following physical hazard classes in Part 7 of the HPR:

Subpart 3: Flammable Aerosols

Subpart 7: Flammable Solids

Subpart 8: Self-reactive Substances and Mixtures

Subpart 9: Pyrophoric Liquids

Subpart 10: Pyrophoric Solids

Subpart 11: Self-heating Substances and Mixtures

Subpart 12: Substances and mixtures which in contact with water, emit flammable gases

Subpart 13: Oxidizing Liquids

Subpart 14: Oxidizing Solids

Subpart 15: Organic Peroxides

Subpart 16: Corrosive to Metals

The term "as packaged" is used in Subparts 8 and 15 of Part 7 (Self-reactive Substances and Mixtures and Organic Peroxides, respectively), and is defined in sections 7.8 and 7.15 of the HPR to mean "the form and condition described in test Series B, test Series D, test Series G and test Series H in Part II of the Manual of Tests and Criteria".

"manufacturer" means a supplier who, in the course of business in Canada, manufactures, produces, processes, packages or labels a hazardous product and sells it.

A **"manufacturer"** is different from an importer. An importer is a supplier who brings a hazardous product into Canada, but does not sell the product. If an importer does modify a hazardous product that they imported (for example, by repackaging or relabeling it), and subsequently sells the modified hazardous product, then the importer meets the definition of a "manufacturer" under the HPR.

A manufacturer is also different from a distributor. A distributor is a Canadian supplier to whom a hazardous product was sold, who resells the hazardous product without modifying it in any way. If a distributor does modify a hazardous product that they purchased (for example, by repackaging or relabeling it) and subsequently sells it, then the distributor meets the definition of a "manufacturer" under the HPR.

The term "supplier" is defined, in section 2 of the HPA, as "a person who, in the course of business, sells or imports a hazardous product". Therefore, all of the above-mentioned parties (i.e., a manufacturer, an importer or a distributor of a hazardous product) are considered as "suppliers" under the HPA.

"OECD" means the Organisation for Economic Co-operation and Development.

"OECD" is only used in Subparts 2 and 3 of Part 8 (Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation) to refer to the OECD Guideline for the Testing of Chemicals, No. 404 (*Acute Dermal Irritation/Corrosion)* & No. 405 (*Acute Eye Irritation/Corrosion).*

"outer container" means the most outward container of a hazardous product that is visible under normal conditions of handling, but does not include the most outward container if it is the only container of the hazardous product.

"Outer container" means the most outward container of a hazardous product if that product is packaged in more than one container. There must be at least one container that is physically inside another container in order to have an outer container. For example, a box in which there are several bottles of a hazardous product is an outer container. Another example would be a hazardous product that is packaged in a bottle which, in turn, is packaged in a set of two nested boxes. In this example, only the most outward box is considered as an "outer container".

"pictogram" means a graphical composition that includes a symbol along with other graphical elements, such as a border or background colour.

A **"pictogram"** is composed of a symbol against a background within a border. It is intended to convey specific information about the hazard of a product. Except for the pictogram required for biohazardous infectious materials, the format of the HPR pictograms consists of a black symbol against a white background within a red border in the shape of a square set on one point. The Biohazardous Infectious Materials hazard class uses a different pictogram border as this hazard class is unique to Canada and is not part of the GHS. The Biohazardous Infectious Materials pictogram consists of a black biohazard symbol against a white background within a round black border.

In accordance with section 3.1 of the HPR, any pictogram required to be provided on a label must, except with respect to size, be an exact reproduction of that pictogram as set out in column 3 of Schedule 3 of the HPR. An exact reproduction of the pictogram also means that the proportion of the frame versus the symbol must be in accordance with the pictogram in Schedule 3.

"precautionary statement" means a phrase that describes the recommended measures to take in order to minimize or prevent adverse effects resulting from exposure to a hazardous product or resulting from improper storage or handling of a hazardous product.

For the hazard classes that were adopted from the GHS, prescribed precautionary statements are found in section 3 of Annex 3 of the GHS. There are four types of precautionary statements that cover:

(1) prevention;

(2) response (to accidental spillage or exposure);

(3) storage; and

(4) disposal precautions.

Specific precautionary statements have been assigned to each hazard class, category and subcategory. For example, for the Flammable Gases hazard class, Categories 1 and 2, the prevention precautionary statement is "Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking". For a hazardous product that is classified in one or more of the hazard classes adopted from the GHS, the prescribed precautionary statements must be provided on the label and SDS, unless an exemption under Part 5 of the HPR applies.

The following HPR hazard classes are not covered by the GHS:

- Combustible Dusts;
- Simple Asphyxiants;
- Pyrophoric Gases;
- PHNOC;
- HHNOC; and
- Biohazardous Infectious Materials

There are no prescribed precautionary statements for these hazard classes. For a hazardous product that is classified in one or more of these hazard classes, the supplier must provide applicable precautionary statements on the label and SDS, unless an exemption under Part 5 of the HPR applies. In addition to the four types of precautionary statements required for the hazard classes adopted from the GHS, there is also a requirement to provide "general" precautionary statements, if such statements apply.

"product identifier" means, in respect of a hazardous product, the brand name, chemical name, common name, generic name or trade name.

The **"product identifier"** must be the same on both the label and on the SDS for a hazardous product, as required by section 4.2 of the HPR. In the case where the product identifier is the subject of a claim for exemption from the disclosure of Confidential Business Information (CBI) under the *Hazardous Materials Information Review Act*, section 5.7 of the HPR specifies that the product identifier must be replaced by a statement that a claim was filed or granted, the date the claim was filed or granted, the registry number assigned to the claim, and coding to replace the product identifier. Again, the same information must be disclosed on both the label and the SDS.

"risk group classification" means, in relation to the "Biohazardous Infectious Materials" health hazard class, classification in Risk Group 2, Risk Group 3 or Risk Group 4 as defined in subsection 3(1) of the *Human Pathogens and Toxins Act*.

"Risk group classification" refers to the classification of human pathogens in accordance with the *Human Pathogens and Toxins Act*. Pathogens are ranked in terms of level of hazard: a Risk Group 2 is for less hazardous human pathogens, e.g., *E. coli* and the most hazardous are classified in Risk Group 4, e.g., Ebola virus.

"SADT" or "self-accelerating decomposition temperature" means the lowest temperature at which self-accelerating decomposition occurs.

"SADT" or **"Self-accelerating decomposition temperature"** is the lowest temperature at which the rate of decomposition is sufficient to generate heat at a faster rate than the heat can be dissipated to the environment. Temperature is the main factor in determining the decomposition rate, although the size of the package is also important since its dimensions will determine the ability to dissipate heat to the environment.

The SADT is a parameter used only in Subparts 8 and 15 of Part 7 (Self-reactive Substances and Mixtures and Organic Peroxides, respectively) for classification purposes.

"scientifically validated method" means, in relation to a hazard, a method that specifies standards for the evaluation of that hazard and whose results are accurate and reproducible, in accordance with established scientific principles.

"Scientifically validated method" refers to the process that has been established for a particular purpose where the accuracy, reliability, and reproducibility of the process are proven using established scientific principles. As specified in sections 2.1 and 2.2 of the HPR, any test using a scientifically validated method that determines the hazardous properties of a product can be used for purposes of classification of the product under the HPR.

"signal word" means, in respect of a hazardous product, the word "Danger" or "Warning" that is used to alert the reader to a potential hazard and to indicate its severity.

"Signal word" indicates the severity of a hazard through the use of either the word "Danger" or "Warning".

Signal words are assigned to a category or subcategory of a hazard class. For the hazard classes adopted from the GHS, the signal words are assigned by section 3 of Annex 3 of the GHS .

The signal words for the hazard classes that are not covered by the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, Physical Hazards Not Otherwise Classified (PHNOC), Biohazardous Infectious Materials and Health Hazards Not Otherwise Classified (HHNOC)) are assigned in column 4 of Parts 1 to 6 of Schedule 5 of the HPR.

The signal word "Danger" is used for more severe hazards and "Warning" is used for less severe hazards. For example, a product classified in "Reproductive Toxicity - Category 1A or 1B" will require "Danger" as the signal word, whereas a product classified in "Reproductive Toxicity - Category 2" will require "Warning" as the signal word. Some hazard classes or categories do not require the use of a signal word. For example, no signal word is required for a product classified in the "Effects on or via lactation" category of the Reproductive Toxicity hazard class.

For a hazardous product classified in more than one category or sub-category of a hazard class or in more than one hazard class, the same signal word, "Danger" or "Warning", is not required to be repeated. It only needs to appear once on the label and once on the SDS. Furthermore, as permitted by subsection 3.6(1) of the HPR, if there is a requirement to provide both signal words "Danger" and "Warning", then the signal word "Warning" may be omitted.

Comparison to HCS 2012

The signal words assigned by the HPR for Combustible Dusts, Simple Asphyxiants and Pyrophoric Gases are the same as those assigned by HCS 2012.

"solid" means a mixture or substance that is not a liquid or gas.

"Solid" is defined as a mixture or substance that meets the above criteria. This definition does not define a solid *per se*. Instead, it specifies that a solid is a mixture or a substance that is not a liquid or gas, which are two terms that are also defined in subsection 1(1) of the HPR. Hazard definitions and classification criteria in the physical and health hazard classes frequently refer to a physical state, either solid, liquid or gas. This definition of "solid" will allow the supplier to determine if their product is a "solid" within the meaning of the HPR, whenever this term is used. In the definitions and classification criteria for the hazard classes, set out in Parts 7 and 8, where no mention is made with regard to physical state, it must be understood that the hazard class applies to all physical states.

"United Nations Model Regulations" means the United Nations document entitled *Recommendations on the Transport of Dangerous Goods: Model Regulations,* as amended from time to time.

"United Nations Model Regulations" are referred to only in the context of the defined term "UN number" (discussed below) and in relation to transportation information (item 14 of the safety data sheet, for which the provision of information elements is optional).

"UN number" means the four-digit identification number issued in accordance with the United Nations Model Regulations.

"UN number" is a four-digit identification number identified by the UN Model Regulations and is referred to only in Schedule 4 and paragraph 14(a) of Schedule 1. Some hazardous substances have their own UN number (e.g. acrylamide has UN2074), whereas sometimes groups of chemicals or products with similar properties receive a common UN number (e.g. flammable liquids, not otherwise specified, have UN1993). A chemical in its solid state may receive a different UN number than the same chemical in its liquid phase if the hazardous properties differ significantly. Substances with different levels of purity (or concentration in solution) may also receive different UN numbers.

"vapour" means the gaseous form of a mixture or substance released from its liquid or solid state.

"Vapour" is used in Subpart 1 of Part 8 (Acute Toxicity) in relation to inhalation exposure. This term is also used in paragraph 9(k) (vapour pressure) and 9(l) (vapour density) of Schedule 1.

"work place" means a place where a person works for remuneration.

"Work place" is a place where a person works for money or pay. A place of work which is operated and managed entirely by volunteers is not included in this definition. A supplier is required to comply with the requirements of the HPA and the HPR if the supplier imports or sells a hazardous product intended for use, handling or storage in a work place in Canada.

Discussion of the *Hazardous Products Regulations*
Subsection 1(2)

1(2) In these Regulations, a reference to a hazard class is to be read as a reference to a hazard class that is listed in Schedule 2 to the Act.

The list of hazard classes in Schedule 2 of the HPA is the following:

Physical Hazard Classes

1. Explosives*
2. Flammable gases
3. Flammable aerosols
4. Oxidizing gases
5. Gases under pressure
6. Flammable liquids
7. Flammable solids
8. Self-reactive substances and mixtures
9. Pyrophoric liquids
10. Pyrophoric solids
11. Self-heating substances and mixtures
12. Substances and mixtures which, in contact with water, emit flammable gases
13. Oxidizing liquids
14. Oxidizing solids
15. Organic peroxides
16. Corrosive to metals
17. Combustible dusts+
18. Simple asphyxiants+
19. Pyrophoric gases+
20. Physical hazards not otherwise classified+

Health Hazard Classes

1. Acute toxicity
2. Skin corrosion/irritation
3. Serious eye damage/eye irritation
4. Respiratory or skin sensitization
5. Germ cell mutagenicity
6. Carcinogenicity
7. Reproductive toxicity
8. Specific target organ toxicity – single exposure
9. Specific target organ toxicity – repeated exposure

10. Aspiration hazard
11. Biohazardous infectious materials+
12. Health hazards not otherwise classified+

*It is important to note that, although Schedule 2 of the HPA refers to a hazard class for "Explosives", the GHS hazard class for Explosives has not been adopted in the HPR. As specified in Schedule 1 of the HPA, explosives, as defined in section 2 of the *Explosives Act*, are currently excluded from the application of the HPA.
+ These hazard classes are not covered by the GHS.

Comparison to HCS 2012

The hazard classes listed in Schedule 2 of the HPA are consistent with those of the HCS 2012 except for the following:

- The GHS "Explosives" hazard class has been adopted in the HCS 2012, but not in the HPR.
- The HCS 2012 addresses "Hazards Not Otherwise Classified", but does not provide distinct criteria for physical and health hazards not otherwise classified.
- The HCS 2012 does not address biohazardous infectious materials, as OSHA does not regulate these materials in the work place.

Discussion of the *Hazardous Products Regulations*
Subsection 1(3)

Health Professionals

1(3) For the purposes of Parts 5 and 6, health professionals are

(*a*) physicians who are registered, and entitled under the laws of a province to practise medicine and who are practising medicine under those laws in that province; and

(*b*) nurses who are registered or licensed, and entitled under the laws of a province to practise nursing and who are practising nursing under those laws in that province.

The term **"health professionals"** is used in subparagraph 5.7(11)(b)(ii) and in subsections 6(1) and (2) of the HPR. Under these provisions, health professionals (physicians and nurses) are allowed, under specific circumstances, to have access to CBI on hazardous products for the purpose of making a medical diagnosis of, or rendering medical treatment to, an individual in an emergency. As required by subsection 6(2) of the HPR, such information must be kept confidential by the health professional, except for the purpose for which it was provided, if the health professional has been informed by the supplier that the information is to be kept confidential.

Discussion of the *Hazardous Products Regulations*
Subsection 1(4)

Interpretation of "should"

1(4) When the word "should" is used in a text that is referenced or incorporated by reference in these Regulations, it is to be read as imperative, unless the context requires otherwise.

Some provisions of the HPR, including classification criteria for certain hazard classes, refer to documents such as the GHS, the Manual of Tests and Criteria, the OECD Guideline for the Testing of Chemicals, No. 404 and No. 405, etc. If the text that is referenced or incorporated in the HPR in this manner uses the word "should", this word must be understood to mean the imperative, unless the context requires otherwise.

For example, Item 2(a)(iii) in the table to subsection 7.3.1(1) of the HPR (Flammable Aerosols - Classification in a Category of the Class), the criteria for Flammable Aerosols – Category 2 include an aerosol dispenser that generates a time equivalent ≤ 300 s/m^3, based on test results from the enclosed space ignition test performed in accordance with subsection 31.5 of Part III of the Manual of Tests and Criteria. Subsection 31.5 of Part III of the Manual of Tests and Criteria describes the procedure for the enclosed space ignition test. Paragraph 31.5.2.2.1(a) of the Manual states that "A closure system consisting of a hinged cover should be matched to the open end of the receptacle". This text would be interpreted to mean that, in the event that the enclosed space ignition test is carried out using a closure system consisting of a hinged cover, it must be matched to the open end of the receptacle.

References

29 CFR 1910.1200, Hazard Communication

Hazardous Products Act, R.S.C., 1985, c.H-3

Hazardous Products Regulations, SOR/2015-17

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

United Nations Recommendations on the Transport of Dangerous Goods – Manual of Tests and Criteria, Fifth Revised Edition, 2009.

PART 2

Classification of a Product, Mixture, Material or Substance

General

This chapter provides guidance to assist suppliers in determining the appropriate hazard classification of a product, mixture, material or substance (PMMS) in relation to the hazard classes, categories and subcategories set out in the *Hazardous Products Regulations* (HPR). Hazard classification is the process of evaluating all of the available data, in accordance with established scientific principles, to determine whether a PMMS is a "hazardous product" within the definition set out in section 2 of the *Hazardous Products Act* (HPA). When the evaluation is complete, the PMMS is classified, if applicable, in one or more hazard classes and categories or subcategories, depending on the nature and severity of the hazard(s) posed by the PMMS.

Part 2 provides a general overview of the procedures to be followed in the hazard classification process. It specifies the types of data that must be considered and sets out principles that are relevant to the classification of a PMMS in the physical and health hazard classes. It also describes principles that apply specifically to the classification of mixtures in the health hazard classes.

The definitions and classification criteria that are relevant to each hazard class are found in the respective Subpart of Part 7 or 8 of the HPR. In addition, the step-wise procedures to be followed for the classification of a mixture, material or substance in each health hazard class are found in Part 8 of the HPR.

The following definitions from the HPA apply in this Part:

Definitions from the HPA (Section 2)

"container" includes a bag, barrel, bottle, box, can, cylinder, drum or similar package or receptacle but does not include a storage tank;

"hazardous product" means any product, mixture, material or substance that is classified in accordance with the regulations made under subsection 15(1) in a category or subcategory of a hazard class listed in Schedule 2;

"mixture" means a combination of, or a solution that is composed of, two or more ingredients that, when they are combined, do not react with each other, but excludes any such combination or solution that is a substance;

"prescribed", for the purposes of Part II, means prescribed by regulations made under subsection 15(1), and, for the purposes of Part III, means prescribed by regulations made under section 27;

"substance" means any chemical element or chemical compound — that is in its natural state or that is obtained by a production process — whether alone or together with

(a) any additive that is necessary to preserve the stability of the chemical element or chemical compound,

(b) any solvent that is necessary to preserve the stability or composition of the chemical element or chemical compound, or

(c) any impurity that is derived from the production process;

"supplier" means a person who, in the course of business, sells or imports a hazardous product;

The HPR is a hazard based regulation. "Hazard" is defined in the dictionary (Merriam-Webster, tenth edition) as the ability to cause harm; a source of danger. It is an intrinsic property due to the nature of the product. For the purpose of these regulations, a PMMS becomes a "hazardous product", within the meaning of the HPA, when it meets the criteria to be classified in at least one category or subcategory of any of the physical or health hazard classes of the HPR (Part 7 or Part 8).

For example, sodium hydroxide is a hazardous substance by virtue of its chemical nature. Any change to its chemical nature that results in a substance or mixture other than sodium hydroxide being formed, would result in hazards based on the newly formed substance or mixture. For example, if sodium hydroxide is mixed with an acid resulting in a salt being formed, the hazard assessment is based on the salt which could pose different hazards than those posed by sodium hydroxide or by the acid.

The respective Subpart of Part 7 or 8 of the HPR for each hazard class provides both a definition for the hazard class and classification criteria for each category or subcategory of that hazard class. In terms of scope, for most of the physical and health hazard classes in the HPR, the

definition is broader than the criteria. If a PMMS does not meet the definition for a hazard class, it will not meet any of the classification criteria for that hazard class. On the other hand, a PMMS may meet the definition for a hazard class but not its criteria. For a PMMS to be classified in a hazard category or subcategory of a hazard class, it must meet both the definition of the hazard class and the criteria of one or more categories or subcategories of the hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 2(1)

Order of decreasing severity

2(1) In each Subpart of Parts 7 and 8, the categories and subcategories in each of the classification tables to those Subparts are set out in the order of the hazard's decreasing severity, except for the categories of the classification table to Subpart 5 of Part 7.

The HPR includes two hazard groups: physical hazards (Part 7) and health hazards (Part 8). Each group is divided into hazard classes as found in Subparts 1 to 20 of Part 7 and Subparts 1 to 12 of Part 8. Each Subpart includes one or more tables that set out the different classifications possible within the respective hazard class. These are called "classification tables". These tables list the categories and subcategories within the hazard class and the criteria that determine classification within these categories and subcategories.

In most cases, within a single classification table, the order in which the categories and subcategories are laid out is in decreasing order of severity. Thus a PMMS classified in Category 1 is considered more hazardous than a PMMS classified in Category 2 in the same table. For example, a substance that is classified in Flammable Liquids – Category 1 is more hazardous than a substance that is classified in Flammable Liquids – Category 2. This ranking of severity is important for the precedence of classification and the bridging principles (subsections 2.3(1) to (8)), both of which refer to "more severe" or "less severe" hazards.

An exception to this rule is found in Subpart 5 of Part 7 (Gases under Pressure). The categories listed in the table to section 7.5.1 are not in order of decreasing severity; they just represent different types of compressed gases.

Discussion of the *Hazardous Products Regulations*
Subsection 2(2)

Evaluation – more severe hazard

2(2) If a product, mixture, material or substance has been evaluated in accordance with the criteria and requirements of a category or subcategory of a hazard class that represents the more severe hazard in a classification table compared to another category or subcategory of that hazard class in the same classification table and is classified in that category or subcategory, the product, mixture, material or substance need not be evaluated in respect of a category or subcategory of the same classification table of the same hazard class that represents a less severe hazard.

If a PMMS meets the criteria for a more severe hazard category of a hazard class (e.g., Category 1 for most hazard classes), it must be classified in that category and does not need to be further evaluated against the criteria for another less severe hazard category (e.g., Category 2) within the same classification table of that same hazard class.

As mentioned in the discussion of subsection 2(1), in Subpart 5 of Part 7 (Gases Under Pressure hazard class), the categories described in the classification table are not listed in order of decreasing severity. Therefore, it is necessary to evaluate a gas under pressure in relation to all of the criteria in the table to section 7.5.1 to determine in which category(ies) the gas must be classified.

The hazard class set out in Subpart 8 of Part 8 (Specific Target Organ Toxicity – Single Exposure (STOT-SE)) does not follow the rule described in subsection 2(2). In this hazard class, there is one classification table that sets out criteria for Category 1, Category 2, and Category 3. Categories 1 and 2 relate to toxicity in a specific target organ that arises from a single exposure and Category 1 represents a more severe hazard than Category 2. Category 3, which relates to transient narcotic effects and/or transient respiratory tract irritation that arise from a single exposure, represents a less severe hazard than Category 2.

However, as specified in subsections 8.8.1(1) and (2), for the purposes of classification in the STOT-SE hazard class, a substance or mixture must be evaluated against the criteria for all three categories. Using the results of this evaluation, the supplier must then follow the criteria in the table to subsection 8.8.1(2) to determine the classification. It is, therefore, possible to have a substance or mixture that is classified in:

STOT-SE - Category 1,

STOT-SE - Category 2,

STOT-SE - Category 3,

STOT-SE - Category 1 and Category 3, or

STOT-SE - Category 2 and Category 3.

Hazard classes with more than one classification table

There are three hazard classes, set out in Subparts 1, 4, and 7 of Part 8 (Acute Toxicity, Respiratory or Skin Sensitization and Reproductive Toxicity, respectively) that each contain more than one classification table. In these hazard classes, the principle described in subsection 2(2) does not apply from one classification table to another, but only within a classification table. For example, the Reproductive Toxicity hazard class (Subpart 7 of Part 8) has one classification table for Category 1 (further sub-classification in Category 1A or 1B is possible) and Category 2, and a second classification table for Effects on or via lactation. The two tables represent different effects within the hazard class of Reproductive Toxicity and a substance or mixture must be evaluated against the criteria in both tables. As a result, it is possible to have a substance or mixture that is classified in:

Reproductive Toxicity – Category 1, 1A or 1B

Reproductive Toxicity – Category 2,

Reproductive Toxicity – Effects on or via Lactation,

Reproductive Toxicity - Category 1, 1A or 1B and Effects on or via Lactation, or

Reproductive Toxicity – Category 2 and Effects on or via Lactation.

Discussion of the *Hazardous Products Regulations*
Subsection 2(3)

Prescribed classification

2(3) Subject to subsections (4) and (5), any product, mixture, material or substance for which classification in a category or subcategory of a hazard class is prescribed in Schedule 4 is classified in that category or subcategory. The product, mixture, material or substance must also be evaluated in accordance with section 2.1, 2.2 or 2.7 in respect of each of the categories or subcategories of the other hazard classes.

The prescribed classifications found in Schedule 4 maintain the level of protection that was provided by the previous regulations (the repealed *Controlled Products Regulations*). The listing of a PMMS in Schedule 4 does not constitute a complete classification of that PMMS. If the classification of a PMMS is prescribed in Schedule 4, not only is the PMMS classified in the specified hazard class and hazard category as indicated in Schedule 4, but it must also be further evaluated against the criteria of all other applicable hazard classes. The procedures required to determine the further classification are set out in sections 2.1 (for a material or substance), 2.2 (for a mixture) and 2.7 (for a product).

For example: 2-Bromo-2-nitropropane-1,3-diol (UN number 3241; item 24 of Schedule 4) has a prescribed classification of Physical Hazards Not Otherwise Classified – Category 1. This substance must be evaluated against the criteria of all other hazard classes and, as a result, it could potentially be classified in another hazard class and category or subcategory.

It is important to note that, when evaluating a PMMS that is listed in Schedule 4 to determine the appropriate classification of the PMMS in the other hazard classes, subsections 2(4) (Ingredient – more severe hazard) and 2(5) (Prescribed classification – Subpart 1, 4, 7 or 8 of Part 8) must be taken into consideration. These provisions are discussed below.

Discussion of the *Hazardous Products Regulations*
Subsection 2(4)

Ingredient – more severe hazard

2(4) If a product, mixture, material or substance is one for which classification in a category or subcategory of a hazard class is prescribed in Schedule 4, and if it has been mixed with one or more ingredients that are classified in a category or subcategory of the same classification table of the same hazard class that represents a more severe hazard, the mixture as a whole must be classified in the category or subcategory that represents the more severe hazard.

If a PMMS is classified in a category or subcategory of a hazard class as a result of being listed in Schedule 4, and it has been combined with another ingredient that is classified in a more severe category or subcategory of the same classification table of the same hazard class, then the mixture must be classified in the category or subcategory for the more severe hazard. In this situation, the more severe hazard category or subcategory within a classification table takes precedence, not the classification prescribed by Schedule 4.

Currently, all substances listed in Schedule 4 are prescribed a classification in Category 1 of either the Self-Heating Substances and Mixtures or the Physical Hazards Not Otherwise Classified hazard class (Subparts 11 and 20, respectively, of Part 7). Therefore, this provision will not be triggered with the current Schedule 4 items. This provision encompasses the eventuality that a PMMS could, in the future, be added to Schedule 4 and prescribed to be classified in a hazard category or subcategory of a hazard class that is not the most severe category or subcategory.

Discussion of the *Hazardous Products Regulations*
Subsection 2(5)

Prescribed classification – Subpart 1, 4, 7 or 8 of Part 8

2(5) A mixture, material or substance — for which classification in a category or subcategory of a classification table of a hazard class set out in Subpart 1, 4, 7 or 8 of Part 8 is prescribed in Schedule 4 — must also be evaluated in accordance with section 2.1 or 2.2, in the case of Subparts 1, 4 or 7 of Part 8, in respect of each of the categories or subcategories of the other classification tables of the same hazard class, and in the case of Subpart 8 of Part 8, in respect of each of the categories of the same classification table.

It is important to note that subsection 2(5) will not be triggered with the current Schedule 4 items, since there are currently no mixtures, materials or substances that are prescribed to be classified in the Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity or STOT-SE hazard classes (Subparts 1, 4, 7 or 8, respectively, of Part 8). This provision may be triggered in the future following the addition to Schedule 4 of a new mixture, material or substance that would be prescribed to be classified in one of the above-mentioned hazard classes. For these hazard classes, it is possible for a mixture, material or substance to be classified in more than one hazard category within the same hazard class. For example, a substance could be classified in both Respiratory Sensitization – Category 1 and Skin Sensitization – Category 1. Therefore, if additions to Schedule 4 are made, in the future, that prescribe the classification of a mixture, material or substance in the Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity or STOT-SE hazard class, the mixture, material or substance must also be evaluated to determine whether it meets the criteria to be classified in another category of the same hazard class. The procedures to determine classification are set out in section 2.1 (for a material or substance) and 2.2 (for a mixture).

For the Acute Toxicity, Respiratory or Skin Sensitization and Reproductive Toxicity hazard classes (Subparts 1, 4 and 7, respectively, of Part 8), the mixture, material or substance would need to be evaluated against the criteria of the categories set out in the other classification tables that are in the same hazard class. For example, if a substance is prescribed by Schedule 4 to be classified in Acute Toxicity – Oral – Category 1 (subsection 8.1.1(3), Table 1 - Oral Exposure Route), the substance must still be evaluated against the criteria in the classification table for the Dermal Exposure Route (subsection 8.1.1(3), Table 2) and the criteria in the classification table for the Inhalation Exposure Route (subsection 8.1.1(3), Table 3).

For a mixture, material or substance that is prescribed by Schedule 4 to be classified in the STOT-SE hazard class (Subpart 8 of Part 8), the mixture, material or substance would need to be evaluated against the criteria of the other categories in the same classification table of this hazard class (the Table to subsection 8.8.1(1), which sets out criteria in relation to toxic effects on the central nervous system and respiratory tract and other specific target organs). For example, if a substance is prescribed by Schedule 4 to be classified in STOT-SE – Category 1, and there are available data demonstrating transient narcotic effects and/or transient respiratory tract irritation, then, in accordance with item 3 of the Table to subsection 8.8.1.(1), the substance would also fall within Category 3 of the STOT-SE hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 2(6)

Impurities, stabilizing solvents and stabilizing additives - substance

2(6) Any impurities, stabilizing solvents or stabilizing additives that are known to the supplier to be present in a substance and that are classified must be considered for the purpose of classification of the substance if they are present at a concentration above the concentration limit for an ingredient in a mixture set out in a particular category or subcategory of any hazard class.

The term "substance" refers, in principle, to a single entity (e.g., toluene, silver nitrate, ammonia). However, the definition of "substance" in the HPA (above) considers that a substance may have small amounts of other constituents such as stabilizing additives, impurities and stabilizing solvents. Impurities, stabilizing solvents, or stabilizing additives may have their own unique hazards and/or may contribute to the hazards of the substance.

For the purposes of hazard classification under the HPR, impurities, stabilizing solvents, or stabilizing additives that are, by themselves, classified in a category or subcategory of a health hazard class and that are present in a substance at a concentration above the corresponding concentration limit must be considered for the classification of the substance. In such a situation, the substance must be classified in accordance with the data pertaining to the impurity, stabilizing solvent, or stabilizing additive, unless there are test data showing that the substance does not present that particular hazard. Impurities, stabilizing solvents, and stabilizing additives that are part of a substance are present during any tests that have been conducted on the substance, and therefore, their hazards would be reflected in the results of these tests.

Impurities, stabilizing solvents, and stabilizing additives are only given special consideration when they are part of a substance. For example, phenol and diacetone alcohol are impurities that can be present in acetone, which is a substance. When impurities, stabilizing solvents, and stabilizing additives are part of a mixture, they are considered in the same manner as one would consider the ingredients of the mixture (as noted below in the discussion of subsection 2(7)). For example, benzene is an impurity that can be present in paint products.

Discussion of the *Hazardous Products Regulations*
Subsection 2(7)

Impurities, stabilizing solvents and stabilizing additives - mixture

2(7) Any impurities, stabilizing solvents or stabilizing additives that are known to the supplier to be present in a mixture and that are classified must be considered for the purpose of classification of the mixture if they are present at a concentration above the concentration limit for an ingredient in a mixture set out in a particular category or subcategory of any hazard class.

For the purposes of hazard classification under the HPR, impurities, stabilizing solvents or stabilizing additives in mixtures must be considered in the overall classification of a mixture if they are, by themselves, classified in a category or subcategory of a health hazard class and are present at a concentration above the concentration limit for that category or subcategory of that health hazard class. Thus, for the purposes of hazard classification of a mixture, a supplier must consider impurities, stabilizing solvents, and stabilizing additives that are present in the mixture in the same manner as the supplier would consider the ingredients of the mixture. Subsections 2.5(1) (concentration limits – lower concentration) and 2.5(2) (concentration limits – equivalent or higher concentration) must be considered in the assessment of impurities, stabilizing additives, and stabilizing solvents that are part of a mixture.

An example of a stabilizing solvent in a mixture would be toluene or another hydrocarbon in an industrial paint. Without the stabilizing solvent, the resin would dry and not be able to be applied to a substrate.

Discussion of the *Hazardous Products Regulations* Subsection 2(8)

Individually packaged in outer container

2(8) If two or more different and individually packaged products, mixtures, materials or substances, designed to be accessed individually, are packaged together in an outer container for sale or importation, the assemblage of the products, mixtures, materials and substances in the outer container must not be considered as a single product for the purpose of classification, as each product, mixture, material or substance is subject to the classification provisions of this Part.

This provision applies to situations in which two or more distinct PMMS are packaged together in an outer container, such as in a kit. In such a situation, for the purposes of classification, the supplier must not consider the assemblage as one PMMS. Instead, each PMMS must be assessed individually and each PMMS that meets the criteria to be classified in one or more hazard classes must have its own label and SDS.

Notes:

1) "two or more different and individually packaged" PMMS – this means a package containing at least two individually packaged different PMMS. It would exclude, for example, six bottles of the same PMMS in an outer box. Unless one of the exceptions set out in section 5.2 of the HPR applies, where more than one container of the same PMMS is packaged in an outer container to form a multipack, the outer container label must provide the same information elements as the label of each container within the multipack.

2) "designed to be accessed individually" – this means that in the normal course of use, each PMMS is accessed on its own. This type of assemblage is commonly referred to as a "kit", but all assemblages than contain different and individually packaged PMMS that can be accessed individually would be captured by subsection 2(8). For example, in the case of a two-part system (e.g., two containers of different PMMS in one outer box) in which each part has to be opened and used in some way, each part must be assessed individually for the purpose of classification.

An assemblage that is designed to have each PMMS accessed individually and in which the PMMS are packaged together in an outer container, as described in this subsection, often comes with instructions for use that require the PMMS to be combined or mixed together. Section 4.1 of the HPR pertains to situations in which a hazardous product comes with instructions for use that require its combination with one or more PMMS and this combination results in the creation of one or more new materials or substances that present a new or more severe hazard.

For such a hazardous product, additional information with regard to the new or more severe hazard is required on the safety data sheet. Further information, including information regarding hazardous products packaged in multi-compartment containers, can be found in the discussion of subsection 4.1(1).

It is important to note that there is a labelling exemption in section 5.3 of the HPR for the outer container of assemblages that contain at least two different hazardous products packaged together. Further information can be found in the discussion of section 5.3.

Discussion of the *Hazardous Products Regulations*
Subsection 2(9)

Animal data - not relevant to humans

2(9) Animal data that demonstrate conclusively, based on established scientific principles, that the mechanism or mode of action of the substance or mixture in animals is not relevant to humans must not be used for the purpose of classifying a substance or mixture in any of the health hazard classes referred to in Subparts 1 to 10 and 12 of Part 8.

When reviewing animal data for the purpose of classifying a substance or mixture in any of the health hazard classes referred to in Subparts 1 to 10 and 12 of Part 8 (that is, all of the health hazard classes except for Subpart 11 of Part 8 - Biohazardous Infectious Materials (BIM)), if there are data on the mechanism or mode of action of the substance or mixture, these data must be considered. Where there is conclusive evidence, based on established scientific principles, that the mechanism or mode of action of the substance or mixture in animals is not relevant to humans, the animal data must not be used for the purpose of determining classification. However, if the supplier does not have conclusive evidence that the mechanism or mode of action is not relevant to humans, then the animal data must be considered for the purpose of determining classification.

For example, suppose there are animal data which demonstrate that exposure to a substance results in an increased incidence of kidney tumours in male rats, but there is evidence, based on established scientific principles, that the mechanism of tumour formation involves an enzyme which is specific to the male rat and which is not present in humans. In this situation, the animal data which demonstrate the positive association between exposure to the substance and the development of tumours in male rats must not be used for the purpose of classifying the substance in the Carcinogenicity health hazard class (Subpart 6 of Part 8). Other available data of the types specified in section 2.1 would still need to be taken into consideration to determine the classification of the substance in the Carcinogenicity health hazard class.

This provision does not apply to BIM as the scope of the BIM hazard class is not limited to materials that are infectious to humans. It also includes materials that are infectious to animals.

Material or Substance

Discussion of the *Hazardous Products Regulations* Section 2.1

Classification – material or substance

2.1 Subject to sections 2.8 and 2.9, for the purpose of establishing whether a material or substance is classified in a category or subcategory of a hazard class, the material or substance must be evaluated in accordance with established scientific principles, with respect to the criteria and requirements of each category or subcategory of the hazard class as set out in Parts 7 and 8, using available data of the following types, as applicable:

(*a*) in relation to the material or substance itself,

(i) results of testing or studies carried out in accordance with the test methods referred to in Part 7 or 8,

(ii) results of testing or studies carried out in accordance with generally accepted standards of good scientific practice at the time the test or study was carried out,

(iii) conclusions based on established scientific principles, and

(iv) case reports or documented observations; and

(*b*) except for Subparts 2 and 3 of Part 8, if the data of the types referred to in paragraph

(*a*) are insufficient to evaluate the material or substance in accordance with the criteria and requirements set out in Parts 7 and 8, in relation to a material or substance that has similar properties,

(i) results of testing or studies carried out in accordance with the test methods referred to in Part 7 or 8,

(ii) results of testing or studies carried out in accordance with generally accepted standards of good scientific practice at the time the test or study was carried out,

(iii) conclusions based on established scientific principles, and

(iv) case reports or documented observations.

It is the duty of the supplier to ensure that labels and SDSs of hazardous products imported or sold in Canada for use, handling or storage in a work place, comply with all the requirements of the HPR. Distributors who purchase hazardous products that are intended for use, handling or storage in a work place from other Canadian suppliers and sell these hazardous products meet the definition of a “supplier” under the HPA. Therefore, distributors are also required to ensure that the labels and SDSs for the hazardous products that they are selling are compliant with the HPR. Compliance with the HPR requires that the classification of a PMMS be accurate, based on all available data.

When classifying materials or substances with respect to Parts 7 and 8 (Physical and Health hazard classes, respectively), certain requirements are to be met, including the types of data to be considered and the order of precedence for considering these different types of data. The types of data that must be used are as specified in subparagraphs 2.1(a)(i) to (iv) and 2.1(b)(i) to (iv), as applicable.

Data on the material or substance itself take precedence over data on a similar material or substance. Data on the material or substance may include any of the following:

- results of testing or studies carried out in accordance with the test methods referred to in Part 7 or 8;
- results of testing or studies carried out in accordance with generally accepted standards of good scientific practice;
- conclusions based on established scientific principles; and
- case reports or documented observations.

If data on the material or substance are unavailable or are insufficient to evaluate the material or substance in accordance with the applicable criteria, then for each hazard class except Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation (Subparts 2 and 3, respectively, of Part 8), data of the types listed above for a material or substance with similar properties to the material or substance that is being classified must be considered. Subparts 2 and 3 of Part 8 are excluded because these hazard classes provide a sequential approach to the determination of classification that already incorporates the consideration of different types of data, beginning with data on the substance itself and then other types of data, such as pH, followed by data on similar substances.

According to subparagraphs 2.1(a)(iii) and 2.1(b)(iii), conclusions based on established scientific principles are to be considered when classifying a material or substance. This provision permits the consideration of conclusions based on Quantitative Structure Activity Relationships (QSARs) and Structure-Activity Relationships (SARs) to classify a material or substance.

“Documented observations” are meant to encompass a wide range of evidence, including case reports and incident reports (subparagraphs 2.1(a)(iv) and 2.1(b)(iv)).

Where impurities, stabilizing additives and stabilizing solvents are part of a material or substance and are, by themselves, classified in a category or subcategory of a health hazard class, they must be taken into consideration for the classification of the material or substance if they are present at a concentration that exceeds the cut-off value or concentration limit for that category or subcategory of that health hazard class (see discussion of subsection 2(6)).

Classification is based on existing data and no additional testing is required to be undertaken; however, suppliers are not prevented from performing testing. All available data must be evaluated against the criteria for each hazard class to determine the classification of a material or substance.

When classifying a material or substance, section 2.8 (requirement, for certain physical hazard classes, to evaluate solids using data that relate to the physical form in which the solid is sold or imported) and section 2.9 (provision relating to biological availability) must be taken into consideration.

Sources of information that may be used in hazard classification include, but are not limited to, the following:

- Fire Protection Guide to Hazardous Materials;
- Transport Canada Emergency Response Guidebook, most recent version;
- Hazardous Substances Data Bank (HSDB) (http://toxnet.nlm.nih.gov/);
- NIOSH Pocket Guide to Chemical Hazards (http://www.cdc.gov/niosh/npg/);
- International Chemical Safety Cards (http://www.cdc.gov/niosh/ipcs/);
- INCHEM (http://www.inchem.org/);
- OECD eChemPortal (http://www.oecd.org/env/ehs/risk-assessment/echemportalglobalportaltoinformationonchemicalsubstances.htm);
- TLVs and BEIs (ACGIH) (http://www.acgih.org/tlv-bei-guidelines/tlv-chemical-substances-introduction);
- The Merck Index;
- Published literature;
- CRC Handbook of Chemistry and Physics;
- Sax's Dangerous Properties of Industrial Materials, latest edition;
- Bretherick's Handbook of Reactive Chemicals Hazards, latest edition;
- IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (http://monographs.iarc.fr/);
- ATSDR - Toxicological Profiles (http://www.atsdr.cdc.gov/toxprofiles/index.asp);
- Canadian Centre for Occupational Health and Safety (CCOHS) CHEMINFO database (http://ccinfoweb.ccohs.ca/cheminfo/search.html);
- Répertoire Toxicologique (REPTOX) – Recherche une substance (http://www.csst.qc.ca/prevention/reptox/Pages/recherche-produit.aspx);

Mixture

Classification

Discussion of the *Hazardous Products Regulations* Subsection 2.2(1)

Part 7

2.2(1) Subject to section 2.8, for the purpose of establishing whether a mixture is classified in a category or subcategory of a physical hazard class, the mixture must be evaluated, in respect of each category or subcategory of each physical hazard class, using data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) in relation to the mixture or, if the data of those types are insufficient to evaluate the mixture in accordance with the criteria and requirements set out in Part 7, using data of the types referred to in subparagraphs 2.1(*b*)(i) to (iv) in relation to a mixture with similar properties.

It is the duty of the supplier to ensure that labels and SDSs of hazardous products imported or sold in Canada for use, handling or storage in a work place, comply with all the requirements of the HPR. Distributors who purchase hazardous products that are intended for use, handling or storage in a work place from other Canadian suppliers and sell these hazardous products meet the definition of a "supplier" under the HPA. Therefore, distributors are also required to ensure that the labels and SDSs for the hazardous products that they are selling are compliant with the HPR. Compliance with the HPR requires that the classification of a PMMS be accurate, based on all available data.

This subsection provides rules that apply to the classification of mixtures with respect to the physical hazard classes (Part 7). The available data must be evaluated against the criteria for each category of each physical hazard class in order to determine the mixture's classification. Certain rules with respect to the types of data to be considered and the order of precedence for considering these different types of data must be followed. The types of data that must be used are as specified in subparagraphs 2.1(a)(i) to (iv) and 2.1(b)(i) to (iv), as applicable.

Data on the mixture itself take precedence over data on a similar mixture. As for the classification of a material or substance, data on the mixture itself may include any or more than one of the following:

- results of testing or studies carried out in accordance with the test methods referred to in Part 7;
- results of testing or studies carried out in accordance with generally accepted standards of good scientific practice;
- conclusions based on established scientific principles; and
- case reports or documented observations.

If data on the mixture itself are unavailable or are insufficient to evaluate the mixture in accordance with the applicable criteria, then data of the types listed in subparagraphs 2.1(b)(i) to (iv) for a mixture with similar properties to the mixture that is being classified must be considered.

According to subparagraphs 2.1(a)(iii) and 2.1(b)(iii), conclusions based on established scientific principles are to be considered when classifying a mixture. This provision permits the consideration of conclusions based on QSARs and SARs to classify a mixture.

"Documented observations" are meant to encompass a wide range of evidence, including case reports and incident reports (subparagraphs 2.1(a)(iv) and 2.1(b)(iv)).

Classification is based on existing data and no additional testing is required to be undertaken; however, suppliers are not prevented from performing testing. All available data must be evaluated against the criteria for each physical hazard class to determine the physical hazard classification of a mixture.

When classifying mixtures with respect to physical hazards, section 2.8 (requirement, for certain physical hazard classes, to evaluate solids using data that relate to the physical form in which the solid is sold or imported) must be taken into consideration.

In addition to using information on the mixture itself or information on a mixture with similar properties, there are three physical hazard classes which include provisions for classifying mixtures based on information on the ingredients in the mixture.

1. In Subpart 2 of Part 7 (Flammable Gases), subsection 7.2.1(3) allows the use of a calculation method to determine the flammability of a gas mixture. This method uses data on the ingredients to determine the flammability of the gas mixture.

2. In Subpart 6 of Part 7 (Flammable Liquids), paragraph 7.6.1(4)(b) also refers to a calculation method which uses data on ingredients to determine the flammability of a liquid mixture.

3. In Subpart 15 of Part 7 (Organic Peroxides), subsection 7.15.1(4) does not use a calculation method but requires, under certain conditions, that the classification of a mixture of organic peroxides be based on data available on the ingredients (i.e., on the most hazardous organic peroxide in the mixture).

4. In Subpart 4 of Part 7 (Oxidizing Gases), section 7.4.1 allows the use of a calculation method to determine whether a gas mixture is an oxidizing gas. This method uses data on the ingredients to determine the oxidizing power of the gas mixture.

Although these three subparts include provisions that allow the classification of mixtures based on data available on their respective ingredients, it is important to note that for classification purposes, data on the mixture itself or a mixture with similar properties always take precedence over data on the ingredients.

For example, to determine the flammability of a liquid mixture, if there is no information with respect to the flash point or the initial boiling point, then data from a similar liquid mixture must be used. Alternatively, as noted above, an applicable calculation method may be used to determine the flash point of the liquid mixture, provided that the calculation is applied under conditions for which it has been validated according to generally accepted standards of good scientific practice (paragraph 7.6.1 (4)(b)).

Discussion of the *Hazardous Products Regulations*
Subsection 2.2(2)

Part 8

2.2(2) Subject to section 2.9, for the purpose of establishing whether a mixture is classified in a category or subcategory of a health hazard class, the mixture must be evaluated, in respect of each category or subcategory of each health hazard class, using data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv), in relation to the ingredients, the mixture as a whole or a mixture with similar properties, following the order of the provisions, in relation to mixtures, as presented in each Subpart of Part 8.

It is the duty of the supplier to ensure that labels and SDSs of hazardous products imported or sold in Canada for use, handling or storage in a work place, comply with all the requirements of the HPR. Distributors who purchase hazardous products that are intended for use, handling or storage in a work place from other Canadian suppliers and sell these hazardous products meet the definition of a “supplier” under the HPA. Therefore, distributors are also required to ensure that the labels and SDSs for the hazardous products that they are selling are compliant with the HPR. Compliance with the HPR requires that the classification of a PMMS be accurate, based on all available data.

This subsection provides rules that apply to the classification of mixtures with respect to the health hazard classes (Part 8). When classifying a mixture in a health hazard class, the mixture must be evaluated in accordance with data of the types referred to in subparagraphs 2.1(a)(i) to (iv) in relation to the mixture as a whole, a mixture with similar properties, or in relation to the ingredients of the mixture. The classification must follow the order of provisions for the classification of mixtures, as set out in each health hazard class. This procedure will generally (but not always) require the following steps:

1. Where test data are available for the mixture itself, the classification of the mixture will be based on that data.

2. Where test data are not available for the mixture itself, then the applicable bridging principles (see subsections 2.3(3) to (8)) must be used. In order to apply the bridging principles, sufficient test data must be available for similar mixtures and for individual ingredients of the mixture to be classified.

3. If test data are not available for the mixture itself, and sufficient data to allow the application of bridging principles are also not available, then the method(s) described in each subpart for determining the hazards based on the ingredients of the mixture must be applied to classify the mixture (e.g., application of cut-off values/concentration limits/calculation methods).

According to subparagraph 2.1(a)(iii), conclusions based on established scientific principles are to be considered when classifying a mixture. This provision permits the consideration of conclusions based on QSARs and SARs to classify a mixture.

"Documented observations" are meant to encompass a wide range of evidence, including case reports and incident reports (subparagraph 2.1(a)(iv)).

Where impurities, stabilizing additives and stabilizing solvents are part of a mixture and are, by themselves, classified in a category or subcategory of a health hazard class, they must be taken into consideration for the classification of the mixture if they are present at a concentration that exceeds the cut-off value or concentration limit for that category or subcategory of that health hazard class (see discussion of subsection 2(7)). Subsection 2.5(1) (concentration limits – lower concentration) and 2.5(2) (concentration limits – equivalent or higher concentration) must be considered in the assessment of impurities, stabilizing additives and stabilizing solvents that are part of a mixture.

Classification is based on existing data and no additional testing is required to be undertaken; however, suppliers are not prevented from performing testing. All available data must be evaluated against the criteria for each health hazard class to determine the health hazard classification of a mixture.

It is important to note that section 2.9 (biological availability) must be taken into consideration when classifying mixtures with respect to health hazards.

Discussion of the *Hazardous Products Regulations*
Subsection 2.2(3)

Part 8 – order of provisions

2.2(3) When following the order of the provisions in accordance with subsection (2), the mixture must be classified in accordance with the first provision that permits its classification. Once the mixture is classified, the provisions that follow within the same Subpart in relation to mixtures do not apply, except in the case of Subparts 1, 4, 7 and 8 of Part 8.

Except in the case of Subparts 1, 4, 7 and 8 of Part 8 (Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity and STOT-SE, respectively), the first provision that results in a mixture being classified in a category or subcategory of a health hazard class concludes the process of classification with regard to that particular health hazard class. No further evaluation of the mixture in relation to the remaining provisions for the classification of mixtures in that health hazard class is necessary.

Subparts 1, 4, 7 and 8 of Part 8 are different because, for these health hazard classes, it is possible for a mixture to be classified in more than one category. As described in the discussion of subsection 2(1), these health hazard classes contain more than one classification table and it is necessary to evaluate the data for a mixture against the criteria in each classification table. For Subpart 8 of Part 8 (STOT-SE), a supplier must evaluate the data for a mixture against the criteria for all three of the categories in the table to subsection 8.8.1(1) and then follow the criteria in the table to subsection 8.8.1(2) to determine the resulting classification.

It is important to note that the provisions for classifying mixtures must be applied in the order specified in each Subpart of Part 8. This order is very important because classification using data on the mixture as a whole may result in a more severe or less severe hazard classification than would result if the bridging principles or methods for estimating hazards based on the ingredients of the mixture were used. For example, consider the situation where test data for a mixture shows that it meets the criteria for Skin Irritation - Category 2, but does not meet any of the criteria for Skin Corrosion (Category 1A, 1B or 1C). Even if the mixture contains an ingredient that would trigger the classification of the mixture in Skin Corrosion - Category 1C based on the application of cut-off values/concentration limits, the mixture must be classified in Skin Irritation - Category 2 and not in Skin Corrosion - Category 1C, based on the order of the provisions for the classification of mixtures specified in Subpart 2 of Part 8 (Skin Corrosion/Irritation hazard class).

Bridging Principles

The “GHS” means the United Nations document entitled *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Fifth Revised Edition (GHS).

Bridging principles, which were adopted from the GHS, apply to the classification of mixtures in the health hazard classes set out in Subparts 1 to 10 of Part 8 (these health hazard classes are covered in the GHS). Bridging principles do not apply to the classification of mixtures in the Biohazardous Infectious Materials or Health Hazards Not Otherwise Classified hazard classes (Subparts 11 and 12 of Part 8, respectively). These health hazard classes are not from the GHS.

When a mixture has not been tested, but there are sufficient data on both its ingredients and similar tested mixtures, these data can be used in accordance with the following bridging principles, where appropriate and if there is an indication to that effect within the relevant Subpart of Part 8:

- Dilution (subsection 2.3(3))
- Production batches (subsection 2.3(4))
- Increase in concentration of hazardous ingredient (subsection 2.3(5))
- Interpolation (subsection 2.3(6))
- Substantially similar mixtures (subsection 2.3(7))
- Aerosols – health hazard classes (subsection 2.3(8))

The application of bridging principles ensures that the classification process uses the available data to the greatest extent possible in characterizing the potential hazard. In order to use the bridging principles, the supplier must have test data on another mixture, often referred to, in the HPR, as the "tested mixture", which must be similar to the mixture that the supplier wants to classify. In the absence of such a "tested mixture", the bridging principles cannot be used. In these instances, it is necessary to refer again to the Subpart of Part 8 that deals with the health hazard class under review, and continue with the next provision in the procedure for the classification of mixtures in that health hazard class.

For the "Production batches" bridging principle, as long as batches of a particular mixture are manufactured using the same ingredients and according to the same manufacturing process, the application of this bridging principle to an untested batch requires sufficient data on similar tested batches, but does not require the evaluation of data on the ingredients.

When following the procedure for the classification of a mixture in a health hazard class, at the appropriate step, the provisions in the relevant Subpart of Part 8 will indicate the use of the bridging principles and there will be a reference to some or all of subsections 2.3(3) to (8). The bridging principles are grouped in subsections 2.3(3) to (8) instead of being repeated in the Subpart for each health hazard class.

The Table in the discussion of subsection 2.3(2) shows which bridging principles apply to each health hazard class.

If sufficient data to apply bridging principles are not available, then it is necessary to refer again to the relevant Subpart of Part 8 that deals with the health hazard class under review and continue with the next provision in the procedure for the classification of mixtures in that health hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 2.3(1)

Definitions

2.3(1) The following definitions apply in this section.

"production batch" means a batch that results from a consistent production process using fixed physico-chemical parameters when there is no intention to alter the characteristics of the final product.

"tested" refers to a mixture for which there are data of a type referred to in subparagraph 2.1(*a*)(i), (ii) or (iv).

Regarding the term "production batch", when a mixture is manufactured in batches, usually engineering parameters are put in place to ensure that the variation between batches is limited as much as possible so that every batch produced should essentially be "identical" to all other batches.

"Batch-to-batch variability" refers to situations where products are produced to specified criteria, but product composition varies from batch to batch. Variations in product composition could be due to factors such as production tolerances (fluctuations permitted by the quality control parameters of the manufacturing process) and varying concentrations of starting materials. As a result of these factors, the concentration of a particular hazardous ingredient in a hazardous product may vary from one batch to another. Further guidance regarding batch-to-batch variability and the disclosure of ingredient concentration ranges on SDSs is provided in Part 4 of the Technical Guidance.

The term "tested mixture" means that test data are available on the mixture itself. These data could include results of testing or studies, case reports or documented observations, as appropriate.

Discussion of the *Hazardous Products Regulations* Subsection 2.3(2)

Application of bridging principles

2.3(2) In the case of the health hazard classes set out in Subparts 1 to 10 of Part 8, the bridging principles set out in subsections (3) to (8) must be applied if there is an indication to that effect.

This provision specifies that the bridging principles must not be applied unless indicated in the Subpart of Part 8 that deals with the health hazard class under review. For each of the health hazard classes set out in Subparts 1 to 10 of Part 8, the classification procedure for mixtures specifies which bridging principles are applicable for that hazard class. Bridging principles do not apply to the classification of mixtures in Subpart 11 (Biohazardous Infectious Materials) or Subpart 12 (Health Hazards Not Otherwise Classified) of Part 8.

It is important to note that, as shown below in the Summary Table - Application of the Bridging Principles to the Health Hazard Classes of the HPR, not all bridging principles are to be used for all health hazard classes. The bridging principle that is appropriate to the mixture being classified depends on the type of data available for that mixture and on the hazard being assessed.

Summary Table – Application of the Bridging Principles to the Health Hazard Classes of the HPR

	Bridging Principles					
Health Hazard Class	Dilution	Production Batches	Increase in concentration of hazardous ingredient	Interpolation	Substantially similar mixtures	Aerosols
Acute Toxicity	✓ (see note 1 below)	✓	✓	✓	✓	✓
Skin Corrosion / Irritation	✓ (see note 1 below)	✓	✓ (see note 2 below)	✓	✓	✓
Serious Eye Damage / Eye Irritation	✓ (see note 1 below)	✓	✓ (see note 3 below)	✓	✓	✓
Respiratory or Skin Sensitization	✓	✓	✓	✓	✓	✓
Germ Cell Mutagenicity	✓	✓			✓	
Carcinogenicity	✓	✓			✓	
Reproductive Toxicity	✓	✓			✓	
Specific Target Organ Toxicity – single exposure	✓	✓	✓	✓	✓	✓
Specific Target Organ Toxicity – repeated exposure	✓	✓	✓	✓	✓	✓
Aspiration Hazard	✓	✓	✓	✓	✓	
Biohazardous Infectious Materials	Bridging principles do not apply to this health hazard class.					
Health Hazards Not Otherwise Classified	Bridging principles do not apply to this health hazard class.					

Notes:

1. Special rules apply; please refer to the discussion of paragraph 2.3(3)(a)
2. Special rules apply; please refer to the discussion of paragraph 2.3(5)(b)
3. Special rules apply; please refer to the discussion of paragraph 2.3(5)(c)

Discussion of the *Hazardous Products Regulations*
Subsection 2.3(3)

Dilution

2.3(3) If a tested mixture that is classified in a category or subcategory of a health hazard class set out in Subparts 1 to 10 of Part 8 is diluted with a diluent, the following applies provided that the diluent is a mixture or substance that, with respect to that health hazard class, has an equivalent or less severe hazard classification than the least hazardous ingredient of the tested mixture and, based on established scientific principles, does not affect the classification of the tested mixture:

The "Dilution" bridging principle may be applied, as specified, to the classification of mixtures in all health hazard classes set out in Part 8, except Subparts 11 and 12 (Biohazardous Infectious Materials and Health Hazards Not Otherwise Classified, respectively).

The "Dilution" bridging principle may be applied if a tested mixture is diluted with a diluent that has the same or a less severe classification than the least hazardous ingredient of the tested mixture. The phrase "does not affect the classification of the tested mixture" is included in subsection 2.3(3) because there could be situations where the dilution of the tested mixture with a diluent might affect classification. The determination of whether the diluent affects the hazard classification of the tested mixture must be based on established scientific principles.

Discussion of the *Hazardous Products Regulations*
Paragraphs 2.3(3)(*a*) and (*b*)

Dilution (continued)

2.3(3)(*a*) in the case of a tested mixture that is classified in a category or subcategory of a health hazard class set out in Subparts 1 to 3 of Part 8, either the method referred to in section 8.1.5, 8.2.11 or 8.3.11, as the case may be, must be used to establish whether the diluted mixture must be classified in a category or subcategory of a hazard class, or the diluted mixture must be classified in the same category or subcategory of the health hazard class as the tested mixture; or

For three of the health hazard classes (Subparts 1, 2, and 3, of Part 8 – namely Acute Toxicity, Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation, respectively), a calculation method, as described in section 8.1.5, 8.2.11 or 8.3.11, respectively, can be used to determine the classification of the diluted mixture. The calculation method may result in a less severe hazard classification than if the diluted mixture were to be classified in the same category as the tested mixture.

If the calculation method cannot be or is not used, then the default method of classifying the diluted mixture in the same category as the tested mixture must be used. This conservative

approach assumes that the diluent had no impact on the hazards of the mixture. Either the calculation method or the "default" method may be used.

Dilution (continued)

(*b*) in all other cases, the diluted mixture must be classified in the same category or subcategory of the health hazard class as the tested mixture.

The default method of classifying the diluted mixture in the same category as the tested mixture (as described in paragraph 2.3(3)(b)) is the mandatory method used for the health hazard classes other than Acute Toxicity, Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation. For example: Mixture A, which has been classified in Skin Sensitization - Category 1 based on test data, is diluted with Diluent B to form Mixture C. If Diluent B has an equivalent or lower skin sensitization classification than that of the least hazardous ingredient in Mixture A, i.e., the ingredient in Mixture A with the lowest classification for that hazard class, and Diluent B does not affect the hazard classification of Mixture A, then it can be assumed that the respective hazard of the new mixture C is equivalent to that of the original tested mixture. Therefore, Mixture C must also be classified in Skin Sensitization – Category 1.

As another example, Mixture A, which has been classified in STOT- SE – Category 1, is diluted with Diluent B to form Mixture C. Diluent B is not classified in STOT-SE, and the least hazardous ingredient in Mixture A is, by itself, also not classified in STOT-SE. Diluent B does not affect the hazard classification of Mixture A. Thus, it can be assumed that the respective hazard of the new mixture C is equivalent to that of the original tested mixture. Therefore, Mixture C must also be classified in STOT-SE – Category 1.

Discussion of the *Hazardous Products Regulations* Subsection 2.3(4)

Production batches

2.3(4) The classification is the same for a mixture in all production batches of that mixture that are manufactured, produced or processed by the same supplier, unless there is a significant variation between the batches that affects the classification of the mixture.

As defined in subsection 2.3(1), the term "production batches" means "a batch that results from a consistent production process using fixed physico-chemical parameters when there is no intention to alter the characteristics of the final product".

The "Production batches" bridging principle may be applied, as specified, to the classification of mixtures in all health hazard classes set out in Part 8, except Subparts 11 and 12 (Biohazardous Infectious Materials and Health Hazards Not Otherwise Classified, respectively). If test data are available for one batch of a mixture that is produced under a controlled process, it is assumed that other batches of the same mixture from the same supplier produced under the same conditions have the same properties, and therefore the same classification.

However, if a change occurs during the production process that could influence the toxicity or any other hazard related to the mixture, then the mixture could have a different classification. For example, if temperature controls failed during the production run of a batch, then this batch could have a different classification than that of the other batches. In this situation, it is not possible to apply the "Production batches" bridging principle and it is necessary to refer again to the Subpart of Part 8 that deals with the health hazard class under review, and continue with the next provision in the procedure for the classification of mixtures in that health hazard class.

Discussion of the *Hazardous Products Regulations*
Paragraph 2.3(5)(*a*)

Increase in concentration of hazardous ingredient

2.3(5) If the concentration of a hazardous ingredient of a tested mixture is increased, the following applies:

(*a*) in the case of the health hazard classes set out in Subparts 1, 4 and 8 to 10 of Part 8, if the tested mixture is classified in the Category 1 category of the health hazard class, the new mixture resulting from the increased concentration must be classified in the same category of the same health hazard class, without additional evaluation with regard to that hazard class;

The "Increase in concentration of hazardous ingredient" bridging principle may be applied, as specified, to the classification of mixtures in the health hazard classes set out in Subparts 1, 4 and 8 to 10 of Part 8 (Acute Toxicity, Respiratory or Skin Sensitization, STOT-SE, Specific Target Organ Toxicity – Repeated Exposure (STOT-RE) and Aspiration Hazard, respectively). This bridging principle does not apply to Subparts 5, 6, 7, 11 or 12 of Part 8 (Germ Cell Mutagenicity, Carcinogenicity, Reproductive Toxicity, Biohazardous Infectious Materials or Health Hazards Not Otherwise Classified, respectively).

This provision considers that if a mixture is already classified in the most severe hazard category (i.e., Category 1) of one of the above-mentioned hazard classes, increasing the concentration of a hazardous ingredient in the mixture will not affect this classification, because the classification cannot be more severe than it already is. Therefore, the untested mixture would also be classified in Category 1 without additional testing. In this provision, "increased concentration" means the increased concentration of ingredient(s) in the mixture that is/are classified in the same hazard class in which the Category 1 ingredient is classified. For example, if a mixture is classified in STOT-RE - Category 1, and the supplier increases the concentration of any ingredient in the mixture that is classified in any category of STOT-RE, then the new mixture would remain classified in STOT–RE - Category 1.

This bridging principle only applies within a hazard class; it does not apply across hazard classes.

Comparison to HCS 2012

In the HCS 2012 (paragraph A.0.5.1.3), this provision is referred to as the "Concentration of mixtures" bridging principle, but the principle itself is the same as the "Increase in concentration of hazardous ingredient" principle described in subsection 2.3(5).

Discussion of the *Hazardous Products Regulations*
Paragraph 2.3(5)(*b*)

Increase in concentration of hazardous ingredient (continued)

2.3(5)(*b*) in the case of the health hazard class set out in Subpart 2 of Part 8,

(i) if the tested mixture is classified in the Category 1A subcategory of the health hazard class, the new mixture resulting from the increased concentration must be classified in the same subcategory of the same health hazard class, without additional evaluation with regard to that hazard class, or

(ii) if the tested mixture does not contain any hazardous ingredient classified in the Category 1 category and is classified in the Category 2 category of the health hazard class, the new mixture resulting from the increased concentration must be classified in the same category of the same health hazard class, without additional evaluation with regard to that hazard class; and

A different provision for the "Increase in concentration of hazardous ingredient" bridging principle is provided for Subpart 2 of Part 8 (Skin Corrosion/ Irritation) because corrosion and irritation hazards are considered distinct from each other. For example, increasing the concentration of a skin irritant still results in a mixture that produces skin irritation, not skin corrosion.

The term "increased concentration" should be understood as the increased concentration of an ingredient in the mixture that is classified in this hazard class (i.e., Category 1, 1A, 1B, or 1C skin corrosive or Category 2 skin irritant).

Where sufficient data are available, substances and mixtures which cause skin corrosion can be further sub-classified into Category 1A, 1B, or 1C. To apply the bridging principle described in subparagraph 2.3(5)(b)(i), the tested mixture must be classified in Skin Corrosion – Category 1A. For a tested mixture that is already classified in Category 1A, an increase in the concentration of an ingredient classified in 1A , 1B or 1C of this hazard class requires the new mixture to remain classified in 1A.

This subparagraph cannot be applied to a tested mixture classified in Category 1B or Category 1C.

Category 1 of the Skin Corrosion/Irritation hazard class addresses substances and mixtures which cause skin corrosion. For example, consider a mixture that is classified in Skin Corrosion - Category 1 (without further sub-classification). If the concentration of the Category 1 skin

corrosive ingredient is increased, then, although this is not specified in the Regulations, the resultant mixture could also be classified in Category 1 (without further sub-classification).

This bridging principle can also be applied to mixtures classified in Skin Irritation - Category 2 (subparagraph 2.3.5(b)(ii)). The mixture being classified must not contain any Category 1 ingredients. If a tested mixture is classified in Skin Irritation - Category 2 and there is an increase in the concentration of a Skin Irritation - Category 2 hazardous ingredient, the resultant mixture must also be classified in Skin Irritation - Category 2.

Discussion of the *Hazardous Products Regulations*
Paragraph 2.3.5(*c*)

Increase in concentration of hazardous ingredient (continued)

2.3(5)(*c*) in the case of the health hazard class set out in Subpart 3 of Part 8

(i) if the tested mixture is classified in the Category 1 category of the health hazard class, the new mixture resulting from the increased concentration must be classified in the same category of the same health hazard class, without additional evaluation with regard to that hazard class, or

(ii) if the tested mixture does not contain any hazardous ingredient classified in the Category 1 category and is classified in the Category 2A subcategory of the health hazard class, the new mixture resulting from the increased concentration must be classified in the same subcategory of the same health hazard class, without additional evaluation with regard to that hazard class.

This provision for the “Increase in concentration of hazardous ingredient” bridging principle applies to mixtures classified in the Serious Eye Damage/Eye Irritation hazard class (Subpart 3 of Part 8).

The term “increased concentration” should be understood as the increased concentration of an ingredient in the mixture that is classified in this hazard class (i.e., Serious Eye Damage - Category 1 or Eye Irritation - Category 2 or 2A).

To apply the bridging principle described in subparagraph 2.3.5(c)(i), the tested mixture must be classified in Serious Eye Damage – Category 1. For a tested mixture that is already classified in Category 1, an increase in concentration of an ingredient classified in Category 1 of this hazard class requires the new mixture to remain classified in Category 1.

This bridging principle can also be applied to mixtures classified in Eye Irritation - Category 2A of the Serious Eye Damage/Eye Irritation hazard class (subparagraph 2.3(c)(ii)). The mixture being classified must not contain any Category 1 ingredients. If a tested mixture is classified in Eye Irritation - Category 2A and there is an increase in the concentration of an Eye Irritation - Category 2A or 2B hazardous ingredient, the resultant mixture must be classified in Eye Irritation - Category 2A.

Subparagraph 2.3(5)(c)(ii) cannot be applied to a tested mixture classified in Eye Irritation – Category 2B.

In addition, consider a tested mixture that is classified in Eye Irritation - Category 2 (without further sub-classification) and which does not contain any Category 1 ingredients. If there is an increase in the concentration of an Eye Irritation - Category 2 hazardous ingredient, then, although this is not specified in the Regulations, the resultant mixture could also be classified in in Eye Irritation - Category 2 (without further sub-classification).

Discussion of the *Hazardous Products Regulations* Subsection 2.3(6)

Interpolation

2.3(6) In the case of the health hazard classes set out in Subparts 1 to 4 and 8 to 10 of Part 8, when three mixtures (A, B and C) contain identical ingredients — some or all of which are hazardous — if mixtures A and B have been tested and are classified in the same category or subcategory of the same health hazard class and if mixture C has not been tested and has the same hazardous ingredients as mixtures A and B with concentrations intermediate to the concentrations of those hazardous ingredients in mixtures A and B, then mixture C must be classified in the same category or subcategory of the same health hazard class as mixtures A and B.

The “Interpolation” bridging principle may be applied, as specified, to the classification of mixtures in the health hazard classes set out in Subparts 1 to 4 and 8 to 10 of Part 8 (Acute Toxicity, Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Respiratory or Skin Sensitization, STOT-SE, STOT-RE, and Aspiration Hazard, respectively). This bridging principle does not apply to Subparts 5, 6, 7, 11 or 12 of Part 8 (Germ Cell Mutagenicity, Carcinogenicity, Reproductive Toxicity, Biohazardous Infectious Materials or Health Hazards Not Otherwise Classified, respectively).

To use interpolation, there must be three mixtures (A, B and C) with identical ingredients, of which mixtures A and B have been tested and are classified in the same hazard category of the same hazard class. Untested mixture C has the same hazardous ingredients as mixtures A and B but with concentrations intermediate to (i.e., in between) the concentrations found in mixtures A and B. In this case, mixture C must also be classified in the same hazard category of the same hazard class as mixtures A and B.

For example:

	Mixture A (tested) Classification: STOT-RE - Category 2	Mixture B (tested) Classification: STOT-RE - Category 2	Mixture C (untested)
Ingredient X (non-hazardous)	80	65	72
Ingredient Y (hazardous)	15	25	20
Ingredient Z (hazardous)	5	10	8

Based on the above data, and using the bridging principle set out in subsection 2.3(6) of the HPR, mixture C must also be classified in STOT-RE - Category 2 because the concentration of each hazardous ingredient in mixture C falls between the concentrations of the same hazardous ingredient in mixtures A and B.

It is important to note that it is the concentration of each hazardous ingredient in mixture C that must be intermediate to the concentrations of the same hazardous ingredient in mixtures A and B.

For example:

	Mixture A (tested) Classification: STOT-RE - Category 2	Mixture B (tested) Classification: STOT-RE - Category 2	Mixture C (untested)
Ingredient X (non-hazardous)	80	65	68
Ingredient Y (hazardous)	15	25	20
Ingredient Z (hazardous)	5	10	12

In the above example, the concentration of hazardous ingredient Y in mixture C (20%) is intermediate to the concentrations of hazardous ingredient Y in mixtures A (15%) and B (25%). However, the concentration of hazardous ingredient Z in mixture C (12%) is higher than the concentrations of hazardous ingredient Z in both mixtures A (5%) and B (10%). Thus, the Interpolation bridging principle cannot be used. The supplier must refer again to the Subpart of Part 8 that deals with the health hazard class under review (in this example, Subpart 9 of Part 8), and continue with the next provision in the procedure for the classification of mixtures in that health hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 2.3(7)

Substantially similar mixtures

2.3(7) If one of the mixtures (ingredient A + ingredient B) or (ingredient C + ingredient B) is a tested mixture that is classified in a category or subcategory of a health hazard class, the other mixture must be classified in the same category or subcategory of the same health hazard class if the following conditions are met:

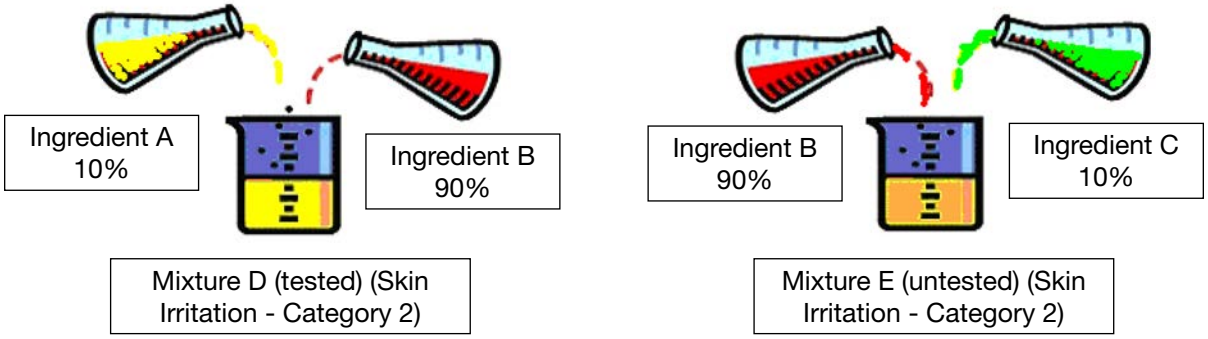
(*a*) the concentration of ingredient B is the same in both mixtures;

(*b*) the concentration of ingredient A is the same as that of ingredient C; and

(*c*) ingredients A and C are classified in the same category or subcategory of the same health hazard class and, based on established scientific principles, do not affect the classification of ingredient B.

The "Substantially similar mixtures" bridging principle may be applied, as specified, to the classification of mixtures in all health hazard classes set out in Part 8, except Subparts 11 and 12 (Biohazardous Infectious Materials and Health Hazards Not Otherwise Classified, respectively).

The following illustrates the bridging principle regarding substantially similar mixtures where Mixture D has been tested and Mixture E is untested.



Ingredient A and ingredient C are both classified in Skin Irritation - Category 2, and they do not affect the classification of ingredient B.

Note: Although subsection 2.3(7) refers to "ingredient A" and "ingredient B", this provision applies also if ingredients A and B are in fact mixtures.

Discussion of the *Hazardous Products Regulations*
Subsection 2.3(8)

Aerosols — health hazard classes

2.3(8) In the case of the health hazard classes set out in Subparts 1 to 4, 8 and 9 of Part 8, a mixture to which a propellant has been added and that is contained in an aerosol dispenser must be classified in the same category or subcategory of the same health hazard class as the mixture to which no propellant was added if, based on established scientific principles, the added propellant does not affect the classification of the mixture on spraying.

The "Aerosols" bridging principle may be applied, as specified, to the classification of mixtures in the health hazard classes set out in Subparts 1 to 4, 8 and 9 of Part 8 (Acute Toxicity, Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Respiratory or Skin Sensitization, STOT-SE, and STOT-RE respectively). This bridging principle does not apply to Subparts 5, 6, 7, 10, 11 or 12 of Part 8 (Germ Cell Mutagenicity, Carcinogenicity, Reproductive Toxicity, Aspiration Hazard, Biohazardous Infectious Materials or Health Hazards Not Otherwise Classified, respectively).

This bridging principle is based on the concept that changing a mixture to an aerosol does not make the mixture more hazardous with respect to its health hazards unless the propellant itself presents a health hazard. For this reason, mixtures to which a propellant is added are attributed the same health hazard classification as they had without the propellant, unless the propellant itself presents a health hazard. Propellants are often flammable (e.g., light hydrocarbons such as butane or isobutane) and may affect the classification of a mixture in one or more of the physical hazard classes, such as the Flammable Aerosols hazard class. However, the addition of a propellant to a mixture in an aerosol dispenser is less likely to affect the classification of the mixture in the health hazard classes.

Other Principles

These principles may apply to the classification of a mixture in any health hazard class. There is no specific reference to them within the respective Subparts of Part 8; however, they must always be considered as part of the classification process.

Discussion of the *Hazardous Products Regulations* Subsection 2.4(1)

Synergistic effects

2.4(1) In order to establish whether a mixture is classified in a category or subcategory of a health hazard class, if the evaluation of the mixture is carried out in accordance with a provision that requires the use of data available on the ingredients in the mixture, then all data available on the potential occurrence of synergistic effects among the ingredients of the mixture must be used in the evaluation carried out in accordance with section 2.2.

When classifying a mixture based on data available in relation to the ingredients in the mixture, all data related to any synergistic effects between the individual ingredients in the mixture must be used in the evaluation. An interaction that produces synergistic effects results in a mixture that is more hazardous than the sum of the hazards of the interacting ingredients.

Discussion of the *Hazardous Products Regulations* Subsection 2.4(2)

Antagonistic effects

2.4(2) If antagonistic effects among the ingredients of the mixture are considered in order to establish the classification of the mixture in a category or subcategory of a health hazard class in the course of the evaluation carried out in accordance with section 2.2, the data in respect of the antagonistic effects must be conclusive, based on established scientific principles.

When classifying a mixture in a health hazard class, if a supplier uses data that show negative or counteractive effects of one ingredient on another ingredient (i.e., antagonistic effects), this data must be conclusive and based on established scientific principles. Otherwise, the data showing antagonistic effects must not be used for the purpose of classifying the mixture.
The consideration of antagonistic effects is subject to a higher scientific standard than the consideration of synergistic effects. The reason for the higher standard is that the consideration of antagonistic effects might result in the classification of a mixture in a less severe category of a particular health hazard class, or even no classification at all in that health hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 2.5(1)

Concentration limits — lower concentration

2.5(1) In the case of Subparts 1 to 10 and 12 of Part 8, if an ingredient is present in a mixture at a lower concentration than the concentration limit for a particular category or subcategory of a health hazard class, but still presents the hazard identified by the category or subcategory of that hazard class at that concentration, the mixture must be classified in that category or subcategory.

This provision applies to the classification of mixtures in all of the health hazard classes except for Subpart 11 of Part 8 (Biohazardous Infectious Materials), for which no concentration limit has been specified.

When classifying a mixture in a particular category or subcategory of a hazard class based on data available for the ingredients of the mixture, if there are data showing that an ingredient still presents the hazard at a concentration which is lower than the applicable concentration limit (cut-off value), then the mixture must be classified in that category or subcategory of that hazard class. This provision takes precedence over the concentration limit rule.

For example, consider a mixture that contains an ingredient which, when evaluated individually, meets the criteria for Respiratory Sensitization – Category 1A and which is present in the mixture at a concentration of 0.05%. The concentration limit for the classification of a mixture in Respiratory Sensitization – Category 1A based on ingredient data is 0.1%. However, there are data which demonstrate that the ingredient presents the hazard of respiratory sensitization, even at a concentration of 0.05%. Therefore, based on subsection 2.5(1), the mixture must be classified in Respiratory Sensitization – Category 1A.

In a situation where subsection 2.5(1) is applied, the ingredient that triggered the classification of the mixture in a category or subcategory of a health hazard class must be disclosed on the SDS under item 3. It is not necessary to disclose the ingredient on the label. Further information on ingredient disclosure on SDSs can be found in the discussion of Schedule I in Part 4 of the Technical Guidance.

This provision does not apply to Subpart 11 of Part 8 because there is no concentration limit for the classification of mixtures as Biohazardous Infectious Materials. Biohazardous infectious materials can present a health hazard even when present in a mixture in miniscule amounts.

Discussion of the *Hazardous Products Regulations*
Subsection 2.5(2)

Concentration limits — equivalent or higher concentration

2.5(2) In the case of Subparts 1 to 10 and 12 of Part 8, subject to subsection 2.4(1), if an ingredient is present in a mixture at an equivalent or higher concentration than the concentration limit for a particular category or subcategory of a health hazard class, but further to evidence based on established scientific principles it does not present the hazard identified by the category or subcategory of that hazard class at that concentration, the mixture need not be classified in that category or subcategory in relation to that specific ingredient.

This provision applies to the classification of mixtures in all of the health hazard classes except for Subpart 11 of Part 8 (Biohazardous Infectious Materials), for which no concentration limit has been specified.

When classifying a mixture in a particular category or subcategory of a hazard class, based on data available for the ingredients of the mixture, this provision may be applied if there is appropriate supporting evidence. The provision specifies that, if an ingredient is present in a mixture at a concentration that is equal to or higher than the concentration limit for a particular category or subcategory of a health hazard class, but there are data showing that, based on established scientific principles, the ingredient does not present the hazard at that concentration, then the mixture need not be classified in that category or subcategory of that hazard class due to the presence of that specific ingredient. The data must be scientifically valid, because the outcome of this evaluation may result in no classification for the mixture in the hazard class and category or subcategory under review.

For example, consider a mixture that contains an ingredient at a concentration of 2.0% which, when evaluated individually, meets the criteria for STOT-SE – Category 1. The concentration limit for the classification of a mixture in STOT-SE – Category 1 based on ingredient data is 1.0%. However, the supplier has scientifically valid data which demonstrate conclusively, based on established scientific principles, that the ingredient, when present in a mixture at a concentration of 2.0%, does not present a specific target organ toxicity hazard. Furthermore, there are no other ingredients present in the mixture that is being evaluated, that would trigger classification in STOT-SE – Category 1. Therefore, this mixture would not be required to be classified in STOT-SE – Category 1.

The consideration for subsection 2.5(2) is subject to a higher scientific standard than the consideration of subsection 2.5(1) because the outcome of this consideration may result in the classification of the mixture in a less severe category, or possibly in no classification at all in the hazard class under review.

If subsection 2.5(2) is applied, then it is not necessary to disclose, under item 3 of the SDS, the ingredient which has been determined not to present the associated hazard in the mixture. It

is also not necessary to disclose the ingredient on the label. Further information on ingredient disclosure on SDSs can be found in the discussion of Schedule I in Part 4 of the Technical Guidance.

It is important to note that synergistic effects between the ingredients in a mixture must be taken into account before concluding that an ingredient, which is present in a mixture at a concentration that is equal to or higher than the concentration limit for a particular category or subcategory of a health hazard class, does not present the associated hazard. Therefore, the supplier must refer to the requirement specified in subsection 2.4(1). If there are test data that specifically relate to the mixture that is being evaluated, then any synergistic effects between the ingredients present in the mixture will already have been reflected in the test results for the mixture.

Subsection 2.5(2) does not apply to Subpart 11 of Part 8 because there is no concentration limit for the classification of mixtures as Biohazardous Infectious Materials. Biohazardous infectious materials can present a health hazard even when present in a mixture in miniscule amounts.

Discussion of the *Hazardous Products Regulations*
Section 2.6

Maximum concentration

2.6 If a mixture with a specific product identifier contains a hazardous ingredient that is not always present at the same concentration, the maximum concentration must be used for the purposes of establishing whether the mixture is classified in a category or subcategory of a health hazard class.

This provision is intended to ensure that the most conservative approach is taken when classifying a mixture that contains ingredients that could be present at varying concentrations. The classification of the mixture with respect to the health hazard classes must reflect the highest level of hazard that the mixture could present.

If, for example, a mixture contains hazardous ingredient A that is present within a concentration range of 10% to 15%, then the highest possible concentration of ingredient A (15%) must be used for the purpose of determining classification in the health hazard classes.

Furthermore, if a supplier has a mixture that contains hazardous ingredients A and B, both of which are present in specific concentration ranges, then both A and B must be considered at their highest possible concentrations, even though it may be impossible for the mixture to contain the highest possible concentration of A and the highest possible concentration of B at the same time (i.e., if both A and B are present in the mixture at their highest possible concentrations, then the total concentration of ingredients may exceed 100%). The most conservative information must be used (that is, the highest possible concentration of each hazardous ingredient must be used) for the purpose of determining classification in the health hazard classes.

This provision would apply, for example, to the health hazard classification of hazardous products in which hazardous ingredients are present at varying concentrations due to batch-to-batch variability. Further information with regard to concentration ranges can be found in Appendix 3 of Part 4 of the Technical Guidance.

Product

Discussion of the *Hazardous Products Regulations* Section 2.7

Classification - product

2.7 Subject to section 2.8, to establish whether a product is classified in a category or subcategory of a physical hazard class, it must be evaluated in accordance with section 2.1 or 2.2.

This provision applies to particular physical hazard classes - Subparts 3, 5, 8, and 15 of Part 7 (Flammable Aerosols, Gases Under Pressure, Self-Reactive Substances and Mixtures, and Organic Peroxides, respectively). For these physical hazard classes, the packaging of the mixture, material or substance, as well as the contents of the packaging, must be considered for the purpose of classification (i.e., if a mixture, material or substance in its package are considered together to form a product, it is the overall product that is classified). This provision specifies that, where classification requires consideration of the product as a whole, including its packaging, the same rules with respect to consideration of data must be applied, and the procedures that must be used to determine the classification of the product as a whole are set out in sections 2.1 (for a material or substance) and 2.2 (for a mixture).

For example, in the case of an aerosol that is packaged in a receptacle made of metal, glass or plastic, the aerosol plus the receptacle together form a product and it is the product as a whole that is evaluated for the purpose of classification.

It is important to note that section 2.8 (requirement, for certain physical hazard classes, to evaluate solids using data that relate to the physical form in which the solid is sold or imported) must be taken into consideration when evaluating whether a product is classified in a category of a physical hazard class. This provision is discussed below.

Specific Rules

Discussion of the *Hazardous Products Regulations*
Section 2.8

Solids

2.8 In the case of the physical hazard classes set out in Subparts 7, 10 to 12 and 14 of Part 7, the data used for the purposes of evaluation of a solid must relate to the solid in the physical form in which it is sold or imported. If the solid is in a physical form that is different from that used to generate the data and the solid in that physical form is liable to display different behaviour, the solid must also be evaluated in that other physical form.

Subparts 7, 10, 11, 12 and 14 of Part 7 are physical hazard classes that specifically relate to solids (Flammable Solids, Pyrophoric Solids, Self-Heating Substances and Mixtures, Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases, and Oxidizing Solids, respectively). Various forms of solids are possible, including massive solid blocks, solid flakes, small pieces, solid granules, solid dusts, powders or particulates. Each of these forms may have different physical and chemical properties, since some physical and chemical properties depend on reactivity which, in turn, depends in part on surface area. For example, dusts have much larger surface areas available for interaction with surrounding oxygen than massive solid blocks. Therefore, dusts may present different hazards than massive solid blocks.

This provision requires the supplier to use data that relate to the solid in the same form as the one in which it is to be sold or imported (e.g., use data on dusts to classify dusts; use data on solid blocks to classify solid blocks, etc.), in order to ensure that the classification reflects the hazards of the product that is being sold or imported.

It is important to note that the Combustible Dusts hazard class is not mentioned here because Subpart 17 of Part 7 already specifies that this hazard class applies only to dusts.

Discussion of the *Hazardous Products Regulations*
Section 2.9

Biological availability

2.9 If it can be shown by conclusive experimental data from scientifically validated methods that the mixture, material or substance is not biologically available, it need not be classified in any health hazard class.

Chapter 4.1 of the GHS provides the following definition and guidance regarding bioavailability: “Bioavailability (or biological availability) means the extent to which a substance is taken up by an organism, and distributed to an area within the organism. It is dependent upon physico-chemical

properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. Availability is not a prerequisite for bioavailability".

For a mixture, material or substance to have an effect on a biological system, there must be some degree of bioavailability. Therefore, if it can be shown by conclusive experimental data from scientifically validated methods (e.g., from Council Regulation (EC) No 440/2008) that a mixture, material or substance is not biologically available, it does not need to be considered for classification in any health hazard class. Bioavailability considerations are only relevant with respect to classification for health hazards.

References

29 CFR 1910.1200, Hazard Communication

Hazardous Products Act, R.S.C., 1985, c. H-3

Hazardous Products Regulations, SOR/2015-17

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

PART 3

Labelling

A systematic approach to promoting the safe use of hazardous products in the work place requires the dissemination of information regarding the potential hazards and appropriate safety precautions from the suppliers to the users of the products. Labels and safety data sheets (SDSs) are the main tools for hazard communication. This Part of the technical guidance addresses labelling requirements, whereas Part 4 addresses SDS requirements.

A label serves as the first alert for workers since the label provides basic information about the hazards of a hazardous product and precautionary measures, thereby allowing workers to avoid injuries, illnesses and incidents related to the use, handling and storage of the hazardous products. While labels provide important information to the workers, they are limited by design in the amount of information they can provide.

The following definitions from the *Hazardous Products Act* (HPA) apply in this Part.

Definitions from the HPA Section 2

"container" includes a bag, barrel, bottle, box, can, cylinder, drum or similar package or receptacle but does not include a storage tank;

"hazardous product" means any product, mixture, material or substance that is classified in accordance with the regulations made under subsection 15(1) in a category or subcategory of a hazard class listed in Schedule 2;

"import" means to import into Canada;

"label" means a group of written, printed or graphic information elements that relate to a hazardous product, which group is designed to be affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged;

"mixture" means a combination of, or a solution that is composed of, two or more ingredients that, when they are combined, do not react with each other, but excludes any such combination or solution that is a substance;

"sell" includes

(a) offer for sale or distribution, expose for sale or distribution, have in possession for sale or distribution or distribute — whether for consideration or not — to one or more recipients, and

(b) make any transfer of possession that creates a bailment or, in Quebec, make any transfer of possession of a movable, for a specific purpose, without transferring ownership, and with the obligation to deliver the movable to a specified person or to return it, such as a transfer by means of a deposit, a lease, a pledge, a loan for use or a contract of carriage;

"substance" means any chemical element or chemical compound — that is in its natural state or that is obtained by a production process — whether alone or together with

(a) any additive that is necessary to preserve the stability of the chemical element or chemical compound,

(b) any solvent that is necessary to preserve the stability or composition of the chemical element or chemical compound, or

(c) any impurity that is derived from the production process;

"supplier" means a person who, in the course of business, sells or imports a hazardous product;

The "GHS" means the United Nations document entitled *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Fifth Revised Edition (GHS).

Alignment with the GHS, provides a harmonized hazard communication system that includes labels and SDSs, which is based on harmonized classification criteria.

Paragraphs 13(1)(b) and 14(b) of the HPA refer to labelling requirements for the sale and importation of hazardous products intended for use, handling or storage in a work place in Canada.

Note: If a Product, Mixture, Material or Substance (PMMS) does not meet the criteria to be classified in any of the HPR hazard classes, that product does not meet the definition of a hazardous product. No label or SDS is required under the HPA for a PMMS that does not meet the definition of a hazardous product under the HPA. There may be labelling requirements under other laws that may apply to products that do not fall under the HPA and HPR.

Items to note:

- The WHMIS 1988 requirement for a hatched border is not required on the label of a hazardous product.
- The WHMIS 1988 requirement for a statement to the effect that an SDS is available is not required on the label of a hazardous product.
- Additional information beyond what is required may be added to the label to provide further detail as long as that information does not contradict or cast doubt on the standardized information.

VARIANCE with HCS 2012: Labelling of mixtures classified in Carcinogenicity-Category 2

HPR

Under the HPR, all mixtures containing a carcinogenic ingredient (whether Category 1 or 2) at a concentration of 0.1% and higher are required to have a label as well as an SDS.

HCS 2012

This requirement differs from the HCS 2012. As specified in the note below Table A.6.1 of the HCS 2012, "*a label warning is optional for mixtures that contain Category 2 carcinogens at concentrations between 0.1 and 1.0%, but an SDS is required*". In the HCS 2012, all mixtures containing a carcinogenic ingredient (whether Category 1 or 2) at a concentration of 0.1% or more are required to have an SDS, and mixtures that contain Category 2 carcinogens at concentrations of 1.0% or more are required to have both a label and an SDS.

Discussion of the *Hazardous Products Regulations*
Paragraphs 3(1)(*a*) and (*b*)

Information Elements

3(1) Subject to section 3.6 and for the purposes of paragraphs 13(1)(*b*) and 14(*b*) of the Act, the label of a hazardous product or the container in which the hazardous product is packaged must provide, in respect of the hazardous product, the following information elements:

(*a*) the product identifier;

(*b*) the initial supplier identifier;

As defined in subsection 1(1) of the HPR, "'product identifier' means, in respect of a hazardous product, the brand name, chemical name, common name, generic name or trade name." In addition to the obligation to provide the product identifier on the label of a hazardous product or the container in which the hazardous product is packaged, the same product identifier must also be provided in item 1(a) of the SDS as per section 4.2 of the HPR.

According to subsection 1(1) of the HPR, initial supplier identifier means the name, address and telephone number of (a) the Canadian manufacturer or (b) the Canadian importer of a hazardous product who operates in Canada. This means that, by default, the name, address and telephone number of a Canadian manufacturer or Canadian importer are required to appear on the label of any hazardous product that is sold in or imported into Canada and is intended for use, handling or storage in a work place in Canada. However, where a hazardous product is sold by a Canadian distributor, the distributor may provide his own name, address and telephone number on the label and SDS in lieu of the name, address and telephone number of the Canadian manufacturer or Canadian importer. Furthermore, a Canadian importer can retain the name, address and telephone number of the foreign supplier on the label and SDS if the hazardous product is imported only for the importer's own use (i.e., only for use in the importer's work place). For further information about these exceptions, see sections 5.8 and 5.9 of the HPR.

It is important to note that if the Canadian distributor provides his name, address and telephone number on the label, then the same contact information of the distributor must also be provided on the SDS.

Furthermore, under the HPR, a Canadian distributor who buys a hazardous product, re-labels the hazardous product and then sells it, is considered to be the initial supplier of the hazardous product. In this situation, the Canadian distributor must provide his name, address and telephone number on the label and SDS.

VARIANCE with HCS 2012: Supplier identifier

HPR

Under the HPR, a Canadian supplier identifier must appear on the label and SDS.

HCS 2012

The HCS 2012 requires the name, address and telephone number of the manufacturer, importer, or other responsible party to appear on the label. The same U.S. address and phone number must appear on the SDS and label (i.e., they must match). When the chemical is imported, the importer is the first point of contact. The importer is therefore the responsible party for complying with the HCS 2012, and must include their name and address on the SDS and label. Although not required, U.S. OSHA prefers the original foreign manufacturer's name and address be removed to prevent confusion.

In the case of a hazardous product that is imported into Canada from a foreign supplier, and the hazardous product is not intended only for use in the importer's own work place (and therefore, does not qualify for the exception specified in section 5.9 of the HPR), it is the Canadian importer (i.e., the Canadian party who is responsible for bringing the hazardous product into Canada) whose name, address and telephone number must be provided on the label and SDS. The Canadian importer is responsible for ensuring that the importation of the hazardous product is in compliance with the requirements of the HPA and the HPR.

Additional information beyond what is required may be included on the label and SDS, as long as the information is not false or misleading (section 14.2 of the HPA prohibits information that is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included in a label or SDS for a hazardous product). Therefore, it would be acceptable for the label and SDS to include the contact information (name, address and telephone number) of both the Canadian importer and the foreign supplier.

In the situation where an existing label does not contain one or more information element(s) required under the HPR, the missing information element(s) must be added to the existing label in a manner that meets the following requirements:

- section 3.3 of the HPR (grouping)
- section 3.4 of the HPR (legibility)
- section 3.5 of the HPR (durability)

- section 14.2 of the HPA (prohibition of misleading information)
- the definition of label under the HPA.

Discussion of the *Hazardous Products Regulations* Paragraphs 3(1)(*c*) and (*d*)

Information Elements (continued)

(*c*) subject to subsections (2) to (5), for each category or subcategory in which the hazardous product is classified, with the exception of the categories referred to in paragraph (d), the information elements, namely, the symbol, signal word, hazard statement and precautionary statement, that are specified for that category or subcategory in section 3 of Annex 3 of the GHS;

(*d*) subject to subsections (2) to (4), for each category set out in Subparts 17 to 20 of Part 7 and in Subparts 11 and 12 of Part 8 in which the hazardous product is classified,

(i) the information elements that are specified for that category in Schedule 5, and

(ii) any precautionary statements that are applicable to the hazardous product in terms of

(A) general precautionary statements,

(B) prevention precautionary statements,

(C) response precautionary statements,

(D) storage precautionary statements, and

(E) disposal precautionary statements;

A product that is classified as a hazardous product must be labelled using prescribed label information elements. For each hazard class adopted from the GHS in which the hazardous product is classified, the corresponding pictogram, signal word, hazard statement and precautionary statements prescribed in section 3 of Annex 3 of the GHS are required on the label. For all other hazard classes in which the hazardous product is classified, those information elements as set out in Schedule 5 of the HPR for the hazard class are required on the label. In a few instances, information elements are not prescribed (e.g., the pictogram for a hazardous product classified in Physical Hazards Not Otherwise Classified (PHNOC) or Health Hazards Not Otherwise Classified (HHNOC) is chosen by the supplier); in these cases, it is up to the supplier to determine the appropriate information elements. The supplier or importer must ensure that the hazardous product or the container in which the hazardous product is packaged has been labelled appropriately. The following prescribed information elements must be provided on the label:

- Pictogram(s)
- Signal word
- Hazard statement(s)
- Precautionary statement(s), and
- Supplemental label element(s) (paragraphs 3(1)(e) and (f))

Any element required by paragraph 3(1)(c) of the HPR must also be provided, if applicable, in accordance with the specific rules in the following subsections of the HPR:

- 3(2) - Codes or instructions
- 3(3) - Substitution by pictogram
- 3(4) - Hazard statements - Specific Target Organ Toxicity - Single Exposure
- 3(5) - Information elements for certain categories or subcategories
- 3.6(1) - Specific rule - signal word
- 3.6(2) - Specific rule – hazard statement
- 3.6(3) - Specific rule - symbol

In addition, any element required by paragraph 3(1)(d) of the HPR must also be provided, if applicable, in accordance with the specific rules in subsections 3(2) to (4) of the HPR (Codes or instructions, Substitution by pictogram and Hazard statement – STOT-SE, respectively).

For each category or subcategory in which a product is classified, the following label elements are required:

Pictogram(s)

A symbol along with other graphical elements, such as a border and background colour constitutes a pictogram (defined in subsection 1(1) of the HPR). Although section 3 of Annex 3 of the GHS provides a symbol for each hazard category or subcategory of each hazard class, the corresponding pictogram(s) in Schedule 3 of the HPR must appear on the label. Subsection 3(3) of the HPR is the provision that requires that the symbol be substituted by the pictogram on the label.

Pictograms are assigned to categories and subcategories of hazard classes and are intended to convey physical and/or health hazard information about hazardous products. The format of a black symbol on a white background with a red frame in the shape of a square set on a point has been adopted for nearly all HPR hazard classes. The only exception is the Biohazardous Infectious Materials (BIM) hazard class for which the biohazard symbol is set in a round black border.

In some cases, pictograms also convey information regarding the severity of hazard. For example, a product classified in Acute Toxicity - Category 1 will require the skull and crossbones pictogram (more severe), while a product classified in Acute Toxicity - Category 4 will require the exclamation mark (less severe) pictogram:


The symbols that are required for categories and subcategories of hazard classes are shown in section 3 of Annex 3 of the GHS and Schedule 5 of the HPR.

For the hazard classes that are not covered in the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, Physical Hazards Not Otherwise Classified (PHNOC), Health Hazards Not Otherwise Classified (HHNOC), and BIM), the required pictogram is found in Schedule 5 of the HPR. Hazardous products classified in PHNOC – Category 1 and HHNOC – Category 1 require a pictogram, but the pictogram is not prescribed by Schedule 5. In this case, the supplier must select the most suitable pictogram from the ones shown in Schedule 3 of the HPR and use it on the label. All symbols and related pictograms used in these regulations can be found in Schedule 3 of the HPR.

VARIANCE with HCS 2012: Label elements for PHNOC and /or HHNOC vs. HNOC

HPR

Under the HPR, label elements are required for PHNOC and HHNOC.

HCS 2012

In the HCS 2012, there are no label elements required for Hazards Not Otherwise Classified (HNOC).

Section 3 of Annex 3 of the GHS and Schedule 5 of the HPR also indicate which categories and subcategories of hazard classes do not require a symbol on the label.

The following hazard categories in a hazard class do not require a symbol:

1. Flammable Gases – Category 2
2. Flammable Liquids – Category 4
3. Self-Reactive Substances and Mixtures - Type G *
4. Organic Peroxides - Type G*
5. Serious Eye Damage/Eye Irritation - Category 2B
6. Reproductive Toxicity – Effects on or via lactation
7. Combustible Dusts - Category 1 (non-GHS hazard class)
8. Simple Asphyxiants - Category 1 (non-GHS hazard class)

* It is important to note that for a PMMS classified in Self-Reactive Substances and Mixtures (Subpart 8 of Part 7) – Type G and/or Organic Peroxides (Subpart 15 of Part 7) – Type G, there is no prescribed pictogram, signal word, hazard or precautionary statement, or supplemental label elements. For these two classifications, only the product identifier and initial supplier identifier are required on the label.

Signal Word

The signal word, as defined in subsection 1(1) of the HPR, is used on the label to alert the user of a hazardous product to a potential hazard and to indicate the severity of hazard. There are two signal words: “Danger” and “Warning”. “Danger” is used for the more severe hazards, while “Warning” is used for less severe hazards. For example, a product classified in Reproductive

Toxicity - Category 1 or 1A or 1B will require “Danger” as the signal word, while a product classified in Reproductive Toxicity - Category 2 will require “Warning” as the signal word. The Effects on or via lactation category of the Reproductive Toxicity hazard class is the only hazard category that does not require the use of a signal word but still requires hazard statement(s) and precautionary statement(s). For a hazardous product classified in more than one category or sub-category of a hazard class or in more than one hazard class, the same signal word, “Danger” or “Warning”, is not required to be repeated. It only needs to appear once on the label and once on the SDS.

The signal word for categories and subcategories of hazard classes adopted from the GHS are assigned by section 3 of Annex 3 of the GHS. For the hazard classes not covered by the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, PHNOC, HHNOC, and BIM), the required signal word is assigned in column 4 of Parts 1 to 6 of Schedule 5 of the HPR.

Hazard Statement(s)

Hazard statements (defined in subsection 1(1) of the HPR) in most cases, are prescribed phrases that describe the nature of a hazard presented by a hazardous product. These statements are assigned to a category or subcategory of a hazard class by section 3 of Annex 3 of the GHS. For example, the hazard statement for Acute Toxicity - Oral Category 1 is “Fatal if swallowed” and the hazard statement for Acute Toxicity - Oral Category 4 is “Harmful if swallowed”. The hazard statements for the hazard classes not covered in the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, PHNOC, HHNOC, and BIM) are found in Schedule 5 of the HPR.

It is important to note that, unlike the hazard statements required for all other hazard classes, the hazard statements required for PHNOC, HHNOC and BIM hazard classes are not prescribed. The supplier must identify and use appropriate wording to describe the nature of the PHNOC, HHNOC or BIM hazard.

In addition, there is an exemption in subsection 5.4(1) of the HPR for hazardous products in a container that has a capacity of less than or equal to 100 ml. Hazardous products in a container that has a capacity of less than or equal to 100 ml must include the following information on the label: the product identifier, the initial supplier identifier, the applicable pictogram and signal word. However, the label of such a hazardous product is not required to bear any hazard statement or precautionary statement.

Furthermore, hazard statements may be combined under specific conditions and repetition of a hazard statement must be avoided.

VARIANCE with HCS 2012: Omission of hazard statements

HPR

The omission of hazard statements from labels is not permitted under the HPR.

HCS 2012

The HCS 2012 allows hazard statements to be omitted if it can be demonstrated that the hazard statement is inappropriate.

For the Germ Cell Mutagenicity, Carcinogenicity, Reproductive Toxicity, STOT-SE and Specific Target Organ Toxicity - Repeated Exposure (STOT-RE) hazard classes, the hazard statements set out in section 3 of Annex 3 of the GHS include some instructions in italics and in parentheses, such as: (*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*); (*state specific effect if known*); (*or state all organs affected if known*). With regards to the following instructions: "*state specific effect if known", "or state all organs affected if known*", these instructions should be understood as an obligation to disclose any known specific effects and/or affected organs.

For example, if a hazardous product classified in STOT-SE causes adverse liver effects, the label must provide this information even though it is not certain whether the liver is the only organ affected. Therefore any known affected organ must appear on the HPR label (as part of the required hazard statement) even if all of the affected organs are not known. As an additional example, if a hazardous product is classified in Reproductive Toxicity because it reduces sperm count, even though this effect may not be the only one, this information must appear on the label of this hazardous product.

Precautionary Statement(s)

Precautionary statements (defined in subsection 1(1) of the HPR) which are, in most cases, prescribed, describe the recommended measures to take in order to minimize or prevent adverse effects resulting from exposure to, or improper storage or handling of, a hazardous product. For those hazard classes adopted in the HPR from the GHS, precautionary statements are found in section 3 of Annex 3 of the GHS.

Section 3 of Annex 3 includes four types of precautionary statements covering: prevention, response (first aid measures, accidental spillage or exposure), storage, and disposal. Specific precautionary statements have been assigned to each category or subcategory of each hazard class and category. For example: "Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking" is used for the Flammable Liquids hazard class.

It is important to note that while paragraph 3(1)(c) of the HPR refers to "precautionary statement" (singular), unless the small capacity container exemption set out in subsection 5.4(1) of the HPR applies, the label of a hazardous product must provide all of the precautionary statements that are specified in section 3 of Annex 3 of the GHS, for each category or subcategory of each

hazard class in which the hazardous product is classified. However, as per subsections 3.2(1) and (2) of the HPR, precautionary statements could be combined (HPR 3.2(1)) or omitted (HPR 3.2(2)) under specific conditions.

For hazard classes not covered by the GHS (Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, PHNOC, HHNOC, and BIM), the supplier must provide appropriate precautionary statements in terms of general, prevention, response, storage and disposal precautions. There are no prescribed precautionary statements for these hazard classes.

It is important to note that for the hazard classes that are not covered by the GHS, there is a requirement to provide "general" precautionary statements, if such statements apply. For example, a general precautionary statement could be "Read the label and safety data sheet before use". The "general" precautionary statements are not required for the hazard classes that are adopted from the GHS.

Supplemental label elements

Discussion of the *Hazardous Products Regulations*
Paragraphs 3(1)(*e*) and (*f*)

Information elements (continued)

(*e*) in the case of a hazardous product classified in a category of Subpart 1 of Part 8 and to which paragraph 8.1.6(*b*) applies, the supplemental label element "[*Insert the total concentration in percentage of ingredients with unknown acute toxicity*] % of the mixture consists of an ingredient or ingredients of unknown acute toxicity/[*Insérez la concentration totale en pourcentage d'ingrédients ayant une toxicité aiguë inconnue*] *% du mélange consiste en ingrédients de toxicité aiguë inconnue*"; and

(*f*) in the case of a hazardous product that is classified as an acute toxicant and that, upon contact with water, releases a gaseous substance that has an LC_{50} that falls into one of the ranges indicated in Table 3 to subsection 8.1.1(3), the supplemental label elements that consist of the following hazard statements:

(i) in the case of Categories 1 and 2, "In contact with water, releases gases which are fatal if inhaled/*Au contact de l'eau, libère des gaz mortels en cas d'inhalation*",

(ii) in the case of Category 3, "In contact with water, releases gases which are toxic if inhaled/*Au contact de l'eau, libère des gaz toxiques en cas d'inhalation*", or

(iii) in the case of Category 4, "In contact with water, releases gases which are harmful if inhaled/*Au contact de l'eau, libère des gaz nocifs en cas d'inhalation*".

The supplemental label elements specified in paragraphs 3(1)(e) and (f) of the HPR are only required for certain hazardous products that fall within the Acute Toxicity hazard class.

If the hazardous product is classified in Acute Toxicity (Category 1, 2, 3 or 4) based on ingredient(s) for which the acute toxicity is known and the hazardous product contains ingredients of unknown acute toxicity, a prescribed supplemental label element is required. The route of exposure should be included in the statement. The supplemental label element is required only for the route(s) of exposure with respect to which the hazardous product is classified. For example, if a hazardous product is classified in Acute Toxicity – Oral – Category 1 based on ingredient(s) for which the acute oral toxicity is known and the hazardous product contains, at a concentration of 5%, ingredients of unknown acute oral toxicity, then the following supplemental label element is required:

5% of the mixture consists of ingredient(s) of unknown acute oral toxicity

This supplemental label element could apply more than once in the situation where a mixture ends up being classified for more than one route of exposure based on ingredients of known acute toxicity. For example, if a mixture is classified as acutely toxic through inhalation and oral routes based on ingredient(s) of known acute toxicity, and 2% of this mixture consists of ingredients of unknown acute oral toxicity and 10% of the same mixture consists of ingredients of unknown acute inhalation toxicity, then the following statements must appear on the label of the hazardous product:

2 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

10 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity

or

2% and 10% of the mixture consists of ingredients of unknown acute oral and inhalation toxicity, respectively.

It is important to note that if the hazardous product does not meet any of the criteria for Acute Toxicity - Category 1, 2, 3 or 4, by any route of exposure, this supplemental label element is not required.

If the hazardous product emits a gaseous substance (also referred to as Water-Activated Toxicants or WAT) a prescribed supplemental label statement is required. “In contact with water, releases gases which are fatal/toxic/harmful if inhaled,” is required, where “fatal” is required for Category 1 or 2, “toxic” is required for Category 3 and “harmful” is required for Category 4. For example, consider a substance which is classified in Acute Toxicity (Inhalation) – Category 2, and which, in contact with water, releases a gaseous substance with an LC_{50} of 600 ppmV. In accordance with subsection 8.1.1(2) of the HPR, this substance would be classified in Acute Toxicity - Inhalation - Category 2.

Although the substance also meets the criteria to be classified in Acute Toxicity -Inhalation - Category 3 based on the LC_{50} of the gas emitted in contact with water, it would not be classified in that category because it is already classified in Category 2 which represents a more severe hazard.

The following hazard statements would be required:

Fatal if inhaled.
In contact with water, releases gases which are toxic if inhaled.

VARIANCE with HCS 2012: Supplemental hazard statement for Water-Activated Toxicants

HPR

Under the HPR, a supplemental hazard statement is required on the label and SDS indicating that in contact with water, the product releases gases which are fatal/toxic/harmful if inhaled.

HCS 2012

Under the HCS 2012, a supplemental hazard statement is required on the SDS for substances which, upon contact with water, release a toxic gas, are present in the work place in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency. A supplemental hazard statement is not required on the label.

Discussion of the *Hazardous Products Regulations*
Subsection 3(2)

Codes or instructions

3(2) The information elements required by paragraph (1)(*c*) need not include alphanumeric codes and the information elements required by paragraphs (1)(*c*) and (*d*) must not include instructions that are for the exclusive use of the competent authority, as defined in the GHS, or the supplier.

Section 3 of Annex 3 of the GHS contains alphanumeric codes that have been assigned to each hazard statement and precautionary statement. These alphanumeric codes need not appear on a label and must not, under any circumstances, replace the hazard statement or precautionary statement to which they relate. In the event where a supplier chooses to indicate the codes on a label, the supplier must ensure that this information does not contravene section 14.2 of the HPA which prohibits information that is false, misleading or likely to create an erroneous impression, with respect to the information that is required to be included on a label.

As an example of a hazard statement, H225 Highly flammable liquid and vapour, the alphanumeric code (H225) is assigned under the GHS to the hazard statement (Highly flammable liquid and vapour) for flammable liquids with a flash point below 23°C and an initial boiling point >35°C. In this case, the supplier does not have to include the code H225 on the label or SDS. This same principle extends to the alphanumeric codes assigned to the prescribed precautionary statements (P codes).

In addition, section 3 of Annex 3 of the GHS and Schedule 5 of the HPR contain instructions in *italics*. These instructions are meant for suppliers or competent authorities and must not be included in the content of a label. For example, in Schedule 5 of the HPR, the instructions for PHNOC "*Wording that describes the nature of the hazard*" must not appear on the label; it is meant for the supplier to provide the appropriate hazard statement for PHNOC. Similarly, the instruction "*state all organs affected if known*" for STOT-SE, in section 3 of Annex 3 of the GHS is meant for the supplier to list the organs affected, if known by the supplier.

Section 3 of Annex 3 of the GHS also contains instructions that are not in italics. These instructions are meant for suppliers or competent authorities and must not be reproduced *per se* in the content of a label or safety data sheet, but the suppliers must follow the instructions and modify the content of the label accordingly. For example, for a hazardous product classified in STOT-SE – Category 1 or STOT-RE – Category 1, the precautionary statement "Wash … thoroughly after handling" is listed in section 3 of Annex 3 of the GHS. The following instructions appear below the precautionary statement: "Manufacturer/supplier or the competent authority to specify parts of the body to be washed after handling". In this case, the supplier or importer must not include these instructions on the label, but must specify the parts of the body to be washed after handling. For example, if hands must be washed after handling, then this precautionary statement would read "Wash hands thoroughly after handling".

In situations where the instruction below the precautionary statement reads "Manufacturer/supplier or competent authority may further specify type of equipment where appropriate", the supplier or importer has a choice of whether to specify the type of equipment.

Discussion of the *Hazardous Products Regulations*
Subsection 3(3)

Substitution by pictogram

3(3) The pictogram associated with a symbol in Schedule 3 must be substituted for the symbol that is specified for a category or subcategory in section 3 of Annex 3 of the GHS or for a category in Schedule 5.

A pictogram, as defined in subsection 1(1) of the HPR, is a graphical composition that includes a symbol along with other graphical elements, such as a border and background colour. Although section 3 of Annex 3 of the GHS and Schedule 5 of the HPR provide a symbol for each hazard category or subcategory of each hazard class, the corresponding pictogram(s) in Schedule 3 of the HPR is what must appear on the label.

On the SDS, under item 2(b), the hazard symbol, not the pictogram, for each category or subcategory of each hazard class in which the hazardous product is classified is required to be provided, as described in Schedule 1 of the HPR. Either the name of the symbol or the symbol itself may be used on the SDS. A pictogram would also be acceptable because it contains the symbol, but it is not required.

Discussion of the *Hazardous Products Regulations*
Subsection 3(4)

Hazard statement – Specific Target Organ Toxicity – Single Exposure

3(4) In the case of a hazardous product that is classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 3" of the hazard class "Specific Target Organ Toxicity — Single Exposure", the hazard statement specified for that category in section 3 of Annex 3 of the GHS that relates to the effects for which the product was classified must be used. If the hazardous product causes narcotic effects and respiratory tract irritation, as those terms are defined in Subpart 8 of Part 8, then both hazard statements must be used.

For STOT-SE – Category 3 (subpart 8 of Part 8 of the HPR), two independent hazard statements are provided in section 3 of Annex 3 of the GHS: one relates to respiratory tract irritation (May cause respiratory irritation) and the other relates to narcotic effects (May cause drowsiness or dizziness). Therefore, the statement that must appear on the label must relate to the hazard (respiratory tract irritation or narcotic effects) for which the hazardous product is classified (at a minimum, at least one statement must appear). For example, if the hazard presented is respiratory tract irritation, then the hazard statement "May cause respiratory irritation" must appear on the label; if the hazard presented is narcotic effects then the hazard statement "May cause drowsiness or dizziness" must appear on the label.

In the event the hazardous product presents both hazards, then both hazard statements are required on the label (i.e., the hazard statements "May cause respiratory irritation" and "May cause drowsiness or dizziness" must appear on the label). The hazard statements could be combined according to subsection 3.2(3) of the HPR, i.e., "May cause respiratory irritation and drowsiness or dizziness".

The terms "respiratory tract irritation" and "narcotic effects" are defined in Subpart 8 of Part 8 of the HPR.

Discussion of the *Hazardous Products Regulations*
Subsection 3(5)

Information elements for certain categories or subcategories

3(5) The information elements, namely, the symbol, signal word, hazard statement and precautionary statement, specified in section 3 of Annex 3 of the GHS that are to be used for hazardous products classified in the categories or subcategories below are as follows:

(a) if the hazardous product is classified in the category "Flammable Gases — Category 1", the information elements specified for the category "Flammable Gases (Including Chemically Unstable Gases)" Hazard category 1;

(b) if the hazardous product is classified in the category "Flammable Gases — Category 2", the information elements specified for the category "Flammable Gases (Including Chemically Unstable Gases)" Hazard category 2;

(c) if the hazardous product is classified in the category "Flammable Aerosols — Category 1", the information elements specified for the category "Aerosols" Hazard category 1, with the exception of the hazard statement "Pressurized container: may burst if heated";

(d) if the hazardous product is classified in the category "Flammable Aerosols — Category 2", the information elements specified for the category "Aerosols" Hazard category 2, with the exception of the hazard statement "Pressurized container: may burst if heated";

(e) if the hazardous product is classified in the category "Skin Corrosion — Category 1", the information elements specified for the subcategory "Skin Corrosion/Irritation" Hazard category 1A;

(f) if the hazardous product is classified in the subcategory "Skin Corrosion — Category 1A", in the subcategory "Skin Corrosion — Category 1B" or in the subcategory "Skin Corrosion — Category 1C", the information elements specified for the subcategory "Skin Corrosion/Irritation" Hazard category 1A to 1C;

(g) if the hazardous product is classified in the category "Skin Irritation — Category 2", the information elements specified for the category "Skin Corrosion/Irritation" Hazard category 2;

(h) if the hazardous product is classified in the category "Serious Eye Damage — Category 1", the information elements specified for the category "Eye Damage/Irritation" Hazard category 1;

(i) if the hazardous product is classified in the category "Eye Irritation — Category 2", the information elements specified for the subcategory "Eye Damage/Irritation" Hazard category 2A;

(j) if the hazardous product is classified in the subcategory "Eye Irritation — Category 2A" or in the subcategory "Eye Irritation — Category 2B", the information elements specified, respectively, for the subcategory "Eye Damage/Irritation" Hazard category 2A or the subcategory "Eye Damage/Irritation" Hazard category 2B;

(k) if the hazardous product is classified in the category "Respiratory Sensitizer — Category 1", in the subcategory "Respiratory Sensitizer — Category 1A" or in the subcategory "Respiratory Sensitizer — Category 1B", the information elements specified for the category or subcategory "Sensitization — Respiratory" Hazard category 1, 1A or 1B;

(l) if the hazardous product is classified in the category "Skin Sensitizer — Category 1", in the subcategory "Skin Sensitizer — Category 1A" or in the subcategory "Skin Sensitizer — Category 1B", the information elements specified for the category or subcategory "Sensitization — Skin" Hazard category 1, 1A or 1B;

(m) if the hazardous product is classified in the subcategory "Germ Cell Mutagenicity — Category 1A" or in the subcategory "Germ Cell Mutagenicity — Category 1B", the information elements specified for the category "Germ Cell Mutagenicity" Hazard category 1;

(n) if the hazardous product is classified in the subcategory "Carcinogenicity — Category 1A" or in the subcategory "Carcinogenicity — Category 1B", the information elements specified for the category "Carcinogenicity" Hazard category 1; and

(o) if the hazardous product is classified in the subcategory "Reproductive Toxicity — Category 1A" or in the subcategory "Reproductive Toxicity — Category 1B", the information elements specified for the category "Reproductive Toxicity" Hazard category 1.

If a hazardous product is classified in one of the hazard categories specified in subsection 3(5), the label elements specified in section 3 of Annex 3 of the GHS are required. This provision provides the requirements with respect to specific cases in which:

- The name of the hazard class in the HPR is not exactly the same as in section 3 of Annex 3 of the GHS.
  - For example, for the GHS hazard class "Aerosols", the corresponding name of the hazard class under the HPR is "Flammable Aerosols". Therefore, for a hazardous product classified in HPR "Flammable Aerosols - Category 1", the information elements for "Aerosols" Hazard category 1 from the GHS are required. However, the hazard statement "Pressurized container: may burst if heated" is not required. Similarly, for a hazardous product classified in HPR "Flammable Aerosols - Category 2" the information elements for "Aerosols" Hazard category 2 from the GHS are required. However, the hazard statement "Pressurized container: may burst if heated" is not required.
  - As another example, for the GHS hazard class "Flammable Gases (Including Chemically Unstable Gases)", the corresponding name of the hazard class under the HPR is "Flammable Gases". Therefore, for a hazardous product classified in HPR "Flammable Gases - Category 1" the information elements for "Flammable Gases (Including

Chemically Unstable Gases)" Hazard category 1 from the GHS are required. Similarly, for a hazardous product classified in HPR "Flammable Gases - Category 2" the information elements for "Flammable Gases (Including Chemically Unstable Gases)" Hazard category 2 from the GHS are required.

- Section 3 of Annex 3 of the GHS provides the labelling elements for hazardous products classified in a subcategory (e.g., Subcategory 1A) of a hazard class but does not provide labelling elements for hazardous products classified in the category (e.g., Category 1).
- Section 3 of Annex 3 of the GHS provides the labelling elements for a category (e.g., Category 1) but does not provide labelling elements for hazardous products further classified in a subcategory (e.g., Subcategory 1A).
  - For example, in the case of a hazardous product classified in Eye Irritation – Category 2 of the HPR (without further sub-classification), section 3 of Annex 3 of the GHS does not clearly specify which labelling elements would be required. Subparagraph 3(5)(i) of the HPR indicates that, for such a hazardous product, the required label elements are those specified for Eye Damage/Irritation – Hazard category 2A, in section 3 of Annex 3 of the GHS. For hazardous products classified in Eye Irritation – Category 2A or 2B of the HPR, the required label elements are those specified for Eye Damage/Irritation – Hazard category 2A or 2B, respectively, in section 3 of Annex 3 of the GHS. This is set out in subparagraph 3(5)(i) of the HPR.

It is important to note that in section 3 of Annex 3 of the GHS the title "Hazard category" may refer to a category or subcategory or both (e.g., Respiratory Sensitization Hazard Category 1, 1A, or 1B).

Discussion of the *Hazardous Products Regulations*
Section 3.1

Pictograms

3.1 Any pictogram required to be provided on a label must, except with respect to size, be an exact reproduction of that pictogram as set out in column 3 of Schedule 3 and must,

(a) except for the pictogram for "Biohazardous Infectious Materials", have a black symbol on a white background with a red border in the shape of a square set on one of its points; and

(b) in the case of the pictogram for "Biohazardous Infectious Materials", have a black symbol on a white background with a black border in the shape of a circle.

"An exact reproduction" of the pictogram required to be provided on a label means that the proportion of the frame versus the symbol must be in accordance with the pictogram as shown in Schedule 3 of the HPR.

An empty pictogram border, i.e., a square red frame set at a point without a hazard symbol, is not a pictogram and is not acceptable since this image would be considered as false or misleading information under section 14.2 of the HPA. In other words, empty pictogram borders (red borders with no symbol) are not permitted. However, a blacked out pictogram frame is acceptable as it is not a square red frame set at a point without a hazard symbol. If a blank red frame is not fully covered or filled in, the label is not acceptable. The red frame along with the inside of the frame is required to be blacked out.

A specific pictogram should appear only once on a label, even if the classification of the hazardous product results in assignment of the same pictogram for multiple hazards. For example, if a hazardous product is classified in STOT-SE – Category 1 as well in Reproductive Toxicity – Category 1, the health hazard symbol is required for both classifications but must appear only once. In this case, the repetition of the health hazard symbol would be considered false and misleading under section 14.2 of the HPA because it could lead the user of the product to believe that the product is more hazardous than it actually is. Multiple, identical pictograms on a hazardous product label are not permitted and would be considered non-compliant under the HPR.

With regard to pictogram sizes, there is no minimum size prescribed in the HPR; however the pictogram must be legible in accordance with section 3.4 of the HPR.

The BIM pictogram is not found in the GHS and has often been used with a circular border even in contexts that are not WHMIS-related. Therefore the BIM pictogram retains its existing round, black border.

For all pictograms, the background colour must be white. A background colour other than white is not acceptable.

Discussion of the *Hazardous Products Regulations*
Subsections 3.2(1), (2) and (3)

Combined precautionary statements

3.2(1) The precautionary statements that are required to be provided on a label may be combined if the combination contains the same information as would have been conveyed by each of the individual precautionary statements.

Non-applicable precautionary statements

(2) If a precautionary statement does not apply in a particular case with regard to the normal conditions of use, handling and storage of the hazardous product, it may be omitted.

Combined hazard statements

(3) The hazard statements that are required to be provided on a label may be combined if the combination contains the same information as would have been conveyed by each of the individual hazard statements.

Precautionary statements may be combined if the combination provides the same information as would have been conveyed by each of the individual precautionary statements. For example, “Keep away from heat, hot surfaces, sparks, open flames and other ignition sources; No smoking;,” “Store in a well-ventilated place,”; and “Keep cool” may be combined to read: “Keep cool, in a well-ventilated place, away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking”.

The prescribed precautionary statements in the GHS may not apply in certain circumstances. Inapplicable precautionary statements with regard to the normal conditions of use, handling and storage of hazardous products can be omitted from the label.

Section 3 of Annex 3 of the GHS does combine prescribed precautionary statements for response and storage in some instances. As an example, the prescribed response and storage precautionary statements assigned to Flammable liquid- Category 2 include:

- P303+P361+P353 “IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse with water [or shower]. “
- P370+P378 “In case of fire: Use…to extinguish.”, and
- P403+P235 “Store in well-ventilated place. Keep Cool.”

It is important to note that the alphanumeric codes assigned to the hazard and precautionary statements are not required on the label and must not, under any circumstances, replace the hazard statement or precautionary statement to which they relate.

It is also important to note that not all hazard classes have precautionary statements prescribed for each type of statement (prevention, response, storage, and disposal). For instance, prevention and response precautionary statements are prescribed for Flammable Solids; while only storage precautionary statements are prescribed for Gases Under Pressure.

When a forward slash or diagonal mark [/] appears in a precautionary statement in section 3 of Annex 3 of the GHS, it indicates that the supplier can select only the precautionary statements that are applicable. For example, “Wear protective gloves/protective clothing/eye protection/face protection” could read “Wear eye protection” (as appropriate for the safe handling of the hazardous product).

When three full stops […] appear in a precautionary statement in section 3 of Annex 3 of the GHS, the three full stops indicate that all applicable conditions may not be listed. For example, “Use explosion-proof electrical/ventilating/lighting/…/equipment”, the use of “…” indicates that other equipment may be specified by the supplier, as applicable and appropriate for the hazardous product.

For precautionary statements, the text in *italics* in section 3 of Annex 3 of the GHS indicates specific conditions applying to their use or allocation. There may be a condition to trigger the presence of a specific precautionary statement on the label. For example, in the Flammable Liquids hazard class, the precautionary statement “Keep container tightly closed” is required if the liquid is volatile and may generate an explosive atmosphere.

Hazard statements may be combined where appropriate, if the combination conveys the same information as would have been conveyed by each of the individual statements. For example, “Fatal if swallowed” and “Fatal if inhaled” can be combined to read “Fatal if swallowed or if inhaled”.

Discussion of the *Hazardous Products Regulations* Section 3.3

Information elements of label

3.3 The pictogram, signal word and hazard statement must be grouped together on the label.

Under section 2 of the HPA, a label is defined as “a group of written, printed or graphic information elements that relate to a hazardous product, which group is designed to be affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged”. Section 3.3 of the HPR specifies that among those information elements, the pictogram(s), signal word, and hazard statement(s) must be grouped together on the label.

Precautionary statements are not required to be grouped with the pictogram, signal word, and hazard statement(s), but must nonetheless appear on the label. Based on the classification of the hazardous product, the pictogram(s), signal word, hazard statement(s) and precautionary statements that are required to appear on the label are found in section 3 of Annex 3 of the GHS. However, for the following hazard classes: Combustible Dusts, Simple Asphyxiants, Pyrophoric Gases, PHNOC, HHNOC, and BIM, the required information elements are found in Schedule 5 and paragraph 3(1)(d) of the HPR.

It is important to note that the Combustible Dusts and Simple Asphyxiants hazard classes are not assigned a pictogram and that the supplier must select the most appropriate pictogram from those set out in Schedule 3 of the HPR. For hazardous products classified in PHNOC – Category 1 and HHNOC – Category 1, the supplier must also select the most appropriate pictogram, from those set out in Schedule 3 of the HPR, and must provide an appropriate hazard statement.

There is no mandatory or prescribed format for the grouping of the pictogram(s), signal word and hazard statement(s). In the examples shown in Annex 7 of the GHS, the pictogram(s) are placed at the left and the signal word and hazard statements are placed immediately to the right of the pictogram(s). Such an arrangement would meet the requirement of section 3.3 of the HPR. An arrangement whereby the items are placed one directly below the other, as illustrated in the sample label shown below the discussion of section 3.6 would also meet this requirement.

Products packaged in multi-compartment containers

Multi-compartment products are products that contain at least two PMMS in separate compartments (see example in Figure 1 below). They may be designed either to allow, or not to allow, access to the individual PMMS.

Figure 1 - Example of a multi-compartment product

In the case of a multi-compartment product that contains one or more hazardous products, each hazardous product must be labelled appropriately. Each label must be placed on a surface of the container that makes it obvious that it refers to the relevant hazardous product in the multi-compartment container. Either the information elements for each individual hazardous product can be provided separately, each on its own label, or all information elements for all the hazardous products can be provided on a single label.

It is important to note that the provision set out in subsection 4.1(1) (Instructions for use – new material or substance) of the HPR applies to safety data sheets and not to labels. However, the supplier may provide information regarding the new material or substance on the label.

Discussion of the *Hazardous Products Regulations*
Section 3.4

Legibility

3.4 The information elements of the label of the hazardous product or container in which it is packaged must be clearly and prominently displayed on a surface that is visible under normal conditions of use, easily legible without the aid of any device other than corrective lenses and contrasted with any other information on the hazardous product or the container.

The label elements must appear on a surface of the container that is visible under normal conditions of use (for example, not on the bottom of a bottle). In the case of hazardous products for which the container is a compressed gas cylinder (e.g., for the Gases Under Pressure hazard class), it is acceptable to place the label on the shoulder of the compressed gas cylinder, as long as, in accordance with section 3.5 of the HPR (discussed below), the label remains affixed to, printed or written on, or attached to the container and remains legible under normal conditions of transport and use.

The HPR does not specify any requirements with regard to the shape of the label (e.g., rectangular vs. square vs. circular). The shape of the label is left to the discretion of suppliers. With regard to sizes, there is no minimum size prescribed in the HPR; however, the text and pictograms must be sufficiently large to be legible.

The label must also be legible without the aid of any device, other than corrective lenses. In other words, a label in a QR code form that requires a scanner (a device, for retrieving information) would not meet the requirements of the HPA and HPR.

Sample QR code for illustrative purposes

Suppliers must ensure that the information elements required by the HPR are laid out on the label or container in a manner that will contrast and stand out from any other information on the label, or from any other information on the hazardous product or container in which the hazardous product is packaged.

The following examples would not meet the requirements of the HPR, as the information elements on the label or container are not considered to be clearly and prominently displayed and easily legible, and are not considered to contrast with other information:

- a clear plastic over label bearing the required information is applied over other graphic matter;
- the precautionary statement is printed in a shade or colour that does not contrast sufficiently with the background;
- the information elements are embossed and in the same colour as the background packaging material in the case of a transparent container;
- the required information elements are placed on the back of a label on the container so that a person would have to look through the contents of the container to see the information.

Discussion of the *Hazardous Products Regulations*
Section 3.5

Durability

3.5 The information elements of the label of the hazardous product or container in which it is packaged must, under normal conditions of transport and use, remain affixed to, printed or written on or attached to the hazardous product or the container and remain legible.

Information elements must remain legible throughout the lifetime of the hazardous product, and not fade, run, rub off, peel off or deteriorate upon exposure to light under normal conditions of use or transport. Print that can be dissolved by the contents, or paper and plastic label sleeves that are easily removable, do not comply with section 3.5 of the HPR. Placing the required safety information on a removable wrapper would not be sufficiently durable to provide a user with the necessary information needed at the time of use of the hazardous product, especially if the hazardous product is intended to be used more than once.

Section 3.5 of the HPR does not apply to the sale or importation of a hazardous product in a container having a capacity of less than or equal to 3 ml if the label interferes with the normal conditions of use of the hazardous product (subsection 5.4(2) of the HPR). In these situations, the label could be affixed in such a manner that it would be easy to remove before use.

Discussion of the *Hazardous Products Regulations*
Subsections 3.6(1), (2) and (3)

Specific rule - signal word

3.6(1) If there is a requirement to provide the signal word "Danger", any requirement to provide the signal word "Warning" does not apply.

Specific rule - hazard statement

(2) If there is a requirement to provide the hazard statement "Causes severe skin burns and eye damage", any requirement to provide the hazard statement "Causes serious eye damage" does not apply.

Specific rule - symbol

(3) In the case of the symbols specified below, the following apply:

(a) if there is a requirement to provide the "skull and crossbones" symbol, any requirement to provide the "exclamation mark" symbol to indicate acute toxicity does not apply;

(b) if there is a requirement to provide the "corrosion" symbol, any requirement to provide the "exclamation mark" symbol to indicate skin or eye irritation does not apply; and

(c) if there is a requirement to provide the "health hazard" symbol to indicate respiratory sensitization, any requirement to provide the "exclamation mark" symbol to indicate skin sensitization or skin or eye irritation does not apply.

Section 3.6 of the HPR is meant to reduce the amount of information displayed on a label. Under the specified conditions, if a more severe symbol, signal word and/or hazard statement are required to be disclosed, there is no need to also disclose the less severe symbol, signal word and/or hazard statement.

Comparison to HCS 2012

Paragraph 3.6(3)(a) differs from the GHS but is aligned with the HCS 2012. The GHS applies this rule for all hazard classes; however the HCS 2012 and the HPR apply this rule only across the same hazard class (Acute Toxicity). If the exclamation mark is required for a different hazard class (e.g., the hazardous product is also classified in Skin Sensitization – Category 1 or 1A or 1B), the exclamation mark would still be required to be displayed on the label, in addition to the skull and crossbones symbol.

The provision set out in subsection 3.6(3) is an exemption. Exemptions are always optional; they are not mandatory requirements. Therefore, with reference to subsection 3.6(3), if you have a hazardous product that, for example, is both a respiratory sensitizer and a skin irritant, the supplier can choose to either only provide the health hazard symbol, or may include both the health hazard symbol and the exclamation mark symbol on the label and SDS.

In a situation where an exemption could be applied, if the supplier instead decides to comply with the full suite of standard requirements of the HPR, provision of the full suite of requirements is acceptable and in compliance with the HPR.

Example of a Label

The example below depicts a sample label which meets the HPR requirements. This example is for informational purposes only and is not meant to represent the only label suppliers may create for these hazards. This label represents a substance or mixture that is classified in the categories: "Acute Toxicity, Oral – Category 1 or 2" and "Skin Corrosion/Irritation- Category 2". As noted previously, the supplier identifier must be that of a Canadian importer or manufacturer and there is no requirement for a label border.

Product K1 / Produit K1

Danger

Fatal if swallowed.
Causes skin irritation.

Precautions:

Wear protective gloves.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.

Store locked up.
Dispose of contents/containers in accordance with local regulations.

IF ON SKIN: Wash with plenty of water.
If skin irritation occurs: Get medical advice or attention.
Take off contaminated clothing and wash it before reuse.
IF SWALLOWED: Immediately call a POISON CENTRE or doctor.
Rinse mouth.

Danger

Mortel en cas d'ingestion.
Provoque une irritation cutanée.

Conseils :

Porter des gants de protection.
Se laver les mains soigneusement après manipulation.
Ne pas manger, boire ou fumer en manipulant ce produit.

Garder sous clef.
Éliminer le contenu/récipient conformément aux règlements locaux en vigueur.

EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau.
En cas d'irritation cutanée : Demander un avis médical/consulter un médecin.
Enlever les vêtements contaminés et les laver avant réutilisation.
EN CAS D'INGESTION : Appeler immédiatement un CENTRE ANTIPOISON ou un médecin.
Rincer la bouche.

ABC Chemical Co., 123 rue Anywhere St., Mytown, ON NON ONO (123) 456-7890

References

29 CFR 1910.1200, Hazard Communication

Hazardous Products Act, R.S.C., 1985, c. H-3

Hazardous Products Regulations, SOR/2015-17

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), *Fifth revised edition*, 2013.

PART 4

Safety Data Sheet

A safety data sheet (SDS) is a document that describes the hazards associated with a hazardous product, and that provides information on safe use, handling, storage and disposal procedures. The SDS provides more detailed information about a hazardous product than the label.

The requirements for the provision of information on SDSs are set out in Part 4, Schedule 1 and Schedule 2 of the *Hazardous Products Regulations* (HPR). Suppliers who sell a hazardous product that is intended for use, handling or storage in a work place in Canada are required to have in their possession an SDS for the hazardous product that meets the requirements of the HPR (paragraph 13(1)(a) of the *Hazardous Products Act* (HPA)). Upon sale in Canada, a supplier must provide the SDS to the person or government who received the hazardous product (paragraph 13(1)(a.1) of the HPA). Similarly, suppliers who import a hazardous product that is intended for use, handling or storage in a work place in Canada are required to obtain or prepare, on or before the importation, an SDS for the hazardous product that meets the requirements of the HPR (paragraph 14(a) of the HPA).

Note:

- The supplier of a hazardous product is responsible for ensuring that the SDS pertaining to the product is accurate, up-to-date and compliant with the regulations made under the HPA, upon the sale or importation of the product into Canada.
- This obligation also existed under WHMIS 1988. However, the *Controlled Products Regulations* (CPR) also contained a provision regarding a mandatory review and updating of SDSs every three years. Although this provision has not been retained under the HPR, the level of protection offered to workers is maintained because suppliers have an ongoing responsibility to ensure that the SDS is accurate and compliant with the HPR at the time of every sale or importation of the hazardous product.

Use of Generic SDSs

Although there is no specific provision in the HPR regarding the use of generic SDSs, it is acceptable to use a generic SDS for a series of hazardous products with similar chemical composition that are all classified in the same hazard class(es) and category(ies) or subcategory(ies) provided that it meets the HPR requirements for each of the hazardous products to which it relates. For example, a generic SDS can be used for a series of paints where the only difference from one hazardous product to another is the pigment used. In such a case, the supplier would be required to list all of the hazardous products to which the SDS applies under the product identifier in item 1 (Identification) of the SDS. A generic SDS must not provide less information, in terms of quantity, quality, and details, than individual SDSs for each hazardous product in the series would provide.

If the concentration or actual concentration range of an ingredient of a particular hazardous product in the series is different from the concentration or actual concentration range disclosed for the rest of the series, either the concentration or the actual concentration range must be indicated beside that ingredient under item 3 (Composition/Information on ingredients) of the SDS. Furthermore, if any other specific information element(s) (such as flash point, numerical measure of toxicity, etc.) for a particular hazardous product in the series differs from that of the other products in the series (without affecting the classification), the information element relevant to that hazardous product must be disclosed on the SDS with an indication to which hazardous product each relates. For example, if one blend of paint uses a yellow-coloured pigment which is more toxic than the pigments used in the other paints in the series, but the blend of paint is still classified in the same hazard class(es) and category(ies) or subcategory(ies) as the other paints in the series, then a note on the generic SDS under item 11 (Toxicological Information) would be required disclosing the additional toxicological information associated with the yellow paint.

The following definitions from the *Hazardous Products Act* (HPA) apply in this Part:

Definitions from the HPA (Section 2)

"safety data sheet" means a document that contains, under the headings that, by virtue of the regulations made under subsection 15(1), are required to appear in the document, information about a hazardous product, including information related to the hazards associated with any use, handling or storage of the hazardous product in a work place;

"document" means anything on which information that is capable of being understood by an individual or being read by a computer or other device is recorded or marked;

Under the amended HPA, the term "material safety data sheet" (MSDS) was replaced by "safety data sheet" (SDS). The terms "safety data sheet" and "document" are defined in the HPA.

An SDS can be provided either as a paper document or as any type of electronic document that can be read using a computer or another device (More information about additional requirements for SDSs can be found in Part 6 of the Technical Guidance).

SDSs are only required for hazardous products within the meaning of the HPA; that is, an SDS must be prepared for a product, mixture, material or substance (PMMS) that meets the classification criteria for at least one physical or health hazard class in the HPR.

VARIANCE with HCS 2012: Language Requirement for SDSs

HPR

As specified in subsection 6.2(1) of the HPR, the information elements provided on an SDS must always be in both official languages of Canada (English and French). It is acceptable to have either a single bilingual SDS that provides the required information in both English and French, or an SDS consisting of two parts, in which one part provides the required information in English and the other part provides the required information in French. If the second option is selected, both the English and French versions must always be provided together.

HCS 2012

Under paragraph (g)(2) of the HCS 2012, SDSs are only required to be in English; however, the supplier may choose to also provide SDSs in other languages.

Discussion of the *Hazardous Products Regulations* Paragraph 4(1)(*a*)

Information Elements

4(1) For the purposes of paragraphs 13(1)(*a*) and 14(*a*) of the Act, the safety data sheet of a hazardous product must provide, in respect of the hazardous product, the following information elements:

(*a*) the headings set out in column 1 of Schedule 1, in the order they are presented, including the corresponding item number, which is to be placed immediately before the heading;

SDSs are required to have a standardized 16-heading format. The SDS must provide the headings set out in Column 1 of Schedule 1 of the HPR, in the order they are presented. The SDS must also include the corresponding item (section) number, which is to be placed immediately before the heading. The specific information elements that correspond to the headings in column 1 must appear on the SDS, if required.

As specified in subsection 4(2) of the HPR, item numbers and headings for items (sections) 12 through 15 are required to appear on the SDS; however, the content of the specific information elements listed in Column 2 of Schedule 1 for these four items may be omitted (i.e., the specific information elements for these sections are optional).

For a detailed description of the headings and information elements for SDSs as per Schedule 1 of the HPR, refer to Appendix 1 to this chapter (Information Elements on Safety Data Sheet – Schedule 1 of the HPR).

Discussion of the *Hazardous Products Regulations*
Subparagraph 4(1)(*b*)(i)

Information Elements (continued)

(*b*) subject to section 4.5, the content of the specific information elements set out in paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 for the heading for item 3 and, for each heading of that Schedule, if the information is available and applicable, the content of the other specific information elements of that Schedule, including the unit of measure, if applicable, taking into account the following:

(i) if any of the information — except that required by paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of that Schedule — is not available or not applicable, an indication to that effect must be clearly stated in lieu of the required specific information element, and

With the following exception, all of the specific information elements listed in Column 2 of Schedule 1 of the HPR must be disclosed on the SDS for a hazardous product if that information is available and applicable. The information required by paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 (see below for description) is mandatory and must be provided on the SDS. It is not acceptable to state “not applicable” or “not available” for these items. If any of the information required for paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 is the subject of a claim for confidential business information (CBI) under the *Hazardous Materials Information Review Act* (HMIRA), then replacement information must appear (refer to the discussion of section 5.7 of the HPR).

Paragraph 3(1)(*a*) of Schedule 1 of the HPR – the chemical name of a hazardous product that is a material or substance

Paragraph 3(2)(*a*) of Schedule 1 of the HPR - for a hazardous product that is a mixture, the chemical name of each ingredient that, individually, is classified in any category or subcategory of a health hazard class and is present either:

- at or above the corresponding concentration limit; or
- at a concentration that results in the mixture being classified in a category or subcategory of any health hazard class.

Paragraph 3(2)(*d*) of Schedule 1 of the HPR - for a hazardous product that is a mixture, the concentration of each ingredient that, individually, is classified in any category or subcategory of a health hazard class and is present either:

- at or above the corresponding concentration limit; or
- at a concentration that results in the mixture being classified in a category or subcategory of any health hazard class.

The mandatory nature of the requirement to disclose the information specified under paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 of the HPR means that the supplier must provide this information on the SDS.

The text listed in Column 2 of Schedule 1 (e.g., "product identifier", "other means of identification", etc.) is not required to be reproduced on an SDS. However, each item must be addressed either by providing the information or, if the information is not available or not applicable for a particular item (other than items mentioned under paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1), by indicating that the information is "not available" or "not applicable", whichever is appropriate. Units of measure must be included where applicable.

As specified in subsection 4(2) of the HPR, item numbers and headings for items 12 through 15 are required to appear on the SDS; however, the content of the specific information elements listed in Column 2 of Schedule 1 for these four items may be omitted (i.e., the specific information elements for these sections are optional).

Note regarding the use of the phrase "Not Applicable"

"Not applicable" may only be used in situations where, based on the information available, the specific information element does not apply to the hazardous product. Some examples of situations where certain information elements required under Schedule 1 of the HPR may not be applicable to a particular hazardous product include:

- Under the heading for item 3, Composition/Information on ingredients, information element 3(1)(*d*) (if there are no known impurities, stabilizing solvents or stabilizing additives that, individually, are classified in any category or subcategory of a health hazard class and that contribute to the classification of the material or substance), it would be appropriate to indicate that this information element is "not applicable".
- Under the heading for item 9, Physical and chemical properties, information element (g) (flash point), for non-flammable substances such as tetrachloroethylene, methylene chloride or nitrogen, it would be appropriate to indicate that this information element is "not applicable".
- Under the heading for item 10, Stability and reactivity, information element (e) (incompatible materials), if the hazardous product is not reactive with any material, then it would be appropriate to indicate that this information element is "not applicable".

It is important to note that it is misleading to state that the information required by the specific information element is "not applicable" when in fact no data is available. In such case, the statement "not available" must be used.

As specified in subsections 14.2(2) and (3) of the HPA , suppliers are prohibited from selling or importing a hazardous product that is intended for use, handling or storage in a work place in Canada if the SDS for the hazardous product contains information that is false, misleading or likely to create an erroneous impression with respect to the information that is required to be included on a label or SDS for a hazardous product.

As an example, it would be considered as misleading to state on an SDS that a toxicological end point is "not applicable" when, in fact, there is no data available to assess that end point for that substance. In this case, "not available" should be used.

Also note that the disclosure of information in accordance with paragraph 4(1)(*b*) of the HPR is subject to the application of section 4.5 of the HPR regarding concentration ranges. See section 4.5 and Appendix 3 to this chapter (Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets).

As specified in subsection 4(2) of the HPR, the content of the specific information elements listed in items 12 through 15 may be omitted, but the item numbers and headings must appear on the SDS.

Discussion of the *Hazardous Products Regulations*
Subparagraph 4(1)(*b*)(ii)

Information Elements (continued)

(ii) in the case of a mixture, the information provided under the heading for item 11 of Schedule 1 must be information that is available on the mixture as a whole, and if information is not available on the mixture as a whole, it must be information that is available on the hazardous ingredients in the mixture, together with a clear indication of the chemical name of the hazardous ingredient to which the information pertains; and

In the case of a mixture, toxicological information, as required by item 11 of Schedule 1 of the HPR must be provided for the hazardous product mixture as a whole. If this information is unavailable for the mixture as a whole, information must be provided for each hazardous ingredient (see definition in subsection 1(1) of the HPR) in the mixture, with a clear indication of the chemical name of the hazardous ingredient to which the toxicological information pertains.

Discussion of the *Hazardous Products Regulations*
Subparagraphs 4(1)(*c*)(i) and (ii)

Information Elements (continued)

(*c*) under any applicable heading, all additional hazard information that is available with respect to

(i) the hazardous product, and

(ii) a product, mixture, material or substance that has similar properties, including any evidence based on established scientific principles, if that information is applicable to the normal conditions of use of the hazardous product and is not redundant, indicated alongside an identification of the product, mixture, material or substance that has similar properties.

In addition to the information elements that are required to be disclosed on the SDS as per Schedule I of the HPR, the supplier must also disclose, under any applicable heading, all additional hazard information that is available about:

- the hazardous product itself and
- any PMMS that has similar properties, if that information is applicable under normal conditions of use and not redundant to information already provided for the hazardous product itself. This information includes any evidence based on established scientific principles. The additional hazard information regarding the PMMS that has similar properties must be indicated on the SDS alongside an identification of that PMMS. This provision requires that data about a similar PMMS be provided when data are lacking on the regulated PMMS.

Paragraph 4(1)(c) has been included in the HPR to maintain the level of worker protection afforded by subsection 12(11) of the repealed CPR. The intent of paragraph 4(1)(c) is to ensure that any additional hazard information with regard to a hazardous product or a PMMS that has similar properties, that is not already addressed by the information elements specified in Schedule 1 of the HPR, will also be required to be disclosed on the SDS.

The following are some examples of additional hazard information with regard to a hazardous product that may not be addressed by the information elements specified in Schedule 1 of the HPR:

- In the case of a flammable hazardous product which, upon exposure to heat or a source of ignition, creates a hazardous combustion product, the **chemical name of the hazardous combustion product**.
- In the case of a substance or mixture which, in contact with water, emits a flammable gas, the **chemical name of the flammable gas**.
- In the case of a substance or mixture which, in contact with water, emits a toxic gas, the **chemical name of the toxic gas**.
- The occurrence of known synergistic or antagonistic effects.

Comparison to HCS 2012

The HCS 2012 does not include a requirement similar to the one set out in paragraph 4(1)(c) of the HPR.

Discussion of the *Hazardous Products Regulations*
Subsection 4(2)

Items 12 to 15 of Schedule 1

4(2) Despite subsection (1), under each heading set out for items 12 to 15 of Schedule 1, the content of the specific information elements in that Schedule may be omitted

A listing of the information elements for each item (heading) required on an SDS is provided in Appendix 1 to this chapter. Subsection 4(2) of the HPR specifies that the specific information elements listed under items 12, 13, 14 and 15 of Schedule 1 of the HPR are optional:

- Item 12: Ecological information;
- Item 13: Disposal considerations;
- Item 14: Transport information; and
- Item 15: Regulatory information.

Therefore, it is acceptable to have an SDS that does not have any content under items 12, 13, 14 or 15. However, the item numbers (12 through 15) and the corresponding headings for each of these items must appear on the SDS, sequentially, as indicated in Column 1 of Schedule 1 of the HPR, in order to respect the 16-heading format. Even though the specific information elements for these headings may be omitted, if the information is available, it is a good practice to provide it on the SDS as it may be useful to users of SDSs.

Discussion of the *Hazardous Products Regulations* Subsection 4(3)

Biohazardous Infectious Materials – additional information elements

4(3) The following information elements must be provided, immediately following the information elements required by subsection (1), on the safety data sheet of a hazardous product that is classified in a category of the hazard class "Biohazardous Infectious Materials":

(*a*) the headings set out in Schedule 2, in the order they are presented;

(*b*) under each heading, the name of each specific information element set out in column 2 in respect of that heading in the order they are presented;

(*c*) under the name of each specific information element, the content of the information element, if the information is available and applicable, including the unit of measure, if applicable, taking into account the following:

(i) if any of the information is not available or not applicable, an indication to that effect must be clearly stated in lieu of the required information, and

(ii) any information provided under one heading of the safety data sheet need not be repeated under any other heading.

This subsection applies to hazardous products that are classified in Biohazardous Infectious Materials (BIM) (Subpart 11 of Part 8 of the HPR), whether they are classified only in this hazard class or in this hazard class as well as one or more other physical and/or health hazard classes of the HPR.

VARIANCE with HCS 2012: SDS requirements for Biohazardous Infectious Materials (BIM)

HPR

For hazardous products classified in BIM, the safety data sheet (SDS) must include not only the item numbers, headings and the content of the specific information elements listed in Schedule 1 of the HPR, but also a nine-heading SDS appendix and the content of the specific information elements listed in Schedule 2 of the HPR (for each BIM), which provide information that specifically pertains to the BIM(s). The Schedule 1 SDS and the Schedule 2 nine-heading appendix/appendices are not two distinct SDSs; together, they constitute one SDS for this hazardous product. Subsection 4(2) of the HPR allows the omission of the content of the specific information elements under items 12 through 15 of Schedule 1 as long as the item numbers and headings appear.

HCS 2012

There is no requirement for an SDS for biohazardous infectious materials, since the U.S. Occupational Safety and Health Administration (U.S OSHA) does not regulate these materials in the work place.

The "GHS" means the United Nations document entitled *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Fifth Revised Edition (GHS).

The 16-heading GHS SDS format detailed in Schedule 1 of the HPR is intended primarily for hazardous products, mixtures and substances. However, as specified in section 8.11 of the HPR, "Biohazardous Infectious Material" means "any microorganism, nucleic acid or protein that causes or is a probable cause of infection, with or without toxicity, in humans or animals". The headings and specific information elements of the Schedule 1 SDS format do not provide all the necessary and useful information on the properties and hazards associated with BIM. Therefore, Health Canada, in collaboration with the Public Health Agency of Canada (PHAC) developed a nine-heading SDS appendix, as set out in Schedule 2 of the HPR, which provides relevant information that workers handling BIM should be aware of. The nine-heading appendix is hereafter referred to, in this part of the Technical Guidance , as the "BIM SDS appendix" (Appendix 2 - Information Elements on Safety Data Sheet – Biohazardous Infectious Materials, Schedule 2 of the HPR)

The format of the BIM SDS appendix set out in Schedule 2 of the HPR (i.e., the headings and their specific information elements) is aligned with the format used in PHAC's Pathogen Safety Data Sheets (PSDSs). To facilitate compliance with the requirement set out in subsection 4(3) of the HPR, a supplier who is selling or importing a hazardous product that is classified in BIM (whether classified only in this hazard class or in one or more other hazard classes as well) may access the appropriate PSDS from PHAC's website (if PHAC has prepared a PSDS for the BIM in question). PHAC has prepared numerous PSDSs which are publicly available on their website at:

http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

The supplier of a hazardous product that is classified in BIM must obtain or prepare an SDS that complies with subsection 4(1) and Schedule 1 of the HPR. Then, the supplier must add the information required by Schedule 2 of the HPR directly below item 16 of the Schedule 1 part of the SDS to produce the **complete** SDS that is required for hazardous products classified in BIM. The supplier may be able to use the PSDS to fulfill the information requirements of the Schedule 2 part of the SDS, but it is important to note that the supplier is always responsible for ensuring that the information on an SDS is accurate, up-to-date, and compliant with the HPR. Refer to the section below on **SDS Requirements for Hazardous Products that are BIM only** for further information.

With regard to the BIM SDS appendix:

(1) The BIM SDS appendix must immediately follow the standard 16-heading SDS prepared in accordance with subsection 4(1) and Schedule 1 of the HPR.

(2) The **name** of each specific information element listed in Column 2 of Schedule 2 is required in the BIM SDS appendix, as well as the content related to the information element. An example is shown below.

Example: Section I of a BIM SDS appendix for *Streptococcus pneumoniae*

SECTION I - INFECTIOUS AGENT

NAME: *Streptococcus pneumoniae*

SYNONYM OR CROSS REFERENCE: (information to be added here)

CHARACTERISTICS: (information to be added here)

In each section, the subheadings (shown in bold and uppercase in the above example) must be provided on the SDS, as well as the content related to each corresponding specific information element.

Note that, for the Schedule 1 portion of the SDS, it is not necessary to reproduce the text listed in Column 2 of Schedule 1 of the HPR (for example, “product identifier”, “other means of identification”, etc.). Only the **content** related to each specific information element listed in Column 2 of Schedule 1 is required.

(3) In the case of each specific information element listed in Column 2 of Schedule 2, either the specified information or the indication that the information is “not available” or “not applicable” must appear on the SDS. This requirement is the same as the one specified in subparagraph 4(1)(b)(i) of the HPR.

(4) The unit of measure, where applicable, must be included.

(5) Repetition of information under multiple headings is not required. This applies not only to the headings within Schedule 1 and the headings within Schedule 2, but also to the combined headings of Schedules 1 and 2. For example, heading 7 of Schedule 1 addresses information relating to “Handling and storage”. However, heading 8 of Schedule 2 also addresses information relating to “Handling and storage”. Therefore, if, for example, the Schedule 1 portion of the SDS provides accurate and complete information under heading 7, relating to precautions for safe handling and conditions for safe storage, then this information need not be repeated under heading 8 of the BIM SDS appendix (Refer to section below on **SDS Requirements for Hazardous Products that are BIM only** for further information). If the

required information is available under another heading, it is recommended that an indication to this effect be included. For example, if heading 8 of the Schedule 2 part of the SDS contains all the required information relating to "Handling and storage", then, under heading 7 of the Schedule 1 part of the SDS, a statement such as "the required information is found under heading 8 of the appendix to this SDS" is recommended.

(6) The PSDSs available on PHAC's website at http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php are only for **human pathogens**. However, the scope of the BIM hazard class under the HPR includes not only human pathogens, but also **animal pathogens** as well. Information regarding animal pathogens should be obtained from reliable sources.

For a more detailed description of the headings and specific information elements set out in Schedule 2 of the HPR, refer to Appendix 2 to this chapter (Information Elements on Safety Data Sheet – Biohazardous Infectious Materials, Schedule 2 of the HPR).

SDS Requirements for Hazardous Products that are Biohazardous Infectious Materials (BIM) only

The guidance provided in this section **only** applies to **hazardous products that are only classified in the BIM hazard class** (Subpart 11 of Part 8 of the HPR).

The 16-heading GHS SDS format, which appears in Schedule 1 of the HPR, is intended primarily for hazardous chemicals. Although there is no specific provision in Part 4 of the HPR regarding hazardous products that are BIM only, it is recognized that some of the specific information elements listed in Column 2 of Schedule 1 may not apply to BIM only products. In addition, other specific information elements that are listed in Column 2 of Schedule 1 may be adequately addressed in the BIM SDS appendix, which, in many cases, could be filled out by accessing the appropriate PSDS from PHAC's website and copying and pasting the text into the SDS. The supplier is always responsible for ensuring that the information taken from PHAC's PSDS is accurate and up-to-date.

For example, heading 8 of Schedule 1 addresses information relating to "Exposure controls/ Personal protection". However, heading 7 of Schedule 2 also addresses information relating to "Exposure controls/Personal protection". As noted above, repetition of information under multiple headings of the SDS for a BIM product is not required.

For suppliers that are selling or importing hazardous products intended for use, handling or storage in a work place in Canada that are only classified in BIM, in order to make compliance with the SDS requirements less onerous, the following guidance is provided. It is important to note, however, that the supplier is always responsible for ensuring that the information on an SDS is accurate, up-to-date and compliant with the HPR.

With regard to the Schedule 1 portion of the SDS, as shown in Table 1 below, some of the specific information elements listed under certain headings of Schedule 1 may be indicated as "not applicable" if they are not applicable to the product or may be omitted if they are already addressed in the BIM SDS appendix. In this case, an indication that the information is

found elsewhere in the SDS is recommended. No header can appear without any associated information, with the exception of items 12 through 15 of the Schedule 1 portion of the SDS.

Table 1 - Guidance on the requirements for the Schedule 1 portion of the SDS for hazardous products that are BIM only

Schedule 1 Item No.	Schedule 1 Heading	Guidance with regard to content under this Schedule 1 heading for hazardous products that are **BIM only** (see Notes below)
1	Identification	Although some of this information may already appear in the BIM SDS appendix, it is expected that items 1(a) through (e) will need to be addressed in the Schedule 1 part of the SDS.
2	Hazard identification	Items 2(a) (classification of the hazardous product, or, in the case of a hazardous product classified in Physical Hazards Not Otherwise Classified or Health Hazards Not Otherwise Classified, a description of the identified hazard) and (b) (symbol, signal word, hazard statement and precautionary statements for each category or subcategory of each hazard class in which the hazardous product is classified) must be addressed. It is not expected that these items would be adequately addressed by the BIM SDS appendix. However, item 2(c) (other hazards known to the supplier with respect to the hazardous product) may be adequately addressed under headings 2 and 6 of the BIM SDS appendix.
3	Composition/Information on ingredients	It is expected that some of the specific information elements listed under item 3 would be addressed in the BIM SDS appendix under heading 1. However, any information element listed under item 3 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
4	First-aid measures	It is expected that most of the specific information elements listed under item 4 would be addressed in the BIM SDS appendix under item 5 of Schedule 2 (First Aid/Medical). However, any information element listed under item 4 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
5	Fire-fighting measures	It is not expected that the specific information elements listed under item 5 will apply to most BIM only products. If this is the case for the BIM only hazardous product in question, then an indication of “not applicable” must appear under this header.

Schedule 1 Item No.	Schedule 1 Heading	Guidance with regard to content under this Schedule 1 heading for hazardous products that are **BIM only** (see Notes below)
6	Accidental release measures	It is expected that most of the specific information elements listed under item 6 would be addressed in the BIM SDS appendix under items 7 (Exposure Controls/ Personal Protection) and 8 (Handling and Storage) of Schedule 2. However, any information element listed under item 6 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
7	Handling and storage	It is expected that most of the specific information elements listed under item 7 would be addressed in the BIM SDS appendix under item 8 of Schedule 2 (Handling and Storage). However, any information element listed under item 7 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
8	Exposure controls/ Personal protection	It is expected that most of the specific information elements listed under item 8 would be addressed in the BIM SDS appendix under item 7 of Schedule 2 (Exposure Controls/Personal Protection). However, any information element listed under item 8 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
9	Physical and chemical properties	It is expected that the specific information elements listed under item 9 of Schedule 1 would not be addressed in the BIM SDS appendix. It is expected that there would be applicable information for items 9(a), (b) and (c) of Schedule 1 (appearance, such as physical state and colour; odour; and odour threshold, respectively) and that therefore information would need to be included to that effect under this header. However, it is possible that items 9(d) through (r) may not be applicable, in which case an indication of “not applicable” must appear.
10	Stability and reactivity	It is expected that some of the specific information elements listed under item 10 would be addressed in the BIM SDS appendix under item 4 of Schedule 2 (Stability and Viability). However, any information element listed under item 10 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.

Schedule 1 Item No.	Schedule 1 Heading	Guidance with regard to content under this Schedule 1 heading for hazardous products that are **BIM only** (see Notes below)
11	Toxicological information	It is expected that some of the specific information elements listed under item 11 would be addressed in the BIM SDS appendix, for example, under item 2(a) (pathogenicity/toxicity), 6(a) (laboratory-acquired infections), 6(c) (primary hazards), and 6(d) (special hazards) of Schedule 2. However, any information element listed under item 11 of Schedule 1 that is not covered in the BIM SDS appendix must be addressed.
12	Ecological information	As permitted by subsection 4(2) of the HPR, the content of the specific information elements listed under items 12, 13, 14 and 15 may be omitted as long as the item numbers and headings appear on the SDS.
13	Disposal considerations	
14	Transport information	
15	Regulatory information	
16	Other information	Although item 9(b) of Schedule 2 requires the last file update, if the PSDS from PHAC is used, the date that would be provided there under 9(b) of the Schedule 2 part of the SDS would be the date of preparation, or update, as applicable, of the PSDS by PHAC. It is important to note, however, that the supplier is always responsible for ensuring that the information taken from PHAC's PSDS is accurate and up-to-date. In addition, the date of preparation, or update, as applicable, of the Schedule 1 portion of the SDS by the supplier is an important piece of information that must also be provided.

Notes:

1) Refer to Schedule 1 of the HPR for the full listing of the specific information elements under each of the 16 headings, and to Schedule 2 of the HPR for the format of the BIM SDS appendix.

2) The BIM SDS appendix must immediately follow the standard 16-heading SDS prepared in accordance with subsection 4(1) and Schedule 1 of the HPR.

3) For each specific information element that must be addressed, with the exception of the information required by paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 of the HPR, it is necessary to provide either the specified information or the indication that the information is "not available" or "not applicable", unless the information is found elsewhere in the SDS. In the latter case, an indication that the information is found elsewhere in the SDS is recommended. Provision of the information required by paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 of the HPR is mandatory. If any of the information required by paragraphs 3(1)(*a*) and (2)(*a*) and (*d*) of Schedule 1 is the subject of a claim for CBI under the HMIRA, then replacement information must appear (refer to the discussion of section 5.7 of the HPR).

4) Under the HCS 2012, there is no requirement for an SDS for biohazardous infectious materials, since OSHA does not regulate these materials in the work place.

Discussion of the *Hazardous Products Regulations*
Subsection 4(4)

More than one biohazardous infectious material

4(4) In the case where a mixture contains more than one ingredient that is classified as a biohazardous infectious material, the information required by subsection (3) must be provided in distinct parts on the safety data sheet, sequentially, for each biohazardous infectious material.

For a mixture that contains more than one BIM, a separate and distinct BIM SDS appendix must be prepared for each BIM in the mixture, in accordance with the format of Schedule 2 of the HPR. It is not acceptable to have just one SDS appendix that provides, under each heading, the specific information elements for more than one BIM.

Discussion of the *Hazardous Products Regulations*
Subsection 4.1(1)

Instructions for use – new material or substance

4.1(1) In the case of a hazardous product for which instructions for use, provided at the time of sale or importation, require its combination with one or more products, mixtures, materials or substances resulting in the creation of one or more new materials or substances that present one or more new or more severe hazards not already identified on the safety data sheet of the hazardous product, the safety data sheet must also provide the following information elements, in respect of each new material or substance and clearly indicate that they pertain to that new material or substance:

(a) the nature of the new or more severe hazard; and

(b) the content of the applicable specific information elements set out in items 4 to 11, column 2, of Schedule 1, for each corresponding heading, that is available.

This provision applies to situations in which the instructions for use, provided with a hazardous product, require its combination with one or more products, mixtures, materials or substances (PMMS). This PMMS may or may not be a hazardous product and may or may not be provided with the hazardous product. If the combination of the hazardous product and the PMMS results in the creation of one or more new materials or substances that present a new or more severe hazard which has not already been identified on the SDS, then the SDS must provide information on the hazards of the new material(s) or substance(s). It is important to note that the instructions for use could be provided by the supplier in any form, such as, on the label, on the SDS or in a written document provided with the product.

This situation could arise, for example, when two or more PMMS packaged together in a kit are used in accordance with the instructions for use provided at the time of sale or import. For

example, hazardous product ABC is classified in Acute Toxicity (Dermal) – Category 2 and comes with instructions for use, provided at the time of sale or import, which inform the worker to mix it with another product. The result is the formation of a new substance that is classified in Eye Irritation – Category 2. In this example, the SDS of hazardous product ABC must also provide information on the hazards of the new substance, because it presents a new hazard that has not already been identified on the SDS. The same requirement would apply if a hazardous product that is classified in Acute Toxicity (Dermal) – Category 2 comes with instructions for use that involve mixing with another product that may or may not be hazardous, and this results in the formation of a new substance that is classified in Acute Toxicity (Dermal) – Category 1 (a more severe hazard than the original hazardous product).

Additional hazard information with respect to the new material or substance must be provided on the SDS of each hazardous product that is involved in the combination. There must be a clear indication on the SDS that the additional information pertains to the new material or substance. First, the nature of the new or more severe hazard must be described (for example: “upon mixing as per the instructions, will emit a new substance classified in Skin Irritation - Category 2”). Secondly, the supplier must address each of the applicable specific information elements for which information is available under the following item numbers and headings of Schedule 1 of the HPR (as specified in subsection 4.1(2) of the HPR, this information may appear anywhere on the SDS):

4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/Personal protection
9. Physical and chemical properties
10. Stability and reactivity; and
11. Toxicological information

The supplier is required to provide information on the end material(s) or substance(s) and not on the intermediate material(s) or substance(s) that are formed during the reaction. This provision does not apply to situations where the instructions for use, provided with the hazardous product, require its combination with one or more PMMS (hazardous or not) but do not create a new hazardous material or substance which presents a new or more severe hazard.

Products packaged in multi-compartment containers

Multi-compartment products are products that contain at least two PMMS in separate compartments (see example in Figure 2 below). The multi-compartment product may be designed either to allow, or not to allow, access to the individual PMMS.

In the case of a multi-compartment product that contains one or more hazardous products, each hazardous product must be labelled appropriately and must have a corresponding SDS. Each

label must be placed on a surface of the container that makes it obvious to which hazardous product in the multi-compartment container it refers. Either a separate SDS for each individual hazardous product or one SDS for all the hazardous products included in the multi-compartment container is acceptable. If the product comes with instructions which involve mixing the components and this mixture results in the formation of a new material or substance that poses a new or more severe hazard, then the provision set out in subsection 4.1(1) of the HPR would apply [see the discussion of subsection 4.1(1)].

Figure 2 – Example of a multi-compartment product

Discussion of the *Hazardous Products Regulations*
Subsection 4.1(2)

Placement of information elements

4.1(2) Despite subsection 4(1), the information elements required by subsection (1) may appear anywhere on the safety data sheet.

The additional information elements required by subsection 4.1(1) of the HPR do not have to appear under items 4 through 11, respectively, of the SDS. Rather, they may appear anywhere on the SDS, as long as the information elements are addressed and there is always an indication that the information pertains to the new material or substance that presents one or more new or more severe hazards not already identified on the SDS.

Discussion of the *Hazardous Products Regulations*
Section 4.2

Identical identifiers

4.2 The product identifier and the initial supplier identifier that are provided on the safety data sheet of a hazardous product must be identical to those provided on the label.

To create a clear link between the label and the SDS of any hazardous product, the product identifier and initial supplier identifier, as defined in subsection 1(1) of the HPR, that are disclosed on the SDS of the hazardous product must be exactly the same as the product identifier and initial supplier identifier that are disclosed on the product label. The product identifier and initial supplier identifier are required to be disclosed on the SDS under item 1, Identification, as per Schedule 1 of the HPR.

Furthermore, as set out in section 5.8 of the HPR, in a situation where a hazardous product is being sold by a distributor, the distributor may provide his name, address and telephone number on the label and SDS instead of the contact information of the initial supplier. Since the label and SDS must match with regard to the product identifier and the initial supplier identifier, the distributor must replace the initial supplier's information with his information on both the label and the SDS.

Discussion of the *Hazardous Products Regulations*
Section 4.3

Concentration units

4.3 If the concentration of a material or substance in a hazardous product is expressed as a percentage on the safety data sheet, the units used to calculate the percentage must be provided.

This provision applies to hazardous products that are mixtures. If the concentration or the actual concentration range of an ingredient is expressed as a percentage, the units used to calculate the percentage must be provided. The term "actual concentration range" is used in section 4.5 of the HPR and is discussed in detail in Appendix 3 to this chapter (Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets).

Examples showing the application of section 4.3 include:

- the weight of the ingredient in proportion to the weight of the hazardous product (e.g., 9.85% weight/weight);
- the volume of the ingredient in proportion to the volume of the hazardous product (e.g., 1.7% volume/volume); or
- the weight of the ingredient in proportion to the volume of the hazardous product (e.g., 0.463% weight/volume).

Alternatively, the concentration of a material or substance in a hazardous product may be expressed using metric units of measurement (e.g., 4.63 g/l, which is equivalent to 0.463% weight/volume). In addition, the HPR does not prohibit the use of units in other systems such as the imperial system.

Discussion of the *Hazardous Products Regulations* Section 4.4

Most hazardous concentration

4.4 If ingredients in a mixture that is a hazardous product are present in a range of concentrations, the information provided on the safety data sheet must be based on data available that correspond to the most hazardous concentration of each ingredient in the mixture, whether those data pertain to an ingredient or the mixture as a whole.

For ingredients that are present in a range of concentrations in a mixture, the information provided on the SDS must correspond to the available data that reflects the most hazardous concentration of each hazardous ingredient in the mixture, whether those data pertain to the hazardous ingredient itself or to the mixture as a whole. For example, if a mixture contains a concentration of the hazardous ingredient A which is present in a range of concentrations between 7 to 9.6%, the information provided on the SDS must be based on 9.6% if this is the most hazardous concentration of ingredient A. In most situations, the most hazardous concentration will be the highest value in the concentration range. If the highest concentration in the range is not the most hazardous, then the information provided in the SDS must be based on the concentration that is the most hazardous. In the event where there is available data on the mixture as a whole and this data is based on tests performed on the mixture, through this provision the supplier must ensure that the ingredients in the tested mixture were present in their most hazardous concentration within their respective ranges, if such data is available.

Further guidance on the disclosure of ingredient concentrations and concentration ranges on SDSs is provided in Appendix 3 to this chapter (Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets).

Discussion of the *Hazardous Products Regulations* Section 4.5

Concentration ranges

4.5 If the concentration of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is not always present at the same concentration, the safety data sheet must provide, in lieu of the concentration of the material or substance, the actual concentration range of the material or substance in the hazardous product.

Guidance on the disclosure of ingredient concentrations and concentration ranges on SDSs is provided in Appendix 3 to this chapter (Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets).

Appendix 1: Information Elements on Safety Data Sheet – Schedule 1 of the HPR

Additional guidance on the preparation of SDSs is found in Annex 4 of the GHS.

Note:

In the case of any discrepancy between Annex 4 of the GHS and either this Technical Guidance or the HPR, the Technical Guidance or the HPR, as the case may be, shall prevail.

Item 1: Identification: The required information in this section consists of:

- The product identifier used on the label (the brand name, chemical name, common name, generic name or trade name of the product)
- Other means of identification of the product (any other common names or synonyms by which the product is known)
- The recommended use of the product (a brief description of what the product actually does, such as “flame retardant”) and any restrictions on its use
- The initial supplier identifier (the full name, address and telephone number of the Canadian manufacturer or the Canadian importer of the hazardous product). “Manufacturer” is defined in subsection 1(1) of the HPR. Canadian importer means the person who, in the course of business in Canada, is responsible for importing the hazardous product into Canada
- An emergency telephone number and any restrictions on the use of that number (e.g., days and hours of operation), if applicable. The emergency telephone number is a telephone number that will enable a caller to obtain information regarding the hazardous product. It does not have to be a Canadian telephone number. If the language spoken at the emergency telephone number is neither English nor French, this should be indicated on the SDS as part of the restrictions on the use of the number.

Other means of identification of the product: The SDS must also disclose other names and synonyms that are commonly known in the work place. It is not expected that a long list of common names and synonyms would be provided.

With regard to the address that must be provided as part of the initial supplier identifier, this may be any valid Canadian postal address such as a full street address of the premises of the supplier or a post office box number with the address of the post office. A Canadian distributor who is not a Canadian importer may provide their contact information in lieu of the initial supplier identifier. For further information about this exception, see the Technical Guidance for section 5.8 of the HPR.

Under the HPR, a distributor who buys a hazardous product, re-labels the product and then sells it, is considered to be the initial supplier of the hazardous product. In this situation, the Canadian distributor must provide his name, address and telephone number on the label and SDS.

If a hazardous product is being imported only for use in the importer's own workplace, the Canadian importer may retain the name, address and telephone number of the foreign supplier on the SDS instead of replacing it with his own contact information. This is the only situation in which a hazardous product, which is intended for use, handling or storage in a Canadian work place, may be imported into Canada with only the name, address and telephone number of a foreign supplier on the SDS. For further information, see the discussion in section 5.9 of the HPR.

In the case of a hazardous product that is being imported into Canada from a foreign supplier, but that is not intended only for use in the importer's own work place (i.e., the importer does not qualify for the exception specified in section 5.9 of the HPR), it is the Canadian importer (i.e., the Canadian party who is responsible for bringing the hazardous product into Canada) whose name, address and telephone number must be provided on the SDS. The Canadian importer is responsible for ensuring that the importation of the hazardous product is in compliance with the requirements of the HPA and the HPR (e.g., labels and SDSs).

It would be acceptable for the SDS to include the contact information of both the Canadian importer and the foreign-based supplier. Additional information may be included on the SDS, as long as the information is not false or misleading (section 14.2 of the HPA prohibits information that is false, misleading or likely to create an erroneous impression with respect to the information that is required to be included in a label or SDS for a hazardous product).

VARIANCE with HCS 2012: Initial supplier identifier

HPR

The initial supplier identifier (i.e., the name, address and telephone number of either the Canadian manufacturer or the Canadian importer) must be disclosed on the SDS for a hazardous product that is sold in or imported into Canada and intended for use, handling or storage in a work place in Canada. This requirement means that the coordinates of the Canadian manufacturer or the Canadian importer are required to appear on the SDS. However, if a hazardous product is imported for use only in the importer's own work place, the importer may retain the name, address and telephone number of the foreign supplier instead of replacing it with his own contact information. For further information about this exception, refer to the discussion of section 5.9 of the HPR.

HCS 2012

The name, address and telephone number of the manufacturer, importer, or other responsible party must appear on the label and SDS. The same U.S. address and phone number must appear on the SDS and label (i.e., they must match). When the chemical is imported, the importer is the first point of contact. The importer is therefore the responsible party for complying with the HCS 2012, and must include their name and address on the SDS and label. Although not required, U.S. OSHA prefers the original foreign manufacturer's name and address be removed to prevent confusion.

Item 2: Hazard Identification: Note that in the HCS 2012, the heading for this item is "Hazard(s) identification". This section identifies the hazards of the product and the information associated with those hazards. The information elements provided on the label related to hazard communication must be provided in this section along with some additional information. The required information consists of:

- The hazard classification of the product (e.g., Flammable Liquid - Category 1)
- Signal word (if applicable)
- Hazard statement(s) - May be combined (refer to subsection 3.2(3) of the HPR)
- The symbol(s) representing the hazard(s). Either the name of the symbol (e.g., skull and crossbones, flame) or the symbol itself may be used. The names of the symbols are set out in Column 1 of Schedule 3 of the HPR. Note that the pictogram(s) may be used instead of the symbol(s).
- Precautionary statements - May be combined or omitted where appropriate (refer to subsections 3.2(1) and (2) of the HPR)
- Supplemental label elements, if applicable, as specified in paragraphs 3(1)(e) and (f) of the HPR:
    - Mixtures classified in the Acute Toxicity hazard class that contain ingredient(s) with unknown acute toxicity require a supplemental statement indicating what total percentage of the mixture consists of ingredients of unknown acute toxicity. The route of exposure should be included in the statement.
    - Substances and mixtures which, in contact with water, release a toxic gas also require a supplemental statement. Further guidance is provided in the discussion of paragraphs 3(1)(e) and (f) of the HPR.
- Description of any other hazards known to the supplier (e.g., electrical conductance, radioactivity) which did not result in classification.

Classification of the hazardous product: Item 2(a) of Schedule 1 of the HPR (classification of the hazardous product) specifies that, for hazardous products classified in any HPR hazard class other than Physical Hazards Not Otherwise Classified (PHNOC) and Health Hazards Not Otherwise Classified (HHNOC) (Subpart 20 of Part 7 and Subpart 12 of Part 8, respectively), the SDS may disclose either:

- the exact name of the hazard class (as it appears in the HPR), along with the category or subcategory in which the hazardous product is classified, or
- a substantive equivalent of the hazard class name, along with the category or subcategory in which the hazardous product is classified.

Comparison to HCS 2012

This allowance for a substantive equivalent of the hazard class name recognizes that, in the HCS 2012, some hazard classes have a slightly different name. For example, if a hazardous product is classified in Self-Reactive Substances and Mixtures - Type B under the HPR, it would be acceptable to instead disclose "Self-Reactive **Chemicals** - Type B" under section 2 of the SDS, since the HCS 2012 refers to "Self-Reactive Chemicals".

For hazardous products classified in PHNOC or HHNOC, the SDS must disclose either the classification (e.g., Health Hazards Not Otherwise Classified - Category 1) or a description of the hazard. This allowance for using a description of a hazard in lieu of the hazard class name is aligned with the HCS 2012, which requires a description of "any hazards not otherwise classified that have been identified during the classification process" (item 2(c) of Table D.1 of the HCS 2012).

VARIANCE with HCS 2012: Information elements required under item 2(b) of the SDS for PHNOC and HHNOC

HPR

Paragraph 3(1)(d) of the HPR, item 2(b) of Schedule 1 and Parts 4 and 6 of Schedule 5 of the HPR specify that, for hazardous products classified in PHNOC or HHNOC, the following must be disclosed on the SDS under item 2(b):

- a hazard symbol (any symbol in Schedule 3 that is applicable to the hazard);
- the signal word "Danger";
- a hazard statement (the wording, while at the supplier's discretion, must describe the nature of the hazard); and
- precautionary statements (the wording, while at the supplier's discretion; must be applicable to the hazardous product).

HCS 2012

The HCS 2012 does not require a hazard symbol, signal word, hazard statement or precautionary statements for chemicals that present a Hazard Not Otherwise Classified (HNOC).

VARIANCE with HCS 2012: Precautionary Statements for Combustible Dusts, Pyrophoric Gases and Simple Asphyxiants

HPR

For hazardous products classified in Combustible Dusts, Pyrophoric Gases and Simple Asphyxiants, precautionary statements are required under the HPR.

HCS 2012

The HCS 2012 does not require precautionary statements for hazardous products classified in Combustible Dusts, Pyrophoric Gases and Simple Asphyxiants.

Item 3: Composition/Information on Ingredients: This section identifies the hazardous ingredient(s) (as defined in subsection 1(1) of the HPR), including impurities, stabilizing solvents and stabilizing additives, contained in the product. The required information consists of:

For a hazardous product that is a substance or material:

- Chemical name *
- Common name and synonyms*
- Chemical Abstracts Service (CAS) registry number and any unique identifiers*
- The chemical name of the impurities, stabilizing solvents and stabilizing additives known to the supplier which are themselves classified in any health hazard class and which contribute to the classification of the material or substance*

* Unless a CBI claim has been filed or granted to protect the required information element under the HMIRA. In this case, replacement information must appear on the SDS (refer to the discussion of section 5.7 of the HPR).

The requirement to disclose common names and synonyms for the substance or material includes the obligation to disclose other names by which the substance or material is commonly known in the work place. It is not expected that a long list of common names and synonyms would be provided.

For a hazardous product that is a mixture:

The following information is required for each ingredient in the mixture which is, by itself, classified in any health hazard class and is present at or above the cut-off/concentration limit that is designated for the category or subcategory in which it is classified, or is present in the mixture at a concentration which, in accordance with subsection 2.5(1) of the HPR, results in the mixture being classified in any health hazard class:

- Chemical name *
- Common name and synonyms*
- CAS registry number and any unique identifiers*
- Concentration*

* Unless a CBI claim to protect the required information element has been filed under the HMIRA. In this case, replacement information must appear (refer to the discussion of section 5.7 of the HPR).

The requirement to disclose common names and synonyms for each hazardous ingredient includes the obligation to disclose other names by which the ingredients are commonly known in the work place. It is not expected that a long list of common names and synonyms would be provided.

Concentration disclosure: If the concentration or the actual concentration range of an ingredient is expressed as a percentage, the units used to calculate the percentage must be provided, as required by section 4.3 of the HPR.

Section 4.5 of the HPR sets out a provision whereby, under specified circumstances, the SDS must disclose the actual concentration range of an ingredient in a mixture. Further guidance on the disclosure of ingredient concentrations and concentration ranges on SDSs is provided in Appendix 3 to this chapter (Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets). For the ingredients that are present in a range of concentrations in a mixture, the information provided on the SDS must correspond to the data available for the most hazardous concentration of the ingredient, as required by section 4.4 of the HPR.

VARIANCE with HCS 2012: Disclosure of HHNOC ingredients on SDSs

HPR

Information relating to the HHNOC ingredient, including its chemical name and concentration or concentration range, must be disclosed on the SDS under item 3(2) of Schedule 1 of the HPR for any mixture that contains an ingredient classified in HHNOC at a concentration of 1% or more.

HCS 2012

There is no requirement to disclose the chemical name or concentration of the HNOC ingredient on the SDS for a mixture that contains an ingredient that presents a Hazard Not Otherwise Classified (HNOC).

Concentration limits – equivalent or higher concentration: Subsection 2.5(2) of the HPR sets out a provision whereby, if an ingredient is present in a mixture at a concentration equal to or greater than the concentration limit for a particular category or subcategory of a health hazard class, but evidence based on established scientific principles demonstrates that the ingredient does not present the associated health hazard at that concentration, then the mixture need not be classified in that category or subcategory of the health hazard class based on the assessment of this ingredient. (Note that other ingredients in this mixture may result in the mixture being classified in the same health hazard class).

Therefore, in a situation where subsection 2.5(2) of the HPR applies, the ingredient need not be disclosed in section 3 of the SDS, unless the ingredient is required to be disclosed for another reason.

Item 4: First-aid Measures: This section describes the initial care that should be given to an individual who has been exposed to the product. The required information consists of:

- A description of necessary first aid measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion
- A description of the most important symptoms and effects, whether acute or delayed
- An indication for immediate medical attention and special treatment needed, if necessary

Item 5: Fire-fighting Measures: This section provides information for fighting a fire caused by the product. The required information consists of:

- Information about suitable extinguishing equipment and media, and information about extinguishing equipment and media that are not appropriate for a particular situation involving the hazardous product
- Information on specific hazards that may arise as a result of a fire caused by or involving the product, such as the nature of any hazardous combustion products
- Information on special protective equipment and precautions for fire-fighters

Item 6: Accidental Release Measures: This section provides information on the appropriate response to spills, leaks, or releases, including containment and clean-up practices to prevent or minimize exposure to and adverse effects on people, property, or the environment. This includes distinction between responses to large and small spills, if the spill volume has a significant impact on the hazard. The required information consists of:

- Description of the use of personal precautions (such as removal of ignition sources or providing sufficient ventilation) and protective equipment to prevent the hazardous product from coming into contact with skin, eyes, and clothing
- Description of emergency procedures, including instructions for evacuations, consulting experts when needed, and appropriate protective clothing
- Description of methods and materials used for containment (such as covering the drains and capping procedures)
- Description of methods and materials for clean-up (such as appropriate techniques for neutralization, decontamination, cleaning or vacuuming; appropriate techniques for avoiding production of gases/fumes by water or other diluent; use of suitable adsorbent materials; and equipment required for containment and clean-up)

Item 7: Handling and Storage: This section provides information on safe handling practices and conditions for safe storage of hazardous products. The required information consists of:

- Precautions for safe handling of the hazardous product, such as cautionary measures with regard to incompatible products, mixtures, materials and substances (PMMS), and precautions for minimizing the release of the hazardous product into the environment
- Description of the conditions for safe storage (e.g., temperature, humidity, avoiding sunlight), including any incompatibilities
- Description of specific storage conditions (e.g., appropriate ventilation, avoiding sources of ignition, including particular arrangements to avoid static build-up)

Item 8: Exposure Controls/Personal Protection: This section provides the occupational exposure limit values, biological limit values, information on engineering and/or administrative controls, and information on personal protective measures when using the hazardous product in order to minimize exposure. The required information consists of:

- Description of control parameters, including occupational exposure limit values or biological limit values and the source of those values
- Description of appropriate engineering controls (e.g., use local or general exhaust ventilation, use only in an enclosed system or limit workers' exposure in exposure time, etc.)
- Description of personal protective measures to minimize exposure and prevent adverse effects from exposure, such as personal protective equipment to be worn by the worker (e.g., lab coat, appropriate types of eye, face, skin or respiratory protection needed based on hazards and potential exposure, and type of glove material)

Item 9: Physical and Chemical Properties: This section describes the physical and chemical properties associated with the hazardous product. The required information consists of:

- Appearance, such as colour and physical state (e.g., solid, liquid or gas; these terms are defined in subsection 1(1) of the HPR)
- Odour
- Odour threshold
- pH
- Melting point and freezing point
- Initial boiling point and boiling range
- Flash point
- Evaporation rate
- Flammability, in the case of solids and gases
- Upper and lower flammability or explosive limits
- Vapour pressure
- Vapour density
- Relative density
- Solubility
- Partition coefficient- n-octanol/water
- Auto-ignition temperature
- Decomposition temperature, and
- Viscosity

If specific characteristics do not apply or are not available for the hazardous product, a statement that they do not apply (not applicable) or are not available must appear.

Comparison to HCS 2012

The HCS 2012 also requires that, for item 9 (Physical and chemical properties) of the SDS, all information items must be addressed by providing the information or providing an indication that the item is not applicable or no information is available. Thus, under the HCS 2012, even if a physical or chemical property is listed in another section of the SDS (e.g., flash point might also be listed in item 5), it must still be listed in item 9. This is also required under the HPR.

Suppliers may voluntarily add other physical or chemical parameters pertinent to the hazardous product, such as oxidizing properties and molecular weight, to those listed above.

Item 10: Stability and Reactivity: This section describes the possibility of hazardous reactions of the product under certain conditions and provides information on chemical stability.

The required information consists of:

- Description of the reactivity hazards
- Indication of whether the hazardous product is stable or unstable under:
  (a) normal ambient temperature and pressure conditions, and
  (b) temperature and pressure conditions while in storage and being handled.
- Description of any stabilizers that may be needed
- Indication of any safety issues that may arise and which are associated with a change in physical appearance of the hazardous product
- Indication of the possibility of hazardous reactions, including a statement of whether the hazardous product will react or polymerize, and could release excess pressure or heat, or create other hazardous conditions. Also, a description of the conditions under which hazardous reactions may occur
- List of all conditions to avoid, including static discharge, shock, vibrations. Other examples of conditions to avoid may include contact with moisture or air, temperature, pressure, exposure to sunlight
- List of all classes of incompatible PMMS with which the hazardous product could react resulting in a hazardous situation
- List of any known or anticipated hazardous decomposition products that could be produced as a result of use, storage, or heating of the hazardous product.

In the event that a hazardous product meets the criteria of section 4.1 of the HPR (instructions for use involve the combination of the hazardous product with one or more product, mixture, material or substance (PMMS) which creates a new material or substance that poses a new or more severe hazard), the additional information that is required by this provision could be provided here or anywhere on the SDS.

Item 11: Toxicological Information: This section provides a concise but complete description of the various health effects and the data used to identify those effects for either the material, substance or the mixture as whole or as hazardous ingredients. The required information includes:

- Information on likely routes of exposure (inhalation, ingestion, skin and eye contact)
- Description of the delayed and immediate effects
- Description of chronic effects from both short- and long-term exposure
- The numerical measures of toxicity, including acute toxicity estimates such as the LD_{50}. Further guidance is provided in the discussion of the definition of Acute Toxicity Estimate ("ATE") in both Part 1 and section 8.1 of the HPR
- Description of the symptoms following exposure. This description includes first symptoms at the lowest exposures through to the consequences of severe exposure to the hazardous product. For example, "Headaches and dizziness may occur, before/leading to fainting or unconsciousness: large doses may result in coma and death"

In the case of a mixture, the information provided under this heading must be the information that is available on the mixture as a whole, and if information is not available on the mixture as a whole, then it must be information that is available on the hazardous ingredients in the mixture. In the latter case, the chemical name of the hazardous ingredient to which the information applies must be clearly indicated.

Comparison to HCS 2012

Note that in the HCS 2012, under item 11(e) of Table D.1, there is a requirement to disclose whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA. Schedule 1 of the HPR does not include this requirement; however, the information required by the HCS 2012 with regard to the disclosure of carcinogens may be added to section 11 of the SDS.

Item 12: Ecological Information (header required; content optional): As per subsection 4(2) of the HPR, the content of the specific information elements may be omitted as long as the item number and heading appear on the SDS. Environmental hazards are outside the scope of the HPR. If provided, this section offers information to evaluate the environmental impact of the product if it were released to the environment. The information may include:

- Data from toxicity tests performed on aquatic and/or terrestrial organisms, where available (e.g., acute or chronic aquatic toxicity data for fish, algae, crustaceans, and other plants; toxicity data on birds, bees, plants)
- Whether there is a potential for the product to persist and degrade in the environment either through biodegradation or other processes, such as oxidation or hydrolysis
- Results of tests of bioaccumulation potential, making reference to the octanol-water partition coefficient (K_{ow}) and the bioconcentration factor, where available

- The potential for the product to move from the soil to the groundwater (indicate results from adsorption studies or leaching studies) or to a distance from the site of release
- Other adverse effects (e.g., environmental fate (exposure), ozone layer depletion potential, photochemical ozone creation potential, endocrine disrupting potential, and/or global warming potential)

Item 13: Disposal Considerations (header required; content optional): As per subsection 4(2) of the HPR, the content of the specific information elements may be omitted as long as the item number and heading appear on the SDS. If provided, this section offers information on proper disposal practices, recycling or reclamation of the product and/or its container, and safe handling practices. The information may include:

- Description of appropriate disposal containers to use
- Recommendations on appropriate disposal methods to employ
- Description of the physical and chemical properties that may affect disposal activities
- Any special precautions for landfills or incineration activities

Item 14: Transport Information (header required; content optional): As per subsection 4(2) of the HPR, the content of the specific information elements may be omitted as long as the item number and heading appear on the SDS. The provision of information on the transport of dangerous goods is outside the scope of the HPR as this is regulated by Transport Canada.

If provided, this section offers the following transport information, including classification information for shipping and transporting of hazardous products by road, air, rail, or sea:

- United Nations (UN) number (i.e., four-digit identification number of the substance. This term is defined in subsection 1(1) of the HPR.)
- UN proper shipping name as provided for in the United Nations Model Regulations (UNMR)
- Transport hazard class(es) as provided for in the UNMR
- Packing group number as provided for in the UNMR
- Environmental hazards (e.g., identify if it is a marine pollutant) according to the *International Maritime Dangerous Goods Code* (IMDG Code) and the UNMR
- Information on transport in bulk (according to Annex II of the *International Convention for the Prevention of Pollution From Ships, 1973*, as modified by the Protocol of 1978 (MARPOL 73/78) and the *International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk* (IBC Code)
- Any special precautions which an employee should be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

Item 15: Regulatory Information (header required; content optional): As per subsection 4(2) of the HPR, the content of the specific information elements may be omitted as long as the item number and heading appear on the SDS. If provided, this section offers information on the safety, health and environmental regulations, made within or outside Canada, specific to the product in question.

Item 16: Other Information: This section provides the date of the latest revision of the SDS. This section indicates the date of preparation if the SDS has not been revised or the date of the latest revision of the SDS in all other cases. This section may also state where the changes have been made to the previous version. Other information also may be included here (e.g., abbreviations and acronyms used in the SDS).

Appendix 2 – Information Elements on Safety Data Sheet – Biohazardous Infectious Materials, Schedule 2 of the HPR

Further guidance on the Biohazardous Infectious Material (BIM) SDS appendix is provided in the discussion to subsections 4(3) and 4(4) of the HPR.

Section I: Infectious Agent: This section consists of the name, synonym or cross-reference, and characteristics of the BIM.

Section II: Hazard Identification: This section identifies the pathogenicity or toxicity, epidemiology, host range, infectious dose, mode of transmission, incubation period and communicability (whether capable of transmission from person-to-person) of the BIM.

Section III: Dissemination: This section provides information on the reservoir (whether humans or animals), zoonosis (whether disease can be transmitted to humans from animals) and vectors of the BIM.

Section IV: Stability and Viability: This section indicates the drug susceptibility and drug resistance (to which drugs is the BIM susceptible and resistant), susceptibility to disinfectants, physical inactivation (temperature, pressure and time after which the species can be inactivated) and survival of the BIM outside the host.

Section V: First Aid/Medical: This section provides information on the diagnostic methods that can be used to monitor the symptoms of infection, recommendations on the first aid and/or medical treatment, immunization and prophylaxis (preventive treatment or measures taken to prevent the disease).

Section VI: Laboratory Hazard: This section provides information on the laboratory acquired infections, sources and specimens of the BIM, primary hazards and any other special hazards posed by the BIM.

Section VII: Exposure Controls/Personal Protection: This section provides information on the risk group classification of the species (in accordance with the *Human Pathogens and Toxins Act*; further guidance is provided in the discussion of the definition of risk group classification in Part 1 of the HPR), the containment requirements for working with the BIM, protective clothing (such as lab coat, gloves, eye protection to avoid potential risks of exposure to splashes) and other precautions (such as use of biological safety cabinet, needles, syringes and other sharp objects) to be taken while working or handling the BIM.

Section VIII: Handling and Storage: This section provides information on proper handling practices in case of spills, recommendations on appropriate disposal methods to employ, and information on proper storage conditions.

Section IX: Regulatory and Other Information: This section provides information on all the regulations with which the supplier or importer must comply for the import, use and transport of the BIM in Canada. This section also provides information on the date of the preparation of the SDS or, if applicable, the date of the last updated version of the SDS, and the name of the author who prepared or updated the SDS.

Appendix 3 – Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets

Background

On February 11, 2015, the Government of Canada published in the *Canada Gazette*, Part II, the *Hazardous Products Regulations* (HPR) which, in addition to the amendments made to the *Hazardous Products Act* (HPA), modified the Workplace Hazardous Materials Information System (WHMIS) to incorporate the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for work place chemicals. The *Controlled Products Regulations* (CPR) and *the Ingredient Disclosure List* of the original WHMIS 1988 were repealed and replaced by the HPR. The WHMIS requirements of the amended HPA and the HPR are referred to as WHMIS 2015.

Through the publication of the new HPR, Canada fulfilled a key commitment under the Canada-United States (U.S.) Regulatory Cooperation Council (RCC) to "align and synchronize implementation of common classification and labelling requirements for work place chemicals... without reducing the level of safety or of protection to workers". The GHS provides an international standard for the classification and communication of information on hazardous products, and includes new harmonized criteria for hazard classification and requirements for labels and SDSs.

A key objective of the implementation of the GHS is to create a system that allows Canadian and U.S. requirements to be met through the use of a single label and safety data sheet for each hazardous product.

Ingredient Disclosure, Concentrations and Concentration Ranges

The HPR and United States' Hazard Communication Standard (HCS 2012) require suppliers to provide information on hazards and safe use and handling of a hazardous product on the SDS and label. A product's SDS must fully disclose all hazardous ingredients in the product, its toxicological properties, any safety precautions workers need to take when using and handling the product, and first aid treatment required in the case of exposure, along with other information specified in Schedule 1 of the HPR.

Table 1 – Comparison of Requirements on Ingredient Disclosure, Concentrations and Concentration Ranges under the CPR, the HPR and the HCS 2012

Canada WHMIS 1988 (repealed CPR)	The rules with regard to ingredient disclosure, including which ingredients of a mixture need to be disclosed, were set out in subparagraphs 13(a)(i) to (iv) of the HPA prior to its amendment in 2014. **Subsections 11(2) and (3) of the CPR (Range of Concentration of Ingredients)** 11(2) Where the concentration of an ingredient of a controlled product or a complex mixture that is a component of a controlled product is required to be disclosed on a material safety data sheet and the ingredient or complex mixture is not always present in the same concentration in the controlled product, the material safety data sheet may disclose, in lieu of the actual concentration of the ingredient or complex mixture, that the ingredient or complex mixture falls within one of the ranges of concentration set out in subsection (3), where the actual concentration of the ingredient or complex mixture falls within that range. (3) For the purposes of subsection (2), the ranges of concentration are the following: (a) from 0.1 to 1 per cent; (b) from 0.5 to 1.5 per cent; (c) from 1 to 5 per cent; (d) from 3 to 7 per cent; (e) from 5 to 10 per cent; (f) from 7 to 13 per cent; (g) from 10 to 30 per cent; (h) from 15 to 40 per cent; (i) from 30 to 60 per cent; (j) from 40 to 70 per cent; and (k) from 60 to 100 per cent.

Canada WHMIS 2015 (HPR) (came into force on February 11, 2015)	**Section 4.5 of the HPR:** If the **concentration** of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is not always present at the same concentration, the safety data sheet must provide, in lieu of the concentration of the material or substance, the **actual concentration range** of the material or substance in the hazardous product. **Section 3 of Schedule 1 of the HPR (Information Elements on Safety Data Sheet)** (1) In the case of a hazardous product that is a material or substance, (a) its chemical name; (b) its common name and synonyms; (c) its CAS registry number and any unique identifiers; and (d) the chemical name of the impurities, stabilizing solvents and stabilizing additives that are known to the supplier, that individually are classified in any category or subcategory of a health hazard class and that contribute to the classification of the material or substance (2) In the case of a hazardous product that is a mixture, for each material or substance in the mixture that, individually, is classified in any category or subcategory of a health hazard class and is present above the concentration limit that is designated for the category or subcategory in which it is classified or is present in the mixture at a concentration that results in the mixture being classified in a category or subcategory of any health hazard class, (a) its chemical name; (b) its common name and synonyms; (c) its CAS registry number and any unique identifiers; and (d) its concentration.

U.S. HCS 2012	**Under item 3 of Table D.1 (Minimum Information for an SDS)** Except as provided for in paragraph (i) of §1910.1200 on trade secrets: **For Substances** (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. **For Mixtures** In addition to the information required for substances: (a) The chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of §1910.1200 and (1) are present above their cut-off/concentration limits; or (2) present a health risk below the cut-off/ concentration limits. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of §1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used. **For All Chemicals Where a Trade Secret is Claimed** Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.

Appendix 4 to this chapter provides a comparison of ingredient concentration disclosure and Confidential Business Information (CBI) protection requirements across WHMIS 1988, WHMIS 2015 and HCS 2012. These requirements are discussed in further detail below.

Changes Made from WHMIS 1988 to WHMIS 2015 Regarding Concentration Ranges

Under WHMIS 1988, the CPR permitted the use of concentration ranges when ingredients were not always present at the same concentration in a controlled product. A set of prescribed concentration ranges was listed in subsection 11(3) of the CPR, as specified in Table 1. These prescribed concentration ranges were not retained in the HPR.

Section 4.5 of the HPR specifies that, where a hazardous ingredient is required to be disclosed and it is not always present in a hazardous product at the same concentration, then the **actual concentration range** of the ingredient in the hazardous product must be disclosed. This

provision must be used in all situations where a hazardous ingredient is required to be disclosed and it is present in a hazardous product at a range of concentrations.

Terminology - WHMIS 2015 and HCS 2012

The HPR and the HCS 2012 are aligned with regard to what is meant by "**concentration**" (HPR) versus "**concentration (exact percentage)**" (HCS 2012). For the purposes of this Appendix and Appendix 4 to this chapter, the term "**true concentration**" is used to represent the concentration as it is required to be disclosed by WHMIS 2015 and HCS 2012. Under the HPR, the concentration of a hazardous ingredient in a mixture may either be expressed:

- As a percentage, with the type of units specified (e.g., 5.0% weight/volume), or
- As a unit of measurement (e.g., 5.0 g/l).

When a concentration is expressed as a percentage, the exact percentage of the hazardous ingredient in the mixture must be disclosed. Similarly, when a concentration is expressed as a unit of measurement, the exact concentration must be disclosed. The HCS 2012 has the same requirement with regard to "concentration (exact percentage)".

The HPR and the HCS 2012 are also aligned with regard to what is meant by "**actual concentration range**" (HPR) and "**concentration range**" (HCS 2012):

- In the HPR, the term "**actual concentration range**" refers to the range of concentrations within which the true concentration of a hazardous ingredient in a mixture would be expected to fall, given the quality control parameters of the manufacturing process for the mixture.
- The HCS 2012 uses the term "**concentration range**", which has the same meaning.

For the purposes of this Appendix and Appendix 4 to this chapter, the term "**true concentration range**" is used to represent the concentration range as it is required to be disclosed by WHMIS 2015 and HCS 2012.

Disclosing an Ingredient Concentration or Concentration Range

Under both the HPR and HCS 2012:

- The **true concentration** of an ingredient must be disclosed when the ingredient is present in the mixture at a fixed concentration.

- When an ingredient is not always present at the same concentration, then the **true concentration range** of the ingredient in the mixture must be disclosed.

When disclosing a true concentration range, the following conditions apply:

- The ingredient must be present in the mixture at a range of concentrations.
- The range must accurately reflect the concentration variation.

- The hazard classification must accurately reflect the hazards associated with the mixture.

These conditions do not apply to trade secrets, as discussed below.

The concentration of a hazardous ingredient in a mixture may vary due to batch-to-batch variability. In these situations, a supplier must comply with section 4.5 of the HPR to disclose the true concentration range of the hazardous ingredient. This requirement is similar to the provision in the HCS 2012.

Batch-to-batch variability

"Batch-to-batch variability" refers to situations where products are produced to specified criteria, but product composition varies from batch to batch. Variations in product composition could be due to factors such as production tolerances (fluctuations permitted by the quality control parameters of the manufacturing process) and varying concentrations of starting materials.

Example: If the manufacturing formula for a mixture calls for 8% of hazardous ingredient A, but due to batch-to-batch variability, the true concentration is expected to vary from 5% to 10%, then the supplier must disclose 5% to 10% as the true concentration range.

When a range is disclosed, SDSs must be in compliance with requirements in the HPR for hazard classification (section 2.6) and information disclosed on SDSs (section 4.4). Section 2.6 states that "… the maximum concentration must be used for the purposes of establishing whether the mixture is classified in a category or subcategory of a health hazard class". Thus, in the example provided above, where the concentration of ingredient A ranges from 5% to 10% due to batch-to-batch variability, the classification of the mixture with respect to the health hazard classes must be based on the maximum concentration of 10%.

Section 4.4 states that "…the information provided on the safety data sheet must be based on data available that correspond to the most hazardous concentration of each ingredient in the mixture, whether those data pertain to an ingredient or the mixture as a whole". Thus the hazard classification and the health and safety information provided on the SDS must be reflective of the highest degree of hazard that the mixture could present.

In instances where there is greater variability in concentrations, a broader range (e.g., 10 – 20%) would also meet the requirement to disclose the actual concentration range, provided that the range is an accurate representation of the variation. As for all situations where a concentration range is disclosed, the requirements of sections 2.6 and 4.4 of the HPR must be met.

Maintaining documentation on the manufacturing process which demonstrates product composition variability is important to support the disclosure of any existing concentration range.

Protection of Confidential Business Information (CBI)

Canada and the U.S. are aligned with regard to requirements for hazardous ingredient disclosure on SDSs, but the mechanisms to protect CBI are different. In Canada, a supplier must file a trade secret claim with Health Canada under the provisions of the *Hazardous Materials Information Review Act* (HMIRA) to request an exemption from a requirement under the HPA and HPR to disclose specific information, such as the chemical name, the true concentration or true concentration range of a hazardous ingredient. In the U.S., the specific chemical identity and/or

concentration (exact percentage) of a hazardous ingredient may be claimed as a trade secret in accordance with paragraph (i) of the HCS 2012 and there is no government review process. The Canadian and U.S. requirements can still be met through the use of a single label and SDS for each hazardous product, provided that the requirements set out in the relevant legislation, regulation or rule of each jurisdiction are met.

When a trade secret claim is filed with Health Canada to protect the chemical name, the supplier must include in the SDS:

- the true concentration or true concentration range of a hazardous ingredient,
- a statement to indicate that a claim was filed,
- the date of filing and the claim registry number.

Once the claim has been approved, the SDS must indicate that an exemption has been granted, the date of the decision granting the exemption and the claim registry number.

In the circumstance where a concentration or concentration range is protected, suppliers are encouraged to disclose a replacement concentration range on the SDS that encompasses the true concentration or true concentration range, subject to the following conditions:

- The hazard classification based on the replacement concentration range must be the same as that of the true concentration or true concentration range; and
- All other information provided on the SDS must be equally reflective of the true concentration or true concentration range and the replacement concentration range.

Under the HCS 2012, a concentration range of a hazardous ingredient may not be claimed as a trade secret. When a concentration of a hazardous ingredient or its identity is claimed as a trade secret under the HCS 2012, a statement that the specific chemical identity and/or concentration (exact percentage) of composition has been withheld as a trade secret is required. A replacement range may be provided.

References

29 CFR 1910.1200, Hazard Communication

Hazardous Materials Information Review Act, R.S.C. 1985, c. 24 (3rd Supp.), Part III

Hazardous Products Act, R.S.C., 1985, c. H-3

Hazardous Products Regulations, SOR/2015-17

International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans” (latest edition)

National Toxicology Program (NTP) “Report on Carcinogens” (latest edition)

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

Appendix 4 - Comparison of Ingredient Concentration Disclosure and CBI Protection Requirements

Example Ingredient Concentration

Chemical Name	Volume %
Toluene	17%
Acetone	32-41%

		Regulatory System		
		WHMIS 1988 (WHMIS before GHS)	**WHMIS 2015 (GHS in Canada)**	**HCS 2012 (GHS in U.S.)**
Ingredient Concentration (No CBI)	**Concentration** (where concentration does not vary)	True Concentration **Chemical Name** / **Volume %**: Toluene / 17%	True Concentration **Chemical Name** / **Volume %**: Toluene / 17%	True Concentration **Chemical Name** / **Volume %**: Toluene / 17%
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	Standardized Concentration Range **Chemical Name** / **Volume %**: Acetone / 30-60%	True Concentration Range **Chemical Name** / **Volume %**: Acetone / 32-41%	True Concentration Range **Chemical Name** / **Volume %**: Acetone / 32-41%
CBI Protection	**Concentration** (where concentration does not vary)	"Trade Secret" and Registry Number (Range Optional) **Chemical Name** / **Volume %**: Toluene / Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and Registry Number (Range Optional) **Chemical Name** / **Volume %**: Toluene / Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" (Range Optional) **Chemical Name** / **Volume %**: Toluene / Trade Secret
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	"Trade Secret" and Registry Number **Chemical Name** / **Volume %**: Acetone / Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and Registry Number **Chemical Name** / **Volume %**: Acetone / Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	**CBI Claim Not Allowed** **Supplier must disclose True Concentration Range** **Chemical Name** / **Volume %**: Acetone / 32-41%

Alignment of Canada / U.S. Requirements

Aligned | Distinct But Complementary | Not Aligned

Volume %
True Concentration / True Concentration Range Disclosed

Volume %
CBI Protected

PART 5

Exceptions

Part 5 "Exceptions" identifies exemptions from certain requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR).

Sections 13 and 14 of the HPA outline the requirements to provide, obtain or prepare a safety data sheet (SDS) for a hazardous product, and to label a hazardous product. The sale or importation of a hazardous product may be either partly or entirely exempted from the requirements of sections 13 and 14 of the HPA through the provisions of Part 5 of the HPR.

The exemptions from some requirements of the HPA and the HPR that are detailed in Part 5 are always optional; a supplier may choose not to use these exemptions and may instead fully comply with all requirements of the HPA and the HPR.

The following definitions from the HPA apply in this Part.

Definitions in Section 2 of the HPA

"sell" includes

(a) offer for sale or distribution, expose for sale or distribution, have in possession for sale or distribution or distribute — whether for consideration or not — to one or more recipients, and

(b) make any transfer of possession that creates a bailment or, in Quebec, make any transfer of possession of a movable, for a specific purpose, without transferring ownership, and with the obligation to deliver the movable to a specified person or to return it, such as a transfer by means of a deposit, a lease, a pledge, a loan for use or a contract of carriage;

"import" means to import into Canada;

The term "bailment" referred to in this guidance document means the "transfer of possession without the transfer of ownership".

Discussion of the *Hazardous Products Regulations*
Subsection 5(1)

Definition of "laboratory sample"

5(1) In this section, "laboratory sample" means a sample of a hazardous product that is packaged in a container that contains less than 10 kg of the hazardous product and that is intended solely to be tested in a laboratory, but does not include a sample that is to be used

(*a*) by the laboratory for testing other products, mixtures, materials or substances; or

(*b*) for educational or demonstration purposes.

A laboratory sample is, by definition, a sample of a hazardous product (i.e. it must meet the criteria to be classified in at least one of the hazard classes of these regulations), that is intended solely to be tested in a laboratory. Subject to the exemptions in Part 5, in the event that the laboratory sample is known to contain hazardous materials, substances or mixtures and that it meets the classification criteria of at least one hazard class, the HPA requirements to provide a label and SDS that comply with the HPR must be respected upon sale or import of the laboratory sample. It must be remembered that sale includes the provision of the sample for free and bailment of the sample.

Examples of laboratory samples include: diagnostic specimens (infectious blood, mucosa or tissue samples), soil or water samples contaminated with hazardous substances or mixtures, chemical mixtures of hazardous products that are in the process of being developed, and quality control samples of hazardous products (developed products being tested for quality).

If the sample is not a hazardous product (i.e. it does not meet the classification criteria for any hazard class), then it is not subject to the requirements of the HPA and HPR.

In addition to being a hazardous product, a laboratory sample in the context of the HPR

- does not include a sample that is to be used by the laboratory for
    - testing other product, material, mixture or substance (PMMS) (e.g., titrants, HPLC (high pressure liquid chromatography) solvents, GC (gas chromatography) carrier gas, etc.); or
    - educational or demonstration purposes; and
- must individually weigh less than 10 kg.

It is important to note that a sample of a hazardous product that is provided by a supplier to a customer, for the purpose of trying out the hazardous product (trial sample), does not meet the definition of a "laboratory sample". The laboratory sample exemptions set out in subsections 5(2) to (6) of the HPR do not apply in this situation. This hazardous product trial sample is subject to the full labelling and SDS requirements of the HPR, unless another exemption applies (such as subsection 5.4(1) for small containers of a capacity of 100 ml or less). The provision of such

a free trial sample to a customer falls under the HPA definition of "sell" (section 2 of the HPA), since the definition includes "*distribute — whether for consideration or not — to one or more recipients* …".

It must be noted that under the HCS 2012 there is no SDS or labelling exemption for laboratory samples.

Discussion of the *Hazardous Products Regulations*
Subsection 5(2)

Sale or importation — biohazardous infectious materials — safety data sheet

5(2) Subject to subsection (3), the sale or importation of a laboratory sample that is classified only in the category "Biohazardous Infectious Materials — Category 1" is exempt from the application of paragraphs 13(1)(*a*) and (*a.1*) and 14(*a*) of the Act.

This provision exempts laboratory samples of hazardous products that are classified only in the Biohazardous Infectious Materials (BIM) hazard class (Subpart 11 of Part 8 of the HPR) from the SDS requirements of the HPA, whether the sample is sold or imported, i.e., the supplier need not have an SDS in their possession, provide or cause to be provided, obtain or prepare an SDS for such a laboratory sample. Furthermore, as discussed under subsection 5(5) of the HPR, such a sample is also exempted from full label requirements provided that reduced label requirements are met.

Note that, because it is subject to subsection 5(3) which deals with bailment, subsection 5(2) applies only to a sale with transfer of ownership (i.e., paragraph (a) of the HPA definition of "sell") or an importation of laboratory samples classified only in the BIM hazard class. Consequently, for sale of a laboratory sample that constitutes a bailment (i.e., paragraph (b) of the HPA definition of "sell"), please consult subsection 5(3).

It must be noted that these BIM laboratory samples are not to be used for the testing of other products, mixture, materials or substances (paragraph 5(1)(a)).

Discussion of the *Hazardous Products Regulations*
Subsection 5(3)

Transfer of possession – biohazardous infectious materials – safety data sheet and label

5(3) The transfer of possession of a laboratory sample for a specific purpose, without transferring ownership, if that laboratory sample is classified only in the category "Biohazardous Infectious Materials — Category 1", is exempt from the application of section 13 of the Act.

A laboratory sample that is classified only in the BIM hazard class (Subpart 11 of Part 8 of the HPR) and that is bailed (paragraph (b) of the HPA definition of "sell") is exempt from the labelling

and SDS requirements of section 13 of the HPA (i.e., such a laboratory sample does not require any label or SDS).

In many cases, when a laboratory sample is sent by a supplier to a laboratory for testing, the ownership of the sample remains with the supplier. Once the test has been completed, what is left of the sample, if anything, may either be disposed of or returned, as instructed by the supplier. In order for this exemption to apply, the ownership of the sample must always remain with the supplier. In other words, the laboratory may have possession of the laboratory sample but not the ownership; this is what is meant by "transfer of possession without transfer of ownership". It is important to note that bailment cannot occur in the context of importation of laboratory samples (i.e., cross border shipment does not qualify for this exemption).

As an example, this exemption allows health care workers to avoid having to produce an SDS or label for a diagnostic specimen that is known to be contaminated with a BIM.

Discussion of the *Hazardous Products Regulations* Subsection 5(4)

Transfer of possession — safety data sheet

5(4) The transfer of possession of a laboratory sample for a specific purpose, without transferring ownership, if that laboratory sample is one of the following types, is exempt from the application of paragraphs 13(1)(*a*) and (*a.1*) of the Act:

(*a*) a laboratory sample for which the chemical name and concentration of the hazardous product or its ingredients are not known; or

(*b*) a laboratory sample for which the supplier has not offered or exposed the hazardous product for transfer of ownership.

Laboratory samples that meet the description of either paragraph 5(4)(a) or (b) and that are bailed (paragraph (b) of the HPA definition of "sell") are exempted from the SDS requirements of section 13 of the HPA, i.e., the supplier does not need to have in their possession or provide or cause to be provided an SDS for these laboratory samples. These laboratory samples are either samples for which the chemical identity or concentration of the hazardous product or its ingredients are unknown, or samples of hazardous products that are not yet available on the market.

Paragraph (a) of this exemption is meant to address samples of hazardous products sent to a laboratory for analysis to determine information necessary to the preparation of an SDS, while paragraph (b) is meant to address laboratory samples of hazardous products that have not yet been marketed (these samples may be part of a research and development program).

In many cases, when a laboratory sample is sent by a supplier to a laboratory for testing, the ownership of the sample remains with the supplier. Once the test has been completed, what is left of the sample, if anything, may either be disposed of or returned, as instructed by the supplier. In order for this exemption to apply, the ownership of the sample must always remain with the supplier. In other words, the laboratory may have possession of the laboratory sample

but not the ownership; this is what is meant by "transfer of possession without transfer of ownership". It is important to note that bailment cannot occur in the context of importation of laboratory samples (i.e. cross-border shipment does not qualify for this exemption).

This provision creates an exemption for the situation in which a supplier is required to disclose information on a laboratory sample when the supplier is sending the sample for the purpose of obtaining the very information that they are required to disclose, e.g. chemical identity or concentration of the hazardous product or its ingredients.

Furthermore, as discussed under subsection 5(6) of the HPR, such a sample is also exempted from full label requirements provided that reduced label requirements are met.

Discussion of the *Hazardous Products Regulations*
Subsection 5(5)

Sale or importation — biohazardous infectious materials — label

5(5) Subject to subsection (3), the sale or importation of a laboratory sample that is classified only in the category "Biohazardous Infectious Materials — Category 1" is exempt from the application of paragraph 3(1)(*d*) if the label provides the chemical name or generic chemical name of any material that is in the hazardous product and that is classified as a biohazardous infectious material, if known by the supplier, and the statement "Hazardous Laboratory Sample. For hazard information or in an emergency, call/Échantillon pour laboratoire de produit dangereux. Pour obtenir des renseignements sur les dangers ou en cas d'urgence, composez", followed by an emergency telephone number for the purpose of obtaining the information that must be provided on the safety data sheet of the hazardous product.

Laboratory samples that are classified only in the BIM hazard class (Subpart 11 of Part 8 of the HPR) are exempted, upon sale or importation, from the requirement to have on their labels the applicable pictogram, signal word, hazard and precautionary statements if reduced labelling requirements are met instead (i.e., the label provides the chemical name or generic chemical name of the BIM, the required bilingual statement and an emergency number). Requirements relating to information elements such as the product identifier (paragraph 3(1)(a) of the HPR) and the initial supplier identifier (paragraph 3(1)(b) of the HPR) are not exempted; these information elements must still be provided on the label.

Subsection 5(5) of the HPR applies only to importation and sale as defined by paragraph (a) of the HPA definition of "sell". It is not applicable to the bailment of laboratory samples that are classified only in the BIM hazard class. The exemption applicable to the bailment (paragraph (b) of the HPA definition of "sell") of such laboratory samples is found in subsection 5(3).

Since subsection 5(5) of the HPR deals with laboratory samples that are classified only in the BIM hazard class, the requirement to provide the "chemical name or generic chemical name" on the label must be met by providing the name of the infectious material, that is, the scientific

name of the infectious microorganism, nucleic acid or protein. The generic chemical name may be used only when a claim for confidential business information (CBI) is filed or granted under the *Hazardous Materials Information Review Act* (HMIRA). For more information regarding CBI, see the discussions of subsections 5.7(1) to (11) and Appendix A-2 (Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form). The terms "g*eneric chemical name"* and "*commonly known generic name"* must not be confused. The *commonly known generic name* refers to a synonym (e.g., turpentine) of a chemical name, whereas the *generic chemical name* (e.g., primary alcohol) is used to preserve a trade secret (CBI); it provides information about the chemical without revealing its exact identity. For more information about generic chemical names please refer to Appendix 1 to this chapter.

According to subsection 5(2) of the HPR, such samples are also exempted from the SDS requirements of the HPA; that is, the supplier need not have in their possession, provide or cause to be provided, obtain or prepare an SDS for such a laboratory sample.

Discussion of the *Hazardous Products Regulations*
Subsection 5(6)

Transfer of possession — label

5(6) The transfer of possession of a laboratory sample for a specific purpose, without transferring ownership, is exempt from the application of paragraphs 3(1)(*c*) and (*d*) if the label provides the chemical name or generic chemical name of any material or substance that is in the hazardous product and that is referred to in subsection 3(2) of Schedule 1, if known by the supplier, and the statement "Hazardous Laboratory Sample. For hazard information or in an emergency, call/Échantillon pour laboratoire de produits dangereux. Pour obtenir des renseignements sur les dangers ou en cas d'urgence, composez", followed by an emergency telephone number for the purpose of obtaining the information that must be provided on the safety data sheet of the hazardous product, and if that laboratory sample is one of the following types:

(*a*) a laboratory sample for which the chemical name and concentration of the hazardous product or its ingredients are not known; or

(*b*) a laboratory sample in respect of which the supplier has not offered or exposed the hazardous product for transfer of ownership.

Laboratory samples that meet the description of either paragraph 5(6)(a) or (b) and that are bailed (paragraph (b) of the HPA definition of "sell") are exempted from the requirement to have on their labels the applicable pictogram(s), signal word, hazard and precautionary statements if reduced labelling requirements are met instead (i.e., the label provides the chemical name or generic chemical name of the hazardous product or its ingredients, the required bilingual statement and an emergency number).

These are either samples for which the chemical identity or concentration of the hazardous product or its ingredients are unknown, or samples of hazardous products that are not yet available on the market. Requirements relating to information elements such as the product

identifier (paragraph 3(1)(a) of the HPR) and the initial supplier identifier (paragraph 3(1)(b) of the HPR) are not exempted; these information elements must still be provided on the label.

Paragraph (a) of this label exemption is meant to address samples of hazardous products sent to a laboratory for analysis to determine information necessary to the preparation of the label, while paragraph (b) is meant to address laboratory samples of hazardous products that have not yet been marketed (these samples may be part of a research and development program).

Example of a laboratory sample label according to subsection 5(6) is provided below:

Product identifier: Industrial bleach
Chemical name: Sodium hypochlorite

Supplier identifier:
Industrial Products Inc., 12354 Any Street, Any City, Manitoba, J6L 3H8, 890-123-4567
Hazardous Laboratory Sample. For hazard information or in an emergency, call 123-456-7890
Échantillon pour laboratoire de produits dangereux. Pour obtenir des renseignements sur les dangers ou en cas d'urgence, composez le 123-456-7890

It is important to note that a laboratory sample can be subject to both subsection 5(4) (SDS exemption) and subsection 5(6) (partial label exemption).

In many cases, when a laboratory sample is sent by a supplier to a laboratory for testing, the ownership of the sample remains with the supplier. Once the test has been completed, what is left of the sample, if anything, may either be disposed of or returned, as instructed by the supplier. In order for this exemption to apply, the ownership of the sample must always remain with the supplier. In other words, the laboratory may have possession of the laboratory sample but not the ownership; this is what is meant by "transfer of possession without transfer of ownership". It is important to note that bailment cannot occur in the context of importation of laboratory samples (i.e., cross-border shipment does not qualify for this exemption).

This exemption is similar to the one set out in subsection 5(5) which is for laboratory samples that are only classified in the BIM hazard class.

The generic chemical name will be used only when a claim for CBI was filed or granted under the HMIRA. For more information regarding CBI, see the discussions of subsections 5.7(1) to (11) and Appendix A-2 (Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form). The terms "*generic chemical name"* and "*commonly known generic name"* must not be confused. The *commonly known generic name* refers to a synonym (e.g., turpentine) of a chemical name whereas the *generic chemical name* (e.g., primary alcohol) is used to preserve a trade secret (CBI); it provides information about the chemical without revealing its exact identity. For more information about generic chemical names please refer to Appendix 1 to this chapter.

Discussion of the *Hazardous Products Regulations*
Subsection 5.1(1)

Mixture of radioactive nuclides and non-radioactive carriers — section 13 or 14 of Act

5.1(1) The sale or importation of a hazardous product that is a mixture of one or more radioactive nuclides and one or more non-radioactive carriers is exempt from the application of section 13 or 14 of the Act if the carrier

(*a*) is present in an amount that is

(i) in the case of a liquid or gaseous carrier, less than or equal to 1.0 ml, or

(ii) in the case of a solid carrier, less than or equal to 1.0 g; and

(*b*) is not

(i) classified in any category or subcategory of the "Carcinogenicity", "Germ Cell Mutagenicity", "Reproductive Toxicity" or "Biohazardous Infectious Materials" hazard class,

(ii) classified in the category "Acute Toxicity (Oral) — Category 1" or "Acute Toxicity (Dermal) — Category 1" of the "Acute Toxicity" hazard class, or

(iii) classified in the category "Acute Toxicity (Inhalation) — Category 1" or "Acute Toxicity (Inhalation) — Category 2" of the "Acute Toxicity" hazard class.

The *Nuclear Safety and Control Act* (NSC Act), S.C. 1997, c. 9, which came into force on May 31, 2000, and replaced the *Atomic Energy Control Act* , defines "nuclear substance" (formally defined as "prescribed substance") to include only the radioactive components of radioactive nuclide mixtures. As a result, non-radioactive carriers which are hazardous products in radioactive nuclide mixtures are subject to the HPR requirements under the HPA even though the exclusion for nuclear substances pursuant to paragraph 12(d) of the HPA remains.

This provision provides a label and SDS exemption for the sale or importation of mixtures containing radioactive nuclides and small quantities of solid (≤ 1g), liquid or gaseous (≤ 1 ml) non-radioactive carriers which are hazardous products, except where the carrier is classified in one or more of the following hazard classes:

- Carcinogenicity;
- Germ Cell Mutagenicity;
- Reproductive Toxicity;
- Acute Toxicity (Oral or Dermal) – Category 1 or Acute Toxicity (Inhalation) - Category 1 or 2; or
- Biohazardous Infectious Materials.

This exemption takes into account that in chemical and clinical laboratory environments:

- radioactive mixtures usually involve very minimal quantities of carrier materials; and
- laboratory workers who handle radioactive nuclides receive specific training to avoid any exposure.

For example, consider a radioactive nuclide mixture with a non-radioactive carrier that is liquid, present at 2 ml, and is classified in Carcinogenicity – Category 2. If this hazardous product is sold or imported, a label and SDS that are compliant with the HPR are required because the amount of the non-radioactive carrier liquid exceeds 1.0 ml and the carrier is classified in one or more of the hazard classes and categories listed in paragraph 5.1(1)(b). However, as another example, consider a radioactive nuclide mixture with a non-radioactive carrier that is a solid present at 0.5 g, and classified only in Skin Corrosion - Category 1. If this mixture is imported or sold, it is exempt from the labelling and SDS requirements of the HPA because the amount of non-radioactive carrier solid is below 1.0 g and the carrier is not classified in any of the hazard classes listed in paragraph 5.1(1)(b).

Discussion of the *Hazardous Products Regulations* Subsection 5.1(2)

Mixture of radioactive nuclides and non-radioactive carriers — paragraph 13(1)(b) or 14(b) of Act

5.1(2) The sale or importation of a hazardous product that is a mixture of one or more radioactive nuclides and one or more non-radioactive carriers is exempt from the application of paragraph 13(1)(*b*) or 14(*b*) of the Act in respect of the requirement to have a label on the inner container of the hazardous product if the hazardous product is packaged in more than one container and the outer container has a label that provides the information elements required by Part 3.

Under the HPR, a hazardous product or its container must have a label that complies with the regulations. This requirement means that, every subsequent container in which the hazardous product is packaged must provide the same label information elements as the innermost container or the hazardous product. However, section 5.2 of the HPR exempts, under specified conditions, the outer container of a hazardous product from the requirement to have an HPR label (see discussion of section 5.2 for more information).

Subsection 5.1(2) of the HPR exempts mixtures containing radioactive nuclides and one or more non-radioactive hazardous product carriers (which are not already exempted by subsection 5.1(1)) from the label requirements of the HPA with respect to the inner container label, as long as there is an outer label with the required information elements. For example, if such a mixture is packaged in a bottle which is in a red container which, in turn, is in a blue container, through this provision, the label may appear only on the outer blue container. The bottle and the red container are not required to have an HPR label.

This provision is precautionary in nature. Since the outer label has the required information, it would not be necessary to increase the risk of exposure by getting close to the radioactive material in order to read the label on an inner container. As these hazardous products containing radioactive nuclides with one or more non-radioactive hazardous product carriers are handled in entirely closed and shielded "hot cells" or by remote control, every effort is made to avoid personal contact. Only the outer container (as defined in subsection 1(1)) requires labelling

according to the HPR since workers will normally handle only that outer container directly. It is important to note that radioactive nuclides are regulated under the *Nuclear Safety and Control Act* and its regulations.

Discussion of the *Hazardous Products Regulations*
Subsection 5.1(3)

Mixture of radioactive nuclides and non-radioactive carriers

5.1(3) The sale or importation of a hazardous product that is a mixture of one or more radioactive nuclides and one or more non-radioactive carriers is exempt from the application of

(*a*) paragraph 3(1)(*b*); and

(*b*) paragraph 3(1)(*c*) and subparagraph 3(1)(*d*)(ii), in respect of the requirement to provide any precautionary statement on the label of the hazardous product or the container in which it is packaged.

This provision exempts mixtures containing radioactive nuclides and one or more non-radioactive hazardous product carriers (which are not already exempted by subsection 5.1(1) of the HPR) from specific label element requirements, namely, the initial supplier identifier and the precautionary statements. The pictogram(s), signal word and hazard statements must be provided on the label as this exemption only allows the omission of the initial supplier identifier and precautionary statements.

It should be understood that the exemptions in 5.1(2) and (3) can apply at the same time, such that the reduced label information elements would only appear on the outermost container of the radioactive nuclide hazardous product.

Discussion of the *Hazardous Products Regulations*
Section 5.2

Outer container

5.2 The sale or importation of a hazardous product is exempt from the application of paragraph 13(1)(*b*) or 14(*b*) of the Act in respect of the requirement to have a label on the outer container of the hazardous product if

(*a*) the label on the inner container is visible and legible through the outer container under normal conditions of storage and handling; or

(*b*) the outer container has a label that meets the requirements set out in the *Transportation of Dangerous Goods Regulations*.

Under the HPR, a hazardous product or its container must have a label that complies with the regulations.

Paragraph 5.2(a) provides an exemption to this requirement whereby an outer container in which a hazardous product is packaged is not required to have an HPR label if the label on the inner container (or on the hazardous product itself) is visible and legible through the outer container during normal conditions of storage and handling. This applies, for example, in situations where the outer container is either entirely transparent (see image #1 below) or it has a transparent window (see image #2 below) that allows the user to see the label on the inner container that is packaged inside the outer container.

Paragraph 5.2(b) provides another exemption whereby the outer container in which a hazardous product is packaged is not required to have an HPR label if the outer container meets the labelling requirements set out in the *Transportation of Dangerous Goods Regulations (TDGR)* for this hazardous product. See image #3 below for an example of an outer container with TDGR labelling.

It is important to note that if a hazardous product is packaged in only one container, this exemption does not apply. This is because the definition of "outer container" (in subsection 1(1) of the HPR) excludes an outward container if that is the only container of a hazardous product. For example, a pail or drum (of less than 450 liters, i.e., not a bulk shipment as per subsection 5.5(1)) of a hazardous product that has TDGR labelling would also require an HPR compliant label. However, for such a label, the exemption in section 5.10 of these regulations (relating to the repetition of symbols on the label) may apply, as may other applicable exemptions.

Note that, under the HCS 2012, the label is required to be on the immediate container of a hazardous product, but need not appear on the outside packaging.

Image #1 Transparent container

Image #2 Container with a window

Image #3 Outer container with TDGR labelling

Discussion of the *Hazardous Products Regulations*
Section 5.3

Label — outer container — at least two hazardous products

5.3 In the case of an outer container in which at least two different hazardous products are packaged, subsection 3(1) does not apply if the label provides the following information elements:

(*a*) the product identifier for each hazardous product contained in the outer container;

(*b*) the initial supplier identifier;

(*c*) subject to subsection 3.6(3), the pictogram set out in column 3 of Schedule 3 designated for each category or subcategory in which each hazardous product contained in the outer container is classified;

(*d*) the precautionary statement applicable to the storage of each of the hazardous products contained in the outer container; and

(*e*) the statement "See individual product labels for signal words, hazard statements and precautionary statements/Voir les étiquettes sur chacun des produits pour les mentions d'avertissement, les mentions de danger et les conseils de prudence".

Under the HPR, a hazardous product or its container(s) must have a label that complies with the regulations. This requirement means that, unless an exemption applies, every subsequent container in which the hazardous product is packaged must also provide the same label information elements as the innermost container or the hazardous product.

Section 5.3 provides an exemption for different hazardous products with HPR compliant labels that share the same outer container. This provision applies to situations such as a "kit" (see the image below for an example of a kit), where two or more **different** hazardous products are packaged in the same outer container, usually for a common purpose. However, this exemption is not limited to kits; any outer container in which at least two different hazardous products are packaged could benefit from this exemption. It is important to note that outer containers used to transport hazardous products do not require an HPR label if they are labelled in accordance with the TDGR (subsection 5.2(b) of the HPR).

An outer container containing two or more different hazardous products is exempt from the requirement to provide all the label information elements if the label of the outer container provides the following:

- the product identifiers,
- initial supplier identifier(s),
- pictogram(s),
- storage precautionary statements, and
- the statement "**See individual product labels for signal words, hazard statements and precautionary statements/Voir les étiquettes sur chacun des produits pour les mentions d'avertissement, les mentions de danger et les conseils de prudence**".

Therefore, on the outer container, the following label information elements may be omitted:

- signal word,
- hazard statement(s),
- response, prevention and disposal precautionary statements,
- supplemental information (where applicable).

As required by the HPR, each individual hazardous product packaged in the shared outer container must meet the full labelling requirements of the HPR, subject to any other applicable exemptions such as subsections 5.4(1) and (2).

This exemption applies only if there is more than one hazardous product in the outer container; if there is only one hazardous product, then all label information elements of this hazardous product must also be provided on the outer container. Where several containers of the same hazardous product are packaged together in one outer container, this exemption does not apply. In this situation, all label information elements of the hazardous product must also be provided on the outer container.

Note that, under the HCS 2012, only the immediate container of the hazardous product inside the outer container is required to be labelled in accordance with the HCS 2012; however, the label may also appear on the outside packaging.

Example of a kit

Discussion of the *Hazardous Products Regulations*
Subsection 5.4(1)

Small-capacity containers — 100 ml or less

5.4(1) The sale or importation of a hazardous product in a container that has a capacity of less than or equal to 100 ml, including any subsequent container of the same capacity in which that first container is packaged, is exempt from the application of paragraph 3(1)(*c*) and subparagraph 3(1)(*d*)(i) or (ii) in respect of the requirement to provide any precautionary statement or hazard statement on the label of the hazardous product or the container.

This is an exemption for hazardous products packaged in small capacity containers (less than or equal to 100 ml) from the requirements to have precautionary statements and hazard statements on the labels. This exemption is solely limited to labels. A full SDS is still required. Where the container of a capacity of 100 ml or less is packaged in another container that also has a capacity of 100 ml or less, this exemption would also apply to the second container.

Note that, under the HCS 2012, there are no small container exemptions. However, OSHA permits practical accommodations where a manufacturer can show that it is infeasible to include all of the label information directly on the small container. In such cases, at a minimum, the immediate container must bear the product identifier, pictograms, signal word, and the manufacturer's name and telephone number. In addition, the outer package must have the full label information (and the inner label must also note that the outer package has the full label information).

Discussion of the *Hazardous Products Regulations*
Subsection 5.4(2)

Small-capacity containers — 3 ml or less

5.4(2) The sale or importation of a hazardous product in a container that has a capacity of less than or equal to 3 ml is exempt from the application of section 3.5 in respect of normal conditions of use if the label interferes with the normal use of the hazardous product.

This exemption applies to hazardous products packaged in extremely small capacity containers (3 ml or less) where the label must be removed in order to allow the product to be used in the intended manner. This exemption is solely limited to labels; the omitted precautionary statements and hazard statements are required to be provided in section 2 of the SDS. In addition to being allowed to use the exemption under subsection 5.4(1) of the HPR, these labels are not required to remain attached to the hazardous product during normal conditions of use, despite the requirement specified in section 3.5 of the HPR. This exemption is intended to accommodate situations where the label may interfere with the normal use of the product. The label could be made removable to enable product use.

An example of a product for which this exemption would be applied would be a 2 ml High Performance Liquid Chromatography (HPLC) vial containing a hazardous product. The label on this product could be anticipated to be required to be removed, and therefore, at least partially destroyed during the normal use of the product.

On the other hand, a 2 ml vial containing a hazardous product, where the product is intended to be decanted from the vial, would not qualify for this extremely small capacity container exemption. The extremely small capacity container exemption only applies when the label interferes with the normal use of the hazardous product. In this example, the label does not interfere with the normal use of the hazardous product as the hazardous product is only intended to be decanted from the small container.

Contrary to the exemption in subsection 5.4(1) of the HPR, this exemption applies only to the immediate container in which the hazardous product is packaged. If the hazardous product container is packaged in a subsequent container, the exemption does not apply to this subsequent container even if the latter container is also of a capacity of 3 ml or less. This is because the label on this subsequent container cannot possibly interfere with the normal use of the hazardous product, as the immediate container would be removed from the subsequent container prior to use.

Note that, under the HCS 2012, there are no small container exemptions. However, OSHA permits practical accommodations where a manufacturer can show that it is infeasible to include all of the label information directly on the small container. In such cases, at a minimum, the immediate container must bear the product identifier, pictograms, signal word, and the manufacturer's name and telephone number. In addition, the outer package must have the full label information (and the inner label must also note that the outer package has the full label information).

Discussion of the *Hazardous Products Regulations*
Subsections 5.5(1) and (2)

Definition of "bulk shipment"

5.5(1) In this section, "bulk shipment" means a shipment of a hazardous product that is contained in any of the following, without intermediate containment or intermediate packaging:

(*a*) a vessel that has a water capacity equal to or greater than 450 l;

(*b*) a freight container, road vehicle, railway vehicle or portable tank;

(*c*) the hold of a ship; or

(*d*) a pipeline.

Bulk shipments and unpackaged hazardous products

(2) The sale or importation of a bulk shipment or a hazardous product without packaging of any sort is exempt from the application of paragraph 13(1)(*b*) or 14(*b*) of the Act.

This provision exempts the sale and import of unpackaged hazardous products and hazardous products that meet the definition of bulk shipment from the labelling requirements of the HPR. For example, oil in a tanker, polymer pellets for extrusion in a freight container, metal ingots, small (e.g., grain or granule sized solids) and large (e.g., metal beams) unpackaged products would be exempted from the labelling requirements of the HPR. However, if any type of intermediate containment or packaging is used, this exemption would not apply. For example, a pallet of unpackaged hazardous products that is shrink-wrapped is not exempt from the labelling requirements since the shrink-wrap is a packaging to which a label may be applied.

This labelling exemption applies to situations where the hazardous product is shipped to the customer, as well as situations where the hazardous product is picked up by the customer at the supplier's location.

Discussion of the *Hazardous Products Regulations* Subsections 5.6(1) and (2)

Definition of "complex mixture"

5.6(1) In this section, "complex mixture" means a mixture that has a commonly known generic name and that is

(*a*) naturally occurring;

(*b*) a fraction of a naturally occurring mixture that results from a separation process; or

(*c*) a modification of a naturally occurring mixture or a modification of a fraction of a naturally occurring mixture that results from a chemical modification process.

Complex mixture

(2) The sale or importation of a hazardous product that is a complex mixture is exempt from the application of paragraph 4(1)(*b*) in respect of the requirements set out in paragraphs 3(2)(*a*) and (*d*) of Schedule 1, and in paragraphs 3(2)(*b*) and (*c*) of that Schedule, if that information is available and applicable, in relations to the ingredients of the complex mixture, if the commonly known generic name of the complex mixture is provided for item 3 of the safety data sheet.

Under the HPR, the ingredient(s) that trigger the classification of a mixture in a **health** hazard class are required to be disclosed in item 3 of the SDS. In the case of a hazardous product that is a complex mixture, the components of the mixture may be unknown or exceptionally numerous and their concentrations may vary widely. Furthermore, in a significant number of cases, toxicological studies as well as physical tests may have been conducted on the complex mixture. In some cases, results may be available only for the complex mixture, not its individual ingredients. Examples of complex mixtures include: turpentine, petroleum distillates and crude oil. However, a synthetic mixture of gases which has approximately the same composition as atmospheric air does not meet the definition of a complex mixture because it is not naturally occurring.

For any ingredient in a complex mixture that is required to be disclosed on the SDS, subsection 5.6(2) provides an exemption whereby the following information elements for the ingredient may be omitted:

- chemical name,
- common name and synonyms (if that information is available and applicable),
- CAS registry number and any unique identifiers (if that information is available and applicable); and
- concentration.

This exemption applies only if the commonly known generic name of the complex mixture is provided in item 3 of the SDS. Therefore, for such a hazardous product, the SDS may simply

disclose, for example, “Turpentine”, under item 3 of the SDS, instead of the information elements specified in paragraphs 3(2)(a) through (d) of Schedule 1 of the HPR. There is no requirement to list all known ingredients in turpentine that meet the criteria for disclosure.

If a hazardous product is comprised solely of a complex mixture that is only classified in one or more **physical** hazard class(es), this exemption, including its requirement to disclose the commonly known generic name of the complex mixture, does not apply. This is because only ingredients that present **health** hazards are required to be disclosed under item 3(2) of Schedule 1 of the HPR, and in this case, there would be no such ingredients. It is important to note that the requirements with respect to disclosure of the classification or, in the case of physical and health hazards not otherwise classified, a description of the hazards of the complex mixture under item 2 of the SDS must still be met.

The terms *“commonly known generic name”* and “*generic chemical name”* must not be confused. The *commonly known generic name* refers to a synonym (e.g., turpentine) of a chemical name whereas the *generic chemical name* (e.g., primary alcohol) is used to preserve a trade secret (CBI); it provides information about the chemical without revealing its exact identity. A generic chemical name may be used only when a claim for CBI was filed and/or granted under the HMIRA. For more information regarding CBI exemptions, see the discussion of subsections 5.7(1) to (11) and Appendix A-2 (Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form). For more information about generic chemical names, please refer to Appendix 1 to this chapter.

It must be noted that there are no exemptions for complex mixtures under HCS 2012.

Discussion of the *Hazardous Products Regulations*
Subsection 5.6(3)

Complex mixture — ingredient

5.6(3) Subject to subsection (4), the sale or importation of a hazardous product that contains an ingredient that is a complex mixture is exempt from the application of paragraph 4(1)(*b*) in respect of the requirements set out in paragraphs 3(2)(*a*) and (*d*) of Schedule 1, and in paragraphs 3(2)(*b*) and (*c*) of that Schedule, if that information is available and applicable, in relation to the ingredients of the complex mixture if the complex mixture, individually, is classified in a category or subcategory of a health hazard class and the commonly known generic name of the complex mixture and its concentration in the hazardous product are provided for item 3 of the safety data sheet.

This provision is similar to subsection 5.6(2) except that, rather than addressing hazardous products that are entirely comprised of a complex mixture, it addresses hazardous products that contain a complex mixture along with other ingredients (e.g., a mixture that contains 60% turpentine plus other ingredients).

This provision addresses any hazardous product that is a mixture which contains a complex mixture that is classified in a category or sub-category of a health hazard class and is present above the corresponding concentration limit. For any ingredient in the complex mixture that is required to be disclosed on the SDS, subsection 5.6(3) provides an exemption whereby the following information elements may be omitted:

- chemical name,
- common name and synonyms (if that information is available and applicable),
- CAS registry number and any unique identifiers (if that information is available and applicable), and
- concentration.

This exemption applies only if the commonly known generic name of the complex mixture is provided in item 3 of the SDS. Therefore, for such a hazardous product, the SDS may simply disclose, for example, "Turpentine – 60%", under item 3 of the SDS, instead of the information elements specified in paragraphs 3(2)(a) through (d) of Schedule 1 of the HPR. There is no requirement to list all known ingredients in turpentine.

Where a hazardous product that is a mixture contains a complex mixture that is only classified in one or more **physical** hazard class(es), there is no requirement to disclose the commonly known generic name of the complex mixture or its concentration. Item 3(2) of Schedule 1 of the HPR specifies that only ingredients that present health hazards are required to be disclosed.

Discussion of the *Hazardous Products Regulations*
Subsection 5.6(4)

Concentration results in classification

5.6(4) If the complex mixture is present at a concentration that results in the product being classified in a category or subcategory of any health hazard class further to subsection 2.5(1), the commonly known generic name and concentration of the complex mixture must be provided on the safety data sheet of the hazardous product.

When a complex mixture is present as an ingredient in a mixture below the concentration limit that would trigger classification in a category or subcategory of a health hazard class, this ingredient (the complex mixture) is not required to be disclosed. However, when the provision set out in subsection 2.5(1) applies, subsection 5.6(4) specifies that the generic name and the concentration of the complex mixture must be disclosed under item 3 of the SDS. Subsection 2.5(1) addresses situations where available data demonstrate that an ingredient presents a hazard at the concentration at which it is present in the mixture, despite being present in the mixture at a lower concentration than the concentration limit for a particular category or subcategory of a health hazard class. In such situations, since the ingredient (complex mixture) triggers the classification of the mixture in a category or subcategory of the health hazard class, the ingredient (complex mixture) must be disclosed.

Note that *"commonly known generic name"* and "*generic chemical name"* must not be confused. The *commonly known generic name* refers to a synonym (e.g., turpentine) of a chemical name whereas the *generic chemical name* (e.g., primary alcohol) is used to preserve a trade secret (CBI); it provides information about the chemical without revealing its exact identity. The generic chemical name may be used only when a claim for CBI was filed and/or granted under the HMIRA. For more information regarding CBI exemptions, see the Discussion of subsections 5.7(1) to (11) and Appendix A-2 (Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form). For more information about generic chemical names please refer to Appendix 1 to this chapter.

Discussion of the *Hazardous Products Regulations* Subsections 5.7(1), (2) and (3)

Definitions

5.7(1) The following definitions apply in this section.

"first supplier "
"first supplier" means a supplier who is exempted from the requirement to disclose the information specified in subsection 11(1) of the *Hazardous Materials Information Review Act*, by virtue of that Act.

"subsequent supplier"
"subsequent supplier" means a supplier who sells or imports a hazardous product that is the subject of an exemption granted to the first supplier from the requirement to disclose the information specified in subsection 11(1) of the *Hazardous Materials Information Review Act*.

Confidential information

(2) If any information is the subject of an exemption under the *Hazardous Materials Information Review Act*, the information must be replaced by the information required under subsection (3) or (4).

Subsection 11(1) of HMIRA

(3) A supplier who, under subsection 11(1) of the *Hazardous Materials Information Review Act*, files a claim for exemption from a requirement to disclose information in respect of a hazardous product on a safety data sheet or on a label must, in respect of the sale or importation of the hazardous product, provide on the safety data sheet and, if applicable, on the label of the hazardous product or container in which the hazardous product is packaged a statement that a claim was filed, the date that the claim was filed and the registry number assigned to the claim under the *Hazardous Materials Information Review Act* until

(*a*) in the case that an order was issued by a screening officer under subsection 16(1) or 17(1) of the *Hazardous Materials Information Review Act*, the end of the period that begins on the final disposition of the proceedings in relation to the claim for exemption and does not exceed the period specified in the order, as the word "proceedings" is defined in subsection 19(3) of the *Hazardous Materials Information Review Act*; or

(*b*) in any other case, the end of the period not exceeding 30 days after the final disposition of the proceedings in relation to the claim for exemption, as the word "proceedings" is defined in subsection 19(3) of the *Hazardous Materials Information Review Act*.

Hazardous Materials Information Review Act

Subsections 11(1), 11(2), 16(1), 17(1) and 19(1), (2) and (3)

Claim for exemption by supplier

11(1) Any supplier who is required, either directly or indirectly, because of the provisions of the *Hazardous Products Act*, to disclose any of the following information may, if the supplier considers it to be confidential business information, claim an exemption from the requirement to disclose that information by filing with the Chief Screening Officer a claim for exemption in accordance with this section:

(a) in the case of a material or substance that is a hazardous product,

(i) the chemical name of the material or substance,

(ii) the CAS registry number, or any other unique identifier, of the material or substance, and

(iii) the chemical name of any impurity, stabilizing solvent or stabilizing additive that is present in the material or substance, that is classified in a category or subcategory of a health hazard class under the *Hazardous Products Act* and that contributes to the classification of the material or substance in the health hazard class under that Act;

(b) in the case of an ingredient that is in a mixture that is a hazardous product,

(i) the chemical name of the ingredient,

(ii) the CAS registry number, or any other unique identifier, of the ingredient, and

(iii) the concentration or concentration range of the ingredient; and

(c) in the case of a material, substance or mixture that is a hazardous product, the name of any toxicological study that identifies the material or substance or any ingredient in the mixture.

Claim for exemption by employer

11(2) Any employer who is required, either directly or indirectly, because of the provisions of the *Canada Labour Code* or the provisions of the *Accord Act*, as the case may be, to disclose any of the following information may, if the employer considers it to be confidential business information, claim an exemption from the requirement to disclose it by filing with the Chief Screening Officer a claim for exemption in accordance with this section:

(a) in the case of a material or substance that is a hazardous product,

(i) the chemical name of the material or substance,

(ii) the CAS registry number, or any other unique identifier, of the material or substance, and

(iii) the chemical name of any impurity, stabilizing solvent or stabilizing additive that is present in the material or substance, that is classified in a category or subcategory of a health hazard class under the *Hazardous Products Act* and that contributes to the classification of the material or substance in the health hazard class under that Act;

(b) in the case of an ingredient that is in a mixture that is a hazardous product,

(i) the chemical name of the ingredient,

(ii) the CAS registry number, or any other unique identifier, of the ingredient, and

(iii) the concentration or concentration range of the ingredient;

(c) in the case of a material, substance or mixture that is a hazardous product, the name of any toxicological study that identifies the material or substance or any ingredient in the mixture;

(d) the product identifier of a hazardous product, being its chemical name, common name, generic name, trade-name or brand name;

(e) information about a hazardous product, other than the product identifier, that constitutes a means of identification; and

(f) information that could be used to identify a supplier of a hazardous product.

Order of screening officer

16(1) If, under paragraph 13(1)(a), a screening officer determines that a claim or portion of a claim for exemption is not valid, the screening officer shall order the claimant to comply, in the manner and within the period specified in the order, with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the *Accord Act* in respect of which the claim or portion of the claim for exemption was determined not to be valid.

Order re material safety data sheet

17(1) If the screening officer does not receive the signed undertaking, or is not satisfied that the claimant has taken the measures set out in the undertaking in the manner and within the period specified in it, the screening officer shall order the claimant to comply with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the *Accord Act*, as the case may be, except to the extent that they would require the claimant to disclose the information in respect of which the claim is made, in the manner and within the period specified in the order.

Exemption

19(1) Every person who files a claim for exemption in accordance with section 11 is, until the final disposition of the proceedings in relation to the claim for exemption, exempt from the requirement in respect of which the exemption is claimed.

Idem

19(2) Where the final disposition of the proceedings in relation to a claim for exemption is that the claim or a portion of the claim is valid, the claimant is, for a period of three years beginning on the final disposition of the proceedings, exempt from the requirement in respect of which the claim or portion of the claim is determined to be valid.

Definition of proceedings

19(3) In this section, "**proceedings**", in relation to a claim for exemption, means any proceedings under this Act in relation to that claim for exemption and includes proceedings commenced in the Federal Court and proceedings on any appeal from any decision of that Court.

A supplier must file a trade secret claim with Health Canada under subsection 11(1) of the *Hazardous Materials Information Review Act* (HMIRA) to request an exemption from requirements under the HPA and HPR to disclose specific information which the supplier considers to be CBI (e.g., chemical name, concentration or concentration range of a hazardous ingredient).

Under the HMIRA, when a claim for exemption is filed, the supplier is given a temporary exemption during the period in which the claim is being processed by Health Canada (including the time that may be required for an appeal process), to enable the sale of the product during that period.

Subsections 5.7(2) and (3) of the HPR specify the information that must be disclosed on an SDS and, if applicable, on the label during the temporary exemption period, to replace the information elements for which a claim for exemption is filed. The replacement information must consist of:

- a statement that a claim was filed,
- the date that the claim was filed, and
- the registry number assigned to the claim under the HMIRA.

The replacement information must appear in lieu of each information element for which a claim was filed; however, this could be accomplished by inserting an asterisk or other symbol in lieu of the required information, which would refer to this replacement information located elsewhere on the SDS and if applicable, on the label. The replacement information must be presented in a manner that allows it to be easily related to the information for which a claim was filed.

In addition to this reference to the replacement information using, for example, an asterisk or footnote, the information elements on the SDS and if applicable, on the label for which a claim is filed may be replaced with words such as "trade secret".

It is important to note that if a claim was filed for any of the following information elements:

- chemical name,
- common name and synonyms,
- CAS registry number and any other unique identifier, or
- chemical name of impurities, stabilizing solvents or stabilizing additives,

then the generic chemical name (GCN) must also appear to replace any of those information elements, in accordance with subsection 5.7(5) of the HPR.

If a GCN is required, the claimant must propose a GCN upon filing a claim. This GCN will be reviewed by the screening officer as part of the claim for exemption process. The required GCN must appear on the SDS and on the label if applicable with the replacement information. This replacement information and the GCN indicate that a claim for exemption from the disclosure of CBI has been filed with Health Canada in accordance with the HMIRA.

In situations where a decision is issued that a claim is not valid or is only partially valid, the screening officer issues an order for correction relating to the invalid part of the claim. The order could require information that was found not to be CBI to be disclosed, or it could require the removal of the HMIRA number from its association with a trade secret that is not eligible to be CBI under the HMIRA (e.g. because the ingredient is not required to be disclosed).

In situations where a decision is issued that a claim is valid, an order may still be issued if corrections to the SDS or label are required and a satisfactory undertaking is not received by the screening officer (see section 16.1 of the HMIRA for more information about undertakings). The order will require the correction of items on the label or SDS.

In any case, the order includes the time period (usually 30 days) within which compliance with the order must be achieved. If the decision or order is not appealed, the replacement information must remain on the SDS and, if applicable, on the label, only up to the end of the period specified in the order. At the end of the period specified in the order, and provided no appeal was filed, the supplier must comply with the order or cease sale of the product in the Canadian market. If an appeal is filed, the replacement information may remain until the final legal determination of the issue being appealed.

If the claim is found to be valid and no associated order is issued, the replacement information must remain on the SDS and if applicable, on the label, up to a maximum of 30 days after either:

(i) the end of the appeal period with no appeal being filed, or

(ii) if an appeal is filed, until the final legal determination of the issue being appealed.

Once this period of time is over, provided that any orders have been complied with, the replacement information in this provision must be changed to the replacement information indicated in subsection 5.7(4) of the HPR if the claim was granted. This replacement information must be used until the end of the exemption period, which is 3 years after the final disposition of the proceedings, as per subsection 19(2) of HMIRA.

If an applicable order has not been complied with, no further sale or import of the product can take place until compliance has been achieved.

Discussion of the *Hazardous Products Regulations* Subsection 5.7(4)

Information to be disclosed

5.7(4) A supplier who receives notice of a decision made under the *Hazardous Materials Information Review Act* that their claim or a portion of their claim for exemption from a requirement to disclose information in respect of a hazardous product on a safety data sheet or a label is valid must, during the period beginning no later than the end of the applicable period specified in subsection (3) and on compliance with any order issued under subsection 16(1) or 17(1) of the *Hazardous Materials Information Review Act*, if applicable, and ending on the last day of the exemption period, in respect of the sale or importation of the hazardous product, provide on the safety data sheet and, if applicable, on the label of the hazardous product or container in which the hazardous product is packaged the following information:

(*a*) a statement that an exemption has been granted;

(*b*) the date of the decision granting the exemption; and

(*c*) the registry number assigned to the claim under the *Hazardous Materials Information Review Act*.

Subsection 5.7(2) and (4) of the HPR specify that where a decision is made by Health Canada that a claim for exemption is partially or entirely valid, the replacement information in subsection 5.7(3) must be changed to the information specified in subsection 5.7(4). This requirement means that the statement that a CBI claim **was filed** must be changed to a statement that an exemption **has been granted,** and the date when the **claim was filed** must be changed to the **date when the exemption was granted.** The registry number obtained when the claim was filed remains the same. The replacement information applies only for those information elements for which the CBI claim filed under the HMIRA was granted.

The replacement information specified in subsection 5.7(3) must remain on the SDS and if applicable, on the label, up to, either:

(i) in the case that no order was issued, a maximum of 30 days after either the end of the appeal period with no appeal being filed or, if an appeal is filed, until the final legal determination of the issue being appealed, or

(ii) in the case that an order was issued, the end of the period specified in the order.

Refer to subsection 5.7(3) for guidance on the disclosure of the replacement information.

Once this period of time is over, provided that any orders have been complied with, the replacement information in this provision must be changed to the replacement information indicated in subsection 5.7(4) of the HPR if the claim was granted. This replacement information must be used until the end of the exemption period, which is 3 years after the final disposition of the proceedings, as per subsection 19(2) of HMIRA.

If an applicable order has not been complied with, no further sale or import of the product can take place until compliance has been achieved.

Discussion of the *Hazardous Products Regulations* Subsection 5.7(5)

Non-application — paragraphs 3(1)(a) to (d) or (2)(a) to (c) of Schedule 1

5.7(5) The sale or importation of a hazardous product is exempt from the application of paragraph 4(1)(*b*) in respect of the requirements set out in paragraph 3(1)(*a*) or (2)(*a*) of Schedule 1 and, if the information is available and applicable, in paragraphs 3(1)(*b*) to (*d*) or 2(*b*) and (*c*) of that Schedule, if it is the subject of a claim for exemption under paragraph 11(1)(*a*) of the *Hazardous Materials Information Review Act* and if the generic chemical name of the material, substance or ingredient is provided for item 3 of the safety data sheet.

If the information being claimed for exemption from disclosure is the chemical name, common name, synonym, CAS registry number or any unique identifier of an ingredient, material or substance or the chemical name of an impurity or stabilizing solvent or stabilizing additive in the product required to be disclosed on the SDS, these means of identification must be replaced by a *generic chemical name* (GCN) of the ingredient, material or substance. For more information about the GCN please refer to Appendix 1 to this chapter.

The GCN proposed by the claimant when the claim was filed must remain the same unless the screening officer requested changes. The GCN must appear on the SDS with the replacement information specified in subsection 5.7(3) or (4) (as applicable).

The *"generic chemical name"* and "*commonly known generic name"* must not be confused. The *commonly known generic name* refers to a synonym (e.g., turpentine) of a chemical name whereas the GCN (e.g., primary alcohol), as explained above, is used to preserve a trade secret (CBI); it provides information about the chemical without revealing its exact identity.

Discussion of the *Hazardous Products Regulations* Subsection 5.7(6)

Non-application — paragraph 3(2)(d) of Schedule 1

5.7(6) Paragraph 3(2)(*d*) of Schedule 1 does not apply in respect of a hazardous product that is the subject of a claim for exemption under subparagraph 11(1)(*b*)(iii) of the *Hazardous Materials Information Review Act*.

If the concentration or actual concentration range of an ingredient in a hazardous product that is a mixture is the subject of a claim for CBI exemption under the HMIRA, then it need not be disclosed on the SDS. Although subsection 5.7(2) of the HPR states that information element(s) that are the subject of a pending or granted claim for exemption must be changed to the

replacement information pursuant to either subsection 5.7(3) or (4) of the HPR (as applicable), to avoid any confusion, subsection 5.7(6) clearly states that if a CBI claim is filed for concentration then the concentration or actual concentration range need not be disclosed. However, suppliers are encouraged to disclose a replacement concentration range instead of the true concentration or true concentration range. See Appendix 3 for more information on concentration disclosure requirements and CBI.

Discussion of the *Hazardous Products Regulations* Subsection 5.7(7)

Sale or importation — paragraphs 3(1)(a) to (d) or (2)(a) to (c) of Schedule 1

5.7(7) The sale or importation of a hazardous product by a subsequent supplier is exempt from the application of paragraph 4(1)(*b*) in respect of the requirements set out in paragraph 3(1)(*a*) or (2)(*a*) of Schedule 1, and, if the information is available and applicable, in paragraphs 3(1)(*b*) to (*d*) or 2(*b*) and (*c*) of that Schedule, if

(*a*) the first supplier is exempt from those requirements;

(*b*) the information is unknown to the subsequent supplier, or the information is known to the subsequent supplier but the subsequent supplier has obtained the information in confidence, express or implied, and is obligated, expressly or implicitly, by contract or a relationship based on trust and confidence, or otherwise by law or equity, to maintain the confidentiality of the information; and

(c) the safety data sheet for the hazardous product that the subsequent supplier provides on the sale, or obtains or prepares on the importation, provides in lieu of the information referred to in paragraph 3(1)(a) or (2)(a) of Schedule 1, and, if the information is available and applicable, in paragraphs 3(1)(b) to (d) or 2(b) and (c) of that Schedule,

(i) the information referred to in subsection (3) or (4) in respect of,

(A) if the subsequent supplier is exempted from the requirement to provide information that could be used to identify the first supplier, that exemption, or

(B) in any other case, the exemption of the first supplier, with the words "other supplier/autre fournisseur" in parentheses after that information, and

(ii) the generic chemical name of the material, substance or ingredient as provided by the first supplier.

This provision is an exemption for any **subsequent supplier** who wants to **sell** or **import** hazardous products for which a CBI claim was filed by or granted to a first supplier. This exemption provides the subsequent supplier an exemption from disclosure of the ingredient identity information in respect of which a CBI claim was filed by or granted to the first supplier under the HMIRA. It is important to note that replacement information must be provided in lieu of the withheld information elements for which a CBI claim was filed or granted.

It is also important to note that the term "first supplier" must not be confused with "initial supplier identifier" as the term "first supplier" conveys a specific meaning with respect to this CBI provision.

"First supplier" means a supplier who is exempted from the requirement to disclose the information specified in subsection 11(1) of the HMIRA, by virtue of that Act.

"Initial supplier identifier" means the name, address and telephone number of

(a) the manufacturer; or

(b) the importer of the hazardous product who operates in Canada.

"Subsequent supplier" means a supplier who sells or imports a hazardous product that is the subject of an exemption granted to the first supplier from the requirement to disclose the information specified in subsection 11(1) of the HMIRA.

Importation

This exemption applies to the importation of a hazardous product by a Canadian importer (subsequent supplier) from a foreign (non-Canadian) supplier (first supplier) who filed or was granted a CBI claim for exemption under the HMIRA. It must be noted that once the hazardous product is imported, if the importer wants to sell the same hazardous product (or a mixture containing this hazardous product) he may use the "sale" exemption explained below, since he remains a subsequent supplier at that point.

Sale

This exemption may be used by any subsequent supplier (including the importer mentioned above) who wants to **sell** in Canada the same hazardous product (or a mixture containing this hazardous product) for which a CBI claim under the HMIRA was filed by or granted to the "first supplier" (Canadian or foreign). It is important to note that any downstream supplier in the distribution chain who sells the same hazardous product (or a mixture containing this hazardous product) in Canada is also a subsequent supplier and, as such, may use this exemption.

Conditions

As explained above, subsection 5.7(7) allows the subsequent supplier to withhold the same information elements from the SDS, and label if applicable, that were filed or granted as CBI in a claim by the first supplier. This subsection pertains specifically to CBI related to chemical identification information. In order to qualify for this exemption, these information elements must not be known to the subsequent supplier, or these must have been obtained by the subsequent supplier in confidence. In the second situation, the subsequent supplier is obligated to maintain the confidentiality of the information elements. The subsequent supplier may sell the hazardous product as is or may sell a new mixture which contains the first supplier's hazardous product as an ingredient; in both situations subsection 5.7(7) applies.

Where the subsequent supplier **has filed or was granted his own claim** for CBI exemption under the HMIRA, the requirements for replacement information depend on what information the subsequent supplier has claimed for exemption. In this case, discussion about the particular case with Health Canada is recommended.

Where the subsequent supplier **has not filed or was not granted a claim** for CBI exemption under the HMIRA, the replacement information of the first supplier, namely,

- the first supplier's claim registry number,
- the date when the first supplier's claim was filed or granted,
- a statement that a claim for exemption has been filed or granted, and
- the generic chemical name provided by the first supplier,

must appear on the SDS provided by the subsequent supplier, along with the words "other supplier/autre fournisseur" in parentheses next to the first supplier's replacement information.

Discussion of the *Hazardous Products Regulations*
Subsection 5.7(8)

Sale or importation — paragraph 3(2)(d) of Schedule 1

5.7(8) The sale or importation of a hazardous product by a subsequent supplier is exempt from the application of paragraph 4(1)(*b*) in respect of the requirement set out in paragraph 3(2)(*d*) of Schedule 1 if,

(a) the first supplier is exempt from that requirement;

(b) the information is unknown to the subsequent supplier, or the information is known to the subsequent supplier but the subsequent supplier has obtained the information in confidence, express or implied, and is obligated, expressly or implicitly, by contract or a relationship based on trust and confidence, or otherwise by law or equity, to maintain the confidentiality of the information; and

(*c*) the safety data sheet for the hazardous product that the subsequent supplier provides on the sale, or obtains or prepares on the importation, provides in lieu of the information referred to in paragraph 3(2)(*d*) of Schedule 1

(i) the information referred to in subsection (3) or (4) in respect of,

(A) if the subsequent supplier is exempted from the requirement to provide information that could be used to identify the first supplier, that exemption, or

(B) in any other case, the exemption of the first supplier, with the words "other supplier/autre fournisseur" in parentheses after that information, and

(ii) subject to section 4.5, the concentration of the first supplier's hazardous product that is in the subsequent supplier's hazardous product.

This provision is similar to subsection 5.7(7) but relates solely to the concentration or actual concentration range of an ingredient in a hazardous product that is a mixture. Subsection 5.7(8) is an exemption for any subsequent supplier who wants to sell or import hazardous products for

which a CBI claim, for the concentration or actual concentration range of an ingredient, was filed by or granted to a first supplier. This exemption provides the subsequent suppliers an exemption from the disclosure of the concentration or actual concentration range information in respect of which a CBI claim was filed or granted under the HMIRA. Replacement information must be provided in lieu of the withheld information element for which a CBI claim was filed or granted.

It is important to note that the term “first supplier” must not be confused with “initial supplier identifier” as the term “first supplier” conveys a specific meaning with respect to this CBI provision. Refer to subsection 5.7(7) for more information.

Importation

This exemption applies to the importation of a hazardous product by a Canadian importer (subsequent supplier) from a foreign (non-Canadian) supplier (first supplier) who filed or was granted a CBI claim for exemption regarding the concentration or actual concentration range of an ingredient under the HMIRA. It must be noted that once the hazardous product is imported, if the importer wants to sell the same product (or a mixture containing this product), he may use the “sale” exemption explained below, since he remains a subsequent supplier at that point.

Sale

This exemption may be used by any subsequent supplier (including the importer mentioned above) who wants to sell in Canada the same hazardous product (or a mixture containing this hazardous product) for which a CBI claim for exemption regarding the concentration or actual concentration range of an ingredient under the HMIRA was filed by or granted to the “first supplier” (Canadian or foreign). It is important to note that any downstream supplier in the distribution chain who sells the same hazardous product (or a mixture containing this hazardous product) in Canada is also a subsequent supplier and, as such, may use this exemption.

Conditions

As explained above, subsection 5.7(8) allows the subsequent supplier to withhold the same information elements from the SDS, and label if applicable, that were filed or granted as CBI in a claim by the first supplier. Subsection 5.7(8) relates specifically to ingredient concentration information that is CBI. In order to qualify for this exemption, this information element must not be known to the subsequent supplier, or this must have obtained by the subsequent supplier in confidence. In the latter situation, the subsequent supplier is obligated to maintain the confidentiality of the information element. The subsequent supplier may sell the hazardous product mixture as is or may sell a new mixture which contains the first supplier`s hazardous product mixture (as an ingredient); in both situations the same exemption applies.

Where the subsequent supplier **has filed or was granted his own claim** for CBI exemption under the HMIRA, the requirements for replacement information depend on what information the subsequent supplier has claimed for exemption. In this case, discussion about the particular case with Health Canada is recommended.

Where the subsequent supplier **has not filed or was not granted a claim** for CBI exemption under the HMIRA, the replacement information of the first supplier namely,

- the first supplier's claim registry number,
- the date when the first supplier's claim was filed or granted,
- a statement that a claim for exemption has been filed or granted, and
- the concentration or concentration range of the first supplier's hazardous product mixture that is in the subsequent supplier's hazardous product mixture,

must appear on the SDS provided by the subsequent supplier, along with the words "other supplier/autre fournisseur" in parentheses next to the first supplier's replacement information.

For example, suppose the first supplier's mixture contains the following three ingredients:

- ingredient A, a hazardous ingredient present at 5%, and this information is CBI;
- ingredient B, a hazardous ingredient present at 20% (not CBI); and
- ingredient C, a non-hazardous ingredient present at 75%.

The first supplier sells this mixture to a subsequent supplier, who dilutes the mixture with water in a ratio of 1:1. Therefore, the subsequent supplier's SDS need not disclose the concentration of ingredient A in the diluted mixture (since this information is CBI). However, the subsequent supplier's SDS for the diluted mixture must disclose the first supplier's claim registry number, the date when the first supplier's claim was filed or granted, and the words "other supplier" in parentheses, and must state that the diluted mixture contains, at a concentration of 50%, another mixture (i.e., the mixture of the first supplier).

In the above example, suppose the subsequent supplier sells the first supplier's mixture as is (without modification). In this case, the subsequent supplier's SDS must disclose the first supplier's claim registry number, the date when the first supplier's claim was filed or granted, and the words "other supplier" in parentheses, and must state that the hazardous product is comprised, at 100%, of another mixture (i.e., the mixture of the first supplier).

Discussion of the *Hazardous Products Regulations*
Subsection 5.7(9)

Label — confidential product identifier — paragraphs 3(1)(a) and 4(1)(b)

5.7(9) Paragraph 3(1)(*a*) and the requirement in paragraph 4(1)(*b*) in relation to paragraph 1(*a*) of Schedule 1 if the information is available and applicable, do not apply in respect of the sale of a hazardous product to an employer who is exempt under the *Hazardous Materials Information Review Act* or under the laws of a province from the requirement to disclose the product identifier of a hazardous product if the label provides a code name or code number specified by the supplier and

(*a*) if available, the information referred to in subsection (3) or (4) in respect of the employer's claim for exemption under the *Hazardous Materials Information Review Act*; or

(*b*) if the information referred to in paragraph (*a*) is not available, the information required to be provided under the laws of the province.

Subsection 5.7(9) applies to situations where federally or provincially regulated **employers** have filed or were granted claims for CBI under the HMIRA, or have availed themselves of their respective provincial laws pertaining to trade secrets to be exempt from the disclosure of the supplier's product identifier. This provision exempts the supplier, who sells hazardous products to these employers, from providing the product identifier (defined in subsection 1(1) of the HPR) on the label and SDS of the hazardous product for which CBI or a trade secret has been claimed by the employer.

However, the following information must be provided on the label:

a) a code name or a code number specified by the supplier, that replaces the product identifier; and

b) the replacement information referred to in subsection 5.7(3) or (4) of the HPR regarding the claim for exemption under the HMIRA (i.e., the registry number, date of filing or exemption and a statement that a claim for exemption has been filed or granted).

However, if such replacement information is not available (because the employer availed himself of trade secret provisions in OHS provincial or territorial legislation), then the replacement information required under the OHS legislation of the province or territory where the employer is located must be disclosed.

Discussion of the *Hazardous Products Regulations*
Subsection 5.7(10)

Label — confidential supplier identifier — paragraphs 3(1)(b) and 4(1)(b)

5.7(10) Paragraph 3(1)(*b*) and the requirement in paragraph 4(1)(*b*) in relation to paragraph 1(*d*) of Schedule 1, if the information is available and applicable, do not apply in respect of the sale of a hazardous product to an employer who is exempt under the *Hazardous Materials Information Review Act* or under the laws of a province from the requirement to disclose any information that could be used to identify the supplier of the hazardous product if that information is replaced by

(*a*) if available, the information referred to in subsection (3) or (4) in respect of the employer's claim for exemption under the *Hazardous Materials Information Review Act*; or

(*b*) if the information referred to in paragraph (*a*) is not available, the information required to be provided under the laws of the province.

Subsection 5.7(10) applies to situations where federally or provincially regulated **employers** have filed or were granted claims for CBI under the HMIRA, or have availed themselves of their respective provincial laws pertaining to trade secrets to be exempt from the disclosure of any information that could be used to identify the supplier of the hazardous product. This provision exempts the supplier, who sells hazardous products to these employers, from providing information identifying the supplier including the **initial supplier identifier** (defined in subsection 1(1) of the HPR) on the label and SDS of the hazardous product for which CBI or a trade secret has been claimed by the employer.

On the label and SDS, the initial supplier identifier must be changed to the replacement information regarding the claim for exemption under the HMIRA referred to in subsections 5.7(3) or (4) of the HPR (i.e., the registry number, date of filing or exemption and a statement that a claim for exemption has been filed or granted). If such replacement information is not available (because the employer availed himself of trade secret provisions in OHS provincial or territorial legislation), then the information required under the OHS legislation of the province or territory where the employer is located must be disclosed instead.

Discussion of the *Hazardous Products Regulations*
Subsection 5.7(11)

Safety data sheet — sale to employer

5.7(11) The sale of a hazardous product to an employer is exempt from the requirement to disclose information on the safety data sheet that could be the subject of a claim for exemption under subsection 11(2) of the *Hazardous Materials Information Review Act* if

(*a*) the employer is exempt, under that Act or the laws of a province, from the requirement to disclose that information in respect of the hazardous product; and

(*b*) the safety data sheet of the hazardous product provided in respect of that sale provides in lieu of that information

(i) if available, the information referred to in subsection (3) or (4) in respect of the employer's claim for exemption under that Act, or

(ii) if the information referred to in subparagraph (i) is not available, an emergency telephone number of the employer that will enable a health professional to obtain any information referred to in subsection 4(1) that is in the possession of the employer for the purpose of making a medical diagnosis of, or rendering medical treatment to, a person in an emergency.

Subsection 5.7(11) applies to situations where federally or provincially regulated **employers** have filed or were granted claims for CBI under the HMIRA, or have availed themselves of their respective provincial laws pertaining to trade secret to be exempt from the disclosure of any information that could be the subject of a claim under subsection 11(2) of the HMIRA. This provision exempts the supplier, who sells hazardous products to these employers, from providing on the SDS the information for which CBI or trade secret has been claimed by the employer.

Subsection 5.7(11) refers to employers claims under subsection 11(2) of HMIRA, this provision reads as follows:

Hazardous Materials Information Review Act

Claim for exemption by employer

11(2) Any employer who is required, either directly or indirectly, because of the provisions of the *Canada Labour Code* or the provisions of the *Accord Act*, as the case may be, to disclose any of the following information may, if the employer considers it to be confidential business information, claim an exemption from the requirement to disclose it by filing with the Chief Screening Officer a claim for exemption in accordance with this section:

(a) in the case of a material or substance that is a hazardous product,

(i) the chemical name of the material or substance,

(ii) the CAS registry number, or any other unique identifier, of the material or substance, and

(iii) the chemical name of any impurity, stabilizing solvent or stabilizing additive that is present in the material or substance, that is classified in a category or subcategory of a health hazard class under the *Hazardous Products Act* and that contributes to the classification of the material or substance in the health hazard class under that Act;

(b) in the case of an ingredient that is in a mixture that is a hazardous product,

(i) the chemical name of the ingredient,

(ii) the CAS registry number, or any other unique identifier, of the ingredient, and

(iii) the concentration or concentration range of the ingredient;

(c) in the case of a material, substance or mixture that is a hazardous product, the name of any toxicological study that identifies the material or substance or any ingredient in the mixture;

(d) the product identifier of a hazardous product, being its chemical name, common name, generic name, trade-name or brand name;

(e) information about a hazardous product, other than the product identifier, that constitutes a means of identification; and

(f) information that could be used to identify a supplier of a hazardous product.

Subsection 5.7(11) specifies that any information element(s) that may be protected under HMIRA is not required to appear on the supplier's SDS of a hazardous product sold to an employer provided that:

a) The employer is exempt under the HMIRA or the provincial or territorial OHS legislation from the requirement to disclose the information element(s); and

b) The SDS provides the replacement information, as referred to in subsections 5.7(3) or (4) of the HPR, for the employer's CBI claim for exemption.

However, if such replacement information is not available, the following must be disclosed in its place: An emergency telephone number of the employer to enable a health professional to obtain information that must be provided in the SDS, and which is in possession of the employer, for the purpose of making a medical diagnosis or rendering medical treatment, in an emergency.

Discussion of the *Hazardous Products Regulations*
Subsection 5.8(1)

Subsequent sale by supplier — safety data sheet

5.8(1) The sale of a hazardous product by a supplier to whom the hazardous product was sold is exempt from the application of paragraph 4(1)(*b*) in respect of the requirement set out in paragraph 1(*d*) of Schedule 1 to provide the initial supplier identifier on the safety data sheet if their name, address and telephone number are provided on the safety data sheet.

Under the HPR, the initial supplier identifier (name, address and telephone number of either the Canadian manufacturer or Canadian importer) must be provided on the SDS. Further information regarding "initial supplier identifier" is available in Part 1 of the Technical Guidance. This provision exempts a distributor (a Canadian supplier to whom a hazardous product was sold) from providing the initial supplier identifier on the SDS if the distributor provides his own name, address and telephone number instead.

Since this exemption only applies in a situation where a hazardous product is being sold by a Canadian distributor, the use of this exemption still requires the disclosure of the contact information of a Canadian party on the SDS.

It is important to note that according to section 4.2 of the HPR (Identical identifiers), the initial supplier identifier must be identical on the label and the SDS; thus, if the distributor takes advantage of the exemption in subsection 5.8(1) to replace the information on the SDS, he must also, according to subsection 5.8(2), replace the initial supplier identifier on the label.

Discussion of the *Hazardous Products Regulations*
Subsection 5.8(2)

Subsequent sale by supplier — label

5.8(2) The sale of a hazardous product by a supplier to whom the hazardous product was sold is exempt from the application of paragraph 3(1)(*b*) in respect of the requirement to provide the initial supplier identifier on the label if their name, address and telephone number are provided on the label.

Under the HPR, the initial supplier identifier (name, address and telephone number of either the Canadian manufacturer or Canadian importer) must be provided on the label. This provision exempts a distributor (a Canadian supplier to whom a hazardous product was sold) from providing the initial supplier identifier on the label if the distributor provides his own name, address and telephone number instead.

Since this exemption only applies in a situation where a hazardous product is being sold by a Canadian distributor, the use of this exemption still requires the disclosure of the contact information of a Canadian party on the label.

It is important to note that according to section 4.2 of the HPR (Identical identifiers), the initial supplier identifier must be identical on the label and the SDS; thus, if the distributor takes advantage of the exemption in subsection 5.8(2) to replace the information on the label, he must also, according to subsection 5.8(1), replace the initial supplier identifier on the SDS.

Discussion of the *Hazardous Products Regulations*
Subsection 5.8(3)

Following supplier

5.8(3) If the initial supplier identifier referred to in subsection (1) or (2) has been replaced by the name, address and telephone number of a supplier to whom the hazardous product has been sold, any following supplier of the hazardous product may replace that information with their own name, address and telephone number.

Under the HPR, by default, the initial supplier identifier (name, address and telephone number of either the Canadian manufacturer or Canadian importer) must be provided on the label and SDS. This provision exempts a downstream distributor (a downstream Canadian supplier to whom a hazardous product was sold by an upstream Canadian distributor) from providing the initial supplier identifier on the label and SDS, if the distributor provides his own name, address and telephone number instead.

Since this exemption only applies in a situation where a hazardous product is being sold by a downstream Canadian distributor, the use of this exemption still requires the disclosure of the contact information of a Canadian party on the label and SDS.

It is important to note that according to section 4.2 of the HPR (Identical identifiers), the initial supplier identifier must be identical on the label and the SDS; thus, if the distributor takes advantage of the exemption in subsection 5.8(3) to replace the information on the label or SDS, he must replace the initial supplier identifier on both the label and the SDS.

Discussion of the *Hazardous Products Regulations*
Subsection 5.9(1)

Importation for use in own work place — safety data sheet

5.9(1) If an importer imports a hazardous product from a foreign supplier for use in their own work place in Canada and obtains a safety data sheet from the foreign supplier, the importer is exempt from the requirement to provide, on the safety data sheet, the specific information element set out in paragraph 1(*d*) of Schedule 1 if the name, address and telephone number of the foreign supplier is retained on the safety data sheet.

Under the HPR, the initial supplier identifier (name, address and telephone number of either the Canadian manufacturer or Canadian importer) is required under item 1(d) of the SDS. However, if

an importer imports a hazardous product **for use in his own work place**, the importer may retain the foreign supplier's name, address and telephone number under item 1(*d*) of the SDS. The Canadian importer is responsible for ensuring that the label and SDS of the hazardous product are in compliance with the requirements of the HPA and the HPR.

The Canadian importer who prepares the SDS for the hazardous product that he imported cannot use this exemption since it is limited to situations where the SDS is obtained from the foreign supplier. It is also important to note that the importer cannot use this exemption if he decides to resell the hazardous product that he imported.

In the case where a foreign supplier sells and ships a hazardous product directly to a Canadian customer, that Canadian customer is the Canadian importer. In any case, it would be acceptable for the SDS to include the contact information of both the Canadian importer and the foreign supplier.

To further clarify, when a hazardous product is imported into Canada, the name, address and telephone number of a foreign manufacturer who does not have a place of business in Canada cannot be provided under item 1(*d*) of the SDS unless:

- the hazardous product is only used in the importer's own workplace, or
- the name, address and telephone number of the Canadian importer is also provided.

Discussion of the *Hazardous Products Regulations*
Subsection 5.9(2)

Importation for use in own work place — label

5.9(2) If an importer imports a hazardous product from a foreign supplier for use in their own work place in Canada, the importer is exempt from the application of paragraph 3(1)(*b*) in respect of the requirement to provide the initial supplier identifier on the label if the name, address and telephone number of the foreign supplier is retained on the label.

Under the HPR, the initial supplier identifier (name, address and telephone number of either the Canadian manufacturer or Canadian importer) must be provided on the label. However, if an importer imports a hazardous product **for use in his own work place**, the importer may retain the foreign supplier's name, address and telephone number on the label. The Canadian importer is responsible for ensuring that the label and SDS of the hazardous product are in compliance with the requirements of the HPA and the HPR. It is also important to note that the importer cannot use this exemption if he decides to resell the hazardous product that he imported.

In the case where a foreign supplier sells and ships a hazardous product directly to a Canadian customer, that Canadian customer is the Canadian importer. In any case, it would be acceptable for the label to include the contact information of both the Canadian importer and the foreign supplier.

To further clarify, when a hazardous product is imported into Canada, the name, address and telephone number of a foreign manufacturer who does not have a place of business in Canada cannot be provided on the label unless:

- the hazardous product is only used in the importer's own workplace,
- the name, address and telephone number of the Canadian importer is also provided, or
- the importer takes advantage of the exemption in section 5.15 (refer to section 5.15 for more information).

Discussion of the *Hazardous Products Regulations* Section 5.10

Repetition of symbols on label

5.10 The sale or importation of a hazardous product is exempt from the application of paragraphs 3(1)(*c*) and (*d*), in respect of the requirement to provide a pictogram on the label of the hazardous product or its container, if the symbol of the pictogram appears on another label in accordance with the *Transportation of Dangerous Goods Regulations* on that same hazardous product or that same container, and if the other label also meets the requirements of section 3.5.

This provision must be read in conjunction with paragraph 5.2(b) which specifies that a HPR label in not required on the outer container of a hazardous product that has a label which meets the requirements set out in the *Transportation of Dangerous Goods Regulations*. Therefore, section 5.10 only addresses situations where a label is provided on the hazardous product or on a single container (without inner or outer container) in which the hazardous product is packaged.

Where a hazardous product is packaged in a single container which does not meet the definition of a bulk shipment (subsection 5.5(1) of the HPR), and the single container is used for shipping the hazardous product, both the *Transportation of Dangerous Goods Regulations* (TDGR) and HPR labels are required on the single container. An example of such a single container is a drum of solvent of less than 450 L. However, if the single container bears a label in accordance with the TDGR and the TDGR label includes a hazard symbol that is also required under the HPR, the pictogram with the same hazard symbol need not appear on the HPR label of the single container.

It is important to note that this labelling exemption in 5.10 can only be used if the TDGR label meets the durability requirement of section 3.5 of the HPR.

It is also important to note that instead of pictogram, the term "symbol" is used in section 5.10 because TDG labels do not include pictograms as defined in the HPR. The TDGR labels include symbols as defined in the HPR, in a shape that also includes numbers, background colors and patterns.

This labelling exemption is only for the HPR pictograms. Any signal word, hazard statement(s) or precautionary statement(s) that are required according to the HPR must be provided on the label, unless another exemption applies.

Discussion of the *Hazardous Products Regulations*
Section 5.11

Safety data sheet for hazardous products — same product identifier

5.11 The sale or importation of a hazardous product is exempt from the application of paragraph 13(1)(*a.1*) or 14(*a*) of the Act in respect of the requirement to provide, or cause to be provided, a safety data sheet on the sale or to obtain or prepare a safety data sheet on or before the importation, if

(*a*) the hazardous product is part of a shipment of hazardous products that have the same product identifier and a safety data sheet is obtained, prepared or provided for one of them; or

(*b*) the supplier has provided to the person or government that acquires possession or ownership, or the supplier who imports the hazardous product has in their possession, a safety data sheet for a hazardous product that has the same product identifier and the safety data sheet provides, subject to section 5.12, information that is current at the time of the sale or importation.

Paragraph 5.11(a) specifies that a separate SDS is not required to be provided by the supplier for every single container of the same hazardous product (i.e., a product bearing the same product identifier) in a shipment sold to a customer. Therefore, if 300 bottles of the same hazardous product are shipped to a customer, only one compliant and up-to-date SDS must be provided by the supplier on the sale to the customer.

Paragraph 5.11(a) also applies to importation and specifies that a separate SDS is not required to be obtained or prepared by the importer, on or before the importation, for every single container of the same hazardous product (i.e., a product bearing the same product identifier) in a shipment that is imported by an importer. Therefore, if 300 bottles of the same hazardous product are imported by an importer, only one compliant and up-to-date SDS must be obtained or prepared, on or before the importation, by the importer.

Paragraph 5.11(b) specifies that an SDS is not required to be provided upon every sale of the same hazardous product (i.e. a product bearing the same product identifier) to the same customer, if the SDS that was most recently provided to the customer remains compliant with the HPR. Therefore, if 300 bottles of the same hazardous product are shipped by the same supplier to the same customer every month, it is not necessary for the supplier to provide an SDS with every shipment to that customer as long as the SDS that was initially provided remains up-to date and compliant with the HPR.

Paragraph 5.11(b) also applies to importation and specifies that an SDS is not required to be obtained or prepared, on or before importation, of the same hazardous product (i.e. a product bearing the same product identifier) from the same foreign supplier, if the SDS that was most recently obtained or prepared by the importer remains compliant with the HPR. Therefore, if 300 bottles of the same hazardous product are imported by the same importer from the same foreign supplier every month, it is not necessary that the importer obtain or prepare an SDS, on or before

importation, as long as the SDS that was initially obtained or prepared remains up-to date and compliant with the HPR.

Where significant new data (SND), as defined in subsection 5.12(1), become available within 90 days prior to sale, the supplier is allowed, during this period, to provide to his customer, at the time of sale, the current SDS (with the exception of the SND) and, in writing, the information required in paragraph 5.12(2)(b) (i.e., the SND and the date that it became available) instead of immediately providing an updated SDS. In addition, as per paragraph 5.11(b), if further shipments of the same hazardous product (same product identifier) to the same customer are made within the above mentioned 90-day period of the date when the SND became available, it is not necessary to provide another SDS or to provide another document containing the SND that was already provided to that customer. However, once the 90-day period after the date when the SND became available expires, the supplier must, at the time of the sale, provide to the customer a new updated SDS that includes the SND.

In the case of import, if the next importation of the same hazardous product occurs within 90 days of the date when the SND became available, then the importer must obtain or prepare on or before the importation, the information required in paragraph 5.12(2)(b) (i.e., the SND and the date that it became available). If further importation of the same hazardous product from the same foreign supplier are made within the 90-day period of the date when the SND became available, it is not necessary for the importer to obtain or prepare on or before the importation, another SDS or another document containing the SND that was already obtained or prepared by the importer. However, once the 90-day period after the date when the SND became available expires, the importer must, on or before importation, obtain or prepare a new updated SDS that includes the SND.

Discussion of the *Hazardous Products Regulations*
Subsections 5.12(1) and (2)

Definition of "significant new data"

5.12(1) In this section "significant new data" means new data regarding the hazard presented by a hazardous product that change its classification in a category or subcategory of a hazard class, or result in its classification in another hazard class, or change the ways to protect against the hazard presented by the hazardous product.

Significant new data available within 90 days — sale

(2) The sale of a hazardous product for which significant new data became available within 90 days prior to the sale is exempt from the application of subsection 4(1) in respect of the requirement to provide, on the safety data sheet, information that is available at the time of the sale if, at the time of the sale, the supplier ensures that the person or government that acquires possession or ownership is provided with

(*a*) a safety data sheet that includes all information available at the time of the sale with the exception of the significant new data; and

(*b*) the significant new data and the date on which they became available, in writing.

VARIANCE with HCS 2012: Providing SDS significant new data at the time of the sale

HPR

At the time of the sale of a hazardous product, the supplier must provide, in writing, to a person or government that acquires possession or ownership of the hazardous product, any significant new data as well as the date upon which it became available, along with the SDS, for a period of up to 90 days (in the context described in subsection 5.12(2)).

HCS 2012

The HCS 2012 requires that, upon learning of significant new information, the manufacturer, importer, or employer must add this information to the SDS within three months. HCS 2012 does not require the transmission of significant new information to the purchaser in any form prior to the end of this 3-month period.

The SDS provided by a supplier upon the sale of a hazardous product, as required by paragraph 13(1)(a.1) of the HPA, must comply with all applicable requirements of the HPR. This requirement means that the hazardous product must be appropriately classified based on all data available **at the time of sale** to determine which information elements must be provided on the SDS. In the event where significant new data (SND) become available to the supplier within 90 days **prior to the sale of the hazardous product,** subsection 5.12(2) provides an exemption from having to update any information element(s) on the SDS during those 90 days, as long as the SND are provided in writing with the SDS at the time of the sale to the recipient of the hazardous product, along with the date on which the SND became available.

It is important to note that subsection 5.12(2) is not an exemption from having to provide required information about a hazardous product at the time of sale of that product, but rather a provision which permits the information to be provided in a format additional to the SDS.

The term “significant new data” as defined in paragraph 5.12(1) of the HPR means any new data regarding the hazards presented by a hazardous product that changes the classification of the product (category or subcategory of a hazards class or another hazard class), or changes the way to protect against the hazards presented by the product.

In practice, the SND that must be provided by the supplier to the recipient of a hazardous product in the context of subsection 5.12(2) consists of a list of all the changes to the classification of the hazardous product, the data under items 9, 10 and 11 of the SDS that lead to the change in the classification and a list of all the changes to the ways of protecting against the hazard of the product (i.e., the information elements of the SDS that are being changed and what those information elements are being changed to, as the result of the SND).

As per subsection 5.12(2), during the 90-day exemption period, until the SDS is updated to reflect the SND, the SND must be provided on a separate document (see the definition of “document” in section 2 of the HPA), and the separate document must also provide the date on which the SND became available. The requirement to provide the document could be met through an email to

the purchaser of the hazardous product as long as the email is received by the purchaser at the time of the sale.

If the SND became available more than 90 days **prior to the sale of the hazardous product** (for example 98 days prior to the sale), then subsection 5.12(2) is not applicable, and the supplier must, upon the sale of the hazardous product, provide to the purchaser a new updated SDS that incorporates the SND. Of course, the supplier may also update his SDS at any time during the 90-day period mentioned in subsection 5.12(2).

It must be noted that the content of the document (SND and the date on which the SND became available) required pursuant to subsection 5.12(2) and the content of the document (SND and the date on which the SND became available) required under subsection 5.12(4) (SND in the context of labelling requirements) could be provided in one document along with the SDS.

As the HPA requires the provision of all relevant required information relating to a hazardous product, based on data available at the time of sale, suppliers must be vigilant and seek for any new information related to their hazardous products in order to determine if the classification of their hazardous products or the ways to protect against the hazard(s) presented by the hazardous products are affected.

In a situation where the exemption set out in subsection 5.12(2) is used, the SND must be provided in both official languages.

Discussion of the *Hazardous Products Regulations*
Subsection 5.12(3)

Significant new data available within 90 days — importation

5.12(3) The importation of a hazardous product for which significant new data became available within 90 days prior to the importation is exempt from the application of subsection 4(1) in respect of the requirement to provide, on the safety data sheet, information that is available at the time of the importation if, at the time of the importation, the supplier

(*a*) obtains a safety data sheet that includes all of the information available at the time of the importation, with the exception of the significant new data; and

(*b*) obtains or prepares a document that provides the significant new data and the date on which they became available and appends that document to the safety data sheet referred to in paragraph (*a*).

VARIANCE with HCS 2012: Providing SDS significant new data at the time of the importation

HPR

At the time of the importation of a hazardous product, the importer must obtain or prepare a document that provides the significant new data, as well as the date upon which it became available, and must append this document to the SDS for a period of up to 90 days (in the context described in subsection 5.12(3)).

HCS 2012

The HCS 2012 requires that, upon learning of significant new information, the manufacturer, importer, or employer must add this information to the SDS within three months. HCS 2012 does not require that the importer obtain or prepare significant new information in any form prior to the end of this 3-month period.

The SDS that a supplier who is an importer must obtain or prepare on or before importation of a hazardous product, as required by paragraph 14(a) of the HPA, must comply with all applicable requirements of the HPR. This requirement means that the hazardous product must be appropriately classified based on all data available **on or before importation** to determine which information elements must be provided on the SDS. In the event where SND become available to the importer within 90 days **prior to the importation of the hazardous product,** subsection 5.12(3) provides an exemption from having to update any information element(s) on the SDS during those 90 days, as long as the importer obtains or prepares a document that provides the SND along with the date on which they became available and appends that document to the SDS of the hazardous product which he obtained on or before the importation.

It should be noted that the exemption in subsection 5.12(3) only applies to an importer who has obtained the SDS, and not to an importer who has prepared the SDS.

It is important to note that subsection 5.12(3) is not an exemption from having to obtain required information about a hazardous product on or before importation of that product, but rather a provision which permits the information to be provided in a format additional to an SDS that has been obtained.

The term “significant new data” as defined in paragraph 5.12(1) of the HPR means any new data regarding the hazards presented by a hazardous product that changes the classification of the product (category or subcategory of a hazards class or another hazard class), or changes the way to protect against the hazards presented by the product.

In practice, the SND that must be obtained or prepared by the supplier (importer) of a hazardous product in the context of subsection 5.12(3) consists of a list of all the changes to the classification of the hazardous product, the data under items 9, 10 and 11 of the SDS that leads to the change in the classification and a list of all the changes to the ways of protecting against the hazard of the product (i.e., the information elements of the SDS that are being changed and what those information elements are being changed to, as the result of the SND).

As per subsection 5.12(3), during the 90-day exemption period, until the obtained SDS is updated to reflect the SND, the SND must be obtained or prepared on a separate document (see the definition of "document" in section 2 of the HPA), and the separate document must also provide the date on which the SND became available.

If the SND became available more than 90 days **prior to importation of the hazardous product** (for example 98 days prior to importation), then subsection 5.12(3) is not applicable, and the importer must, on or before importation of the hazardous product, obtain or prepare a new updated SDS that incorporates the SND. Of course, the supplier (importer) may also obtain or prepare an updated SDS at any time during the 90-day period mentioned in subsection 5.12(3).

It must be noted that the content of the document (SND and the date on which the SND became available) required pursuant to subsection 5.12(3) and the content of the document (SND and the date on which the SND became available) required under subsection 5.12(5) (SND in the context of the labelling requirements) could be provided in one document along with the SDS.

As the HPA requires the provision of all relevant required information relating to a hazardous product, based on data available at the time of sale, suppliers must be vigilant and seek for any new information related to their hazardous products in order to determine if the classification of their hazardous products or the ways to protect against the hazard(s) presented by the hazardous products are affected.

In a situation where the exemption set out in subsection 5.12(3) is used, the document that provides the SND must be obtained or prepared in both official languages.

Discussion of the *Hazardous Products Regulations*
Subsection 5.12(4)

Significant new data available within 180 days — sale

5.12(4) The sale of a hazardous product for which significant new data became available within 180 days prior to the sale is exempt from the application of subsection 3(1) in respect of the requirement to provide, on the label, information elements for each category or subcategory of the hazard class in which the hazardous product is classified at the time of the sale if, at the time of the sale,

(*a*) the hazardous product or container in which the hazardous product is packaged has a label that provides all the information elements for each category or subcategory of the hazard class in which the hazardous product is classified at the time of the sale, with the exception of the significant new data; and

(*b*) the person or government that acquires possession or ownership is provided with the significant new data and the date on which they became available, in writing.

VARIANCE with HCS 2012: Providing label significant new data at the time of sale

HPR

At the time of the sale of a hazardous product, the supplier must provide, in writing, to a person or government that acquires possession or ownership of the hazardous product, any significant new data as well as the date upon which it became available, along with the label, for a period of up to 180 days (in the context described in subsection 5.12(4)).

HCS 2012

HCS 2012 requires that, upon learning of significant new information, chemical manufacturers, importers, distributors, or employers must revise the labels within six months. HCS 2012 does not require the transmission of significant new data on the label prior to the end of this 6-month period.

The label provided by a supplier upon the sale of a hazardous product, as required by paragraph 13(1)(b) of the HPA, must comply with all applicable requirements of the HPR. This requirement means that the hazardous product must be appropriately classified based on all data available **at the time of sale** to determine which information elements must be provided on the label. In the event where SND become available to the supplier within 180 days **prior to the sale of the hazardous product,** subsection 5.12(4) provides an exemption from having to update any information element(s) on the label during those 180 days, as long as the SND are provided in writing with the label at the time of the sale to the recipient of the hazardous product along with the date on which the SND became available.

It is important to note that subsection 5.12(4) is not an exemption from having to provide required information about a hazardous product at the time of sale of that product, but rather a provision which permits the information to be provided in a format additional to the label.

The term “significant new data” as defined in paragraph 5.12(1) of the HPR means any new data regarding the hazards presented by a hazardous product that changes the classification of the product (category or subcategory of a hazards class or another hazard class), or changes the way to protect against the hazards presented by the product.

In practice, the SND that must be provided by the supplier to the recipient of a hazardous product in the context of subsection 5.12(4) consists of a list of all the changes to the classification of the hazardous product and a list of all the changes to the ways of protecting against the hazard of the product (i.e., the information elements of the label that are being changed and what those information elements are being changed to, as the result of the SND).

As per subsection 5.12(4), during the 180-day exemption period, until the label is updated to reflect the SND, the SND must be provided on a separate document (see the definition of “document” in section 2 of the HPA), and the separate document must also provide the date on which the SND became available. The requirement to provide the document could be met through an email to the purchaser of the hazardous product as long as the email is received by the purchaser at the time of the sale.

If the SND became available more than 180 days **prior to the sale of the hazardous product** (for example 188 days prior to the sale), then subsection 5.12(4) is not applicable. The supplier must, upon the sale of the hazardous product, ensure that the hazardous product or the container in which the hazardous product is packaged has a new updated label,that incorporates the SND, affixed to it, printed on it or attached to it in a manner that meets the requirements of the HPR. Of course, the supplier may also update his label at any time during the 180-day period mentioned in subsection 5.12(4).

It must be noted that the content of the document (SND and the date on which the SND became available) required pursuant to subsection 5.12(4) and the content of the document (SND and the date on which the SND became available) required under subsection 5.12(2) (SND in the context of the safety data sheet requirements) could be provided in one document along with the label.

As the HPA requires the provision of all relevant required information relating to a hazardous product, based on data available at the time of sale, suppliers must be vigilant and seek for any new information related to their hazardous products in order to determine if the classification of their hazardous products or the ways to protect against the hazard(s) presented by the hazardous products are affected.

In a situation where the exemption set out in subsection 5.12(4) is used, the SND must be provided in both official languages.

Discussion of the *Hazardous Products Regulations*
Subsection 5.12(5)

Significant new data available within 180 days — importation

5.12(5) The importation of a hazardous product for which significant new data became available within 180 days prior to the importation is exempt from the application of subsection 3(1) in respect of the requirement to provide, on the label, information elements for each category or subcategory of the hazard class in which the hazardous product is classified at the time of the importation if, at the time of the importation,

(*a*) the hazardous product or container in which the hazardous product is packaged has a label that includes all of the information elements for each category or subcategory of the hazard class in which the hazardous product is classified at the time of the importation, with the exception of the significant new data; and

(*b*) the supplier obtains or prepares a document that provides the significant new data and the date on which they became available.

VARIANCE with HCS 2012: Providing label significant new data at the time of importation

HPR

At the time of the importation of a hazardous product, the supplier must obtain or prepare a document that provides the significant new data for the label, as well as the date upon which it became available, for a period of up to 180 days (in the context described in subsection 5.12(5)).

HCS 2012

HCS 2012 requires that, upon learning of significant new information, chemical manufacturers, importers, distributors, or employers must revise the labels within six months. HCS 2012 does not require that the importer obtain or prepare the significant new information on the labels prior to the end of this 6-month period.

As required by paragraph 14(b) of the HPA, a supplier (who is an importer) of a hazardous product must ensure that the hazardous product or the container in which the hazardous product is packaged has an HPR compliant label affixed to it, printed on it or attached to it in a manner that meets the requirements of the HPR. This requirement means that the hazardous product must be appropriately classified based on all data available on or before importation to determine which information elements must be provided on the label. In the event where SND become available to the importer within 180 days **prior to the importation of the hazardous product,** subsection 5.12(5) provides an exemption from having to update any information element(s) on the label during those 180 days, as long as the importer obtains or prepares a document that provides the SND along with the date on which they became available.

It should be noted that the exemption in subsection 5.12(5) only applies to an importer who has imported a product already labelled. It would not apply to any importer making use of the exemption set out in section 5.15 of the HPR to import a product that is not labelled in compliance with the HPR, for the purpose of bringing it into compliance before sale or use.

It is important to note that subsection 5.12(5) is not an exemption from having to obtain required information about a hazardous product on or before importation of that product, but rather a provision which permits the information to be provided in a format additional to an existing label.

The term “significant new data” as defined in paragraph 5.12(1) of the HPR means any new data regarding the hazards presented by a hazardous product that changes the classification of the product (category or subcategory of a hazards class or another hazard class), or changes the way to protect against the hazards presented by the product.

In practice, the SND that must be obtained or prepared by the supplier (importer) of a hazardous product in the context of subsection 5.12(5) consists of a list of all the changes to the classification of the hazardous product and a list of all the changes to the ways of protecting against the hazard of the product (i.e., the information elements of the label that are being changed and what those information elements are being changed to, as the result of the SND).

As per subsection 5.12(5), during the 180-day exemption period, until the existing label is updated to reflect the SND, the SND must be obtained or prepared on a separate document (see the definition of "document" in section 2 of the HPA), and the separate document must also provide the date on which the SND became available.

If the SND became available more than 180 days **prior to importation of the hazardous product** (for example 188 days prior to importation), then subsection 5.12(5) is not applicable. The importer must ensure that the hazardous product or the container in which the hazardous product is packaged has a new updated label that incorporates the SND, affixed to it, printed on it or attached to it in a manner that meets the requirements of the HPR. Of course, the supplier (importer) may also do this at any time during the 180-day period mentioned in subsection 5.12(5).

It must be noted that the content of the document (SND and the date on which the SND became available) required pursuant to subsection 5.12(5) (SND in the context of label requirements) and the content of the document (SND and the date on which the SND became available) required under subsection 5.12(3) (SND in the context of SDS requirements) could be obtained or prepared in one document along with the SDS.

As the HPA requires the provision of all relevant required information relating to a hazardous product, based on data available at the time of sale, suppliers must be vigilant and seek for any new information related to their hazardous products in order to determine if the classification of their hazardous products or the ways to protect against the hazard(s) presented by the hazardous products are affected.

In a situation where the exemption set out in subsection 5.12(5) is used, the document that provides SND must be obtained or prepared in both official languages.

Discussion of the *Hazardous Products Regulations*
Section 5.13

Transfer of possession for purpose of transportation

5.13. The transfer of possession of a hazardous product that creates a bailment for the purpose of transportation or, in Quebec, the transfer of possession of a hazardous product for the purpose of transportation, without transferring ownership, and with the obligation to deliver it to the person or government that acquired possession or ownership, is exempt from the application of paragraph 13(1)(*a.1*) of the Act in respect of the requirement to provide, or cause to be provided, a safety data sheet to the person to whom the possession of the product is transferred for the purpose of transportation.

The term "bailment" referred to in this guidance document means the "transfer of possession without the transfer of ownership".

When a hazardous product is bailed for the purposes of transportation, the supplier is not required to provide an SDS to the bailee, for example, the driver of a delivery company, which is a third party, transporting the hazardous product. For example, when the driver of a delivery company, such as Canada Post, UPS, FedEx etc., is given a hazardous product by a supplier for delivery to a recipient, the supplier is not required to provide an SDS to the driver or the company he represents. This is because a bailment has occurred between the supplier and the delivery company, and as such the exemption in section 5.13 is triggered.

However, the requirement for hazardous products to bear an HPR compliant label applies while they are being transported, unless an exemption under the HPR applies.

Discussion of the *Hazardous Products Regulations*
Subsections 5.14(1), (2) and (3)

Definition of "transit"

5.14(1) In this section, "transit" means, in relation to a hazardous product, its transport through Canada after being imported and before being exported, when the place of initial loading and the final destination are outside of Canada, and, while in transport, its loading, unloading, packing, unpacking or storage.

Importation — transit

(2) The importation of a hazardous product is exempt from the application of section 14 of the Act if

(*a*) the hazardous product is or is intended to be in transit; and

(*b*) the hazardous product is not intended for use in a work place in Canada.

Sale — exportation

(3) The sale of a hazardous product, for the purpose of its exportation, is exempt from the application of section 13 of the Act if

(*a*) the hazardous product is or is intended to be transported or, while in transport, is or is intended to be loaded, unloaded, packed, unpacked or stored, for the purpose of that sale; and

(*b*) the hazardous product is not intended for use in a work place in Canada.

These exemptions from labeling and SDS requirements apply to importation (subsection 5.14(2) of the HPR) and sale, for the purposes of exportation (subsection 5.14(3) of the HPR), of hazardous products that are not meant to be used in a work place in Canada. Such hazardous products do not require an HPR compliant label or SDS. The regulation of hazardous products while in transit or being transported for exportation is under the authority of Transport Canada, under the *Transportation of Dangerous Goods Act* and *Regulations*. The "sale of hazardous

products for the purpose of their exportation" applies to a Canadian supplier who sells a hazardous product to a foreign customer (export) or to a Canadian customer who intends to resell them to a foreign customer.

Note that, for the purpose of the exemption under subsection 5.14(2), the expression "use in a work place" in the context of hazardous products in transit excludes loading, unloading, packing, unpacking or storing of those products. This means that if a hazardous product in transit is loaded, unloaded, packed, unpacked or stored in a workplace, these activities must not be considered as "use in a workplace", and therefore this exemption applies.

Discussion of the *Hazardous Products Regulations*
Subsections 5.15(1) and (2)

Importation to bring into compliance

5.15(1) The importation of a hazardous product is exempt from the application of paragraph 14(*b*) of the Act if the hazardous product is imported for the purpose of being brought into compliance with the labelling requirements of these Regulations before it is used or sold.

Credible evidence

(2) A supplier who imports a hazardous product for the purpose described in subsection (1) must, on the request of an inspector, provide credible evidence to the inspector that it is being brought into compliance with the labelling requirements of these Regulations.

Subsections 5.15(1) and (2) are labelling exemptions that allow an importer to import hazardous products without labels or with labels that do not comply with the HPR, provided that the intent of the importer is to re-label these hazardous products with HPR compliant labels, in a timely manner and before they are used or sold in Canada. It must be noted that these hazardous products must have fully compliant SDSs, which were either obtained or prepared, on or before importation, as there is no equivalent SDS exemption.

Upon the request of an inspector, the onus is on the importer to provide credible evidence to prove that the hazardous products are being brought into compliance with the labelling requirements of the HPR before they will be used or sold. Examples of credible evidence that may be requested by inspectors may include answers to these questions, or similar ones:

- Which printing company has been hired to produce the new compliant labels?
- Where is a draft label or mock-up of the label?
- Where is the work plan or schedule for completion of the necessary work?
- What measures are in place to prevent the use of the product prior to its relabeling?

Appendix 1

GUIDANCE

Developing a Generic Chemical Name

(December 1, 2015)

1.0 Purpose

The intent of this document is to provide suppliers with guidance on developing a generic chemical name (GCN) for the purpose of ingredient disclosure on safety data sheets (SDSs), for use under the *Hazardous Products Regulations* (HPR) and *Hazardous Materials Information Review Act* (HMIRA). A GCN may also be used for a non-hazardous ingredient (not required for disclosure on an SDS) so long as the SDS makes clear that the ingredient is not hazardous under the *Hazardous Products Act* (HPA).

2.0 Background

A supplier or employer may seek an exemption from the requirement to disclose the name of a confidential ingredient on an SDS under the HPR by filing a claim for exemption with Health Canada under the HMIRA. In such cases, the claimant must disclose a GCN on the SDS in lieu of the chemical name (HPR 5.7 (5)). The GCN also must be submitted to Health Canada as part of the claim for exemption filed under the HMIRA.

The subject of developing a GCN has produced many questions by claimants seeking to apply for an exemption.

3.0 Guidance for the derivation of a GCN

A GCN is a chemical name which is less specific than the true chemical name but no more general than is necessary to protect the Confidential Business Information (CBI). A GCN should be unique and unambiguous, and a claimant should be able to explain or justify to Health Canada, upon request, the extent of the name modification that is necessary to protect the CBI. The GCN, like all other information in the SDS, is subject to the prohibition in section 14.2 of the HPA, and as such, must not convey false or misleading information about the nature of the chemical.

3.1 Strategy for developing a GCN

Several sources for a chemical name can be used as the starting point to develop a GCN. Most chemical names are derived using systematic nomenclature such as the one developed by the International Union of Pure and Applied Chemistry (IUPAC) or from the Chemical Abstract Services (CAS). Several sources are available to obtain systematic chemical names, such as ChemID through the National Library of Health (1), the CRC Handbook of Chemistry and Physics (2) and the Merck Index (3).

One method of developing a GCN is to use the approach set out by the *Masked Name Regulations* under the *Canadian Environmental Protection Act, 1999*. This method is useful in that it is very systematic and its application to develop a GCN as required under the HPR and HMIRA is considered acceptable by Health Canada.

A less systematic method is to mask the identity, position or number of functional groups on the chemical molecule. For example:

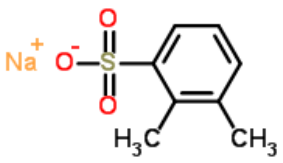
- The position and/or number and/or type of constituents can be masked;
- The parent structure and its primary functional group can be masked;
- The presence and number of other functional groups can be masked;
- Any combination of the above mentioned options.

IUPAC has published documents on class names (4) which can be used to replace the parent structure and functional groups on the molecule.

The GCN should retain some aspect of the chemical structure, as well as one or more functional groups or radicals. For example, a salt should be identified and not masked if there are hazards very specific to its metal cation which are required to be disclosed on the SDS or label.

3.2 Examples of GCNs based on the outlined strategies

1. CAS Name: Sodium dimethylbenzene sulphonate (CAS no: 1300-72-7)



The GCN could be developed by starting with the CAS name and masking the following:

- Na+: the presence of the cation, or salt
- The two CH3 groups (alkyl groups): the specific constituents, the number of constituent groups, position of the constituent groups (positions “5” and “6” on the benzene ring), or even the presence of the constituent groups
- Benzene ring (aryl group): the parent compound

Possible GCNs include:

dimethylbenzene sulphonate (salt)

dialkylbenzenesulphonate sodium salt

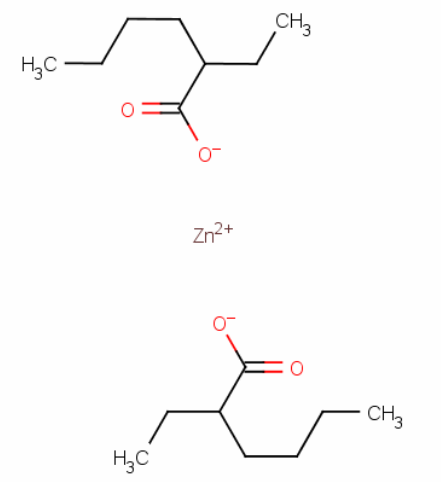
dialkylarylsulphonate sodium salt

dialkylarylsulphonate (salt)

alkylarylsulphonate (salt)

substituted arylsulphonate (salt)

dimethylbenzene inorganic acid, sodium salt



2. CAS Name: Hexanoic acid, 2-ethyl-, zinc salt (CAS no: 136-53-8): $2(2\text{-}(C_2H_5)C_6H_{10}O_2)Zn$

The name Hexanoic acid, 2-ethyl-, zinc salt could be used to start, or zinc bis(2-ethylhexanoate), where the bis indicates two ethylhexanoate components could be used, and the following could be masked:

- Zn^{2+}: the presence of the cation, or salt
- The ethyl (C_2H_5) group (alkyl group): the specific constituent, position of the constituent group (the "2" position), or even the presence of the constituent groups
- Hexanoic acid (carboxylic acid group): the parent compound

Possible GCNs include:

salt of an alkyl substituted carboxylic acid

alkylcarboxylic acid, zinc salt

Keeping the identity of zinc salt would allow the linking of hazards to the organic functional group and structural features of the compound.

3.3 Common errors in developing a GCN

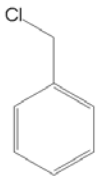
(a) Terms for product/chemical use

Terms such as dye, surfactant (even if qualified with the type such as anionic, cationic, or nonionic), catalyst, binder, colorant, emulsifier, inhibitor, or organic solvent are descriptors of product use and do not provide sufficient information on the chemical itself.

(b) Pseudo chemical names or misleading names

Syllables or masked syllables from the conventional chemical nomenclature may misrepresent a chemical structure. This includes using prefix and suffix syllables in the GCN, when these radicals or functional groups are not present in the molecule.

Juxtaposing a series of simple chemical terms such as "oxo-alcohol ether sulfate" or using creative phrases such as "oxygenated ketone" could cause confusion when considering the chemical functionality.



The order of the components of the name should usually relate to the actual chemical name. For example:

"alkylaryl halide" for chloromethylbenzene would be confusing as it indicates the halide is on the aryl (benzene) group (in this case, the GCN would be more correctly arylalkylhalide or haloalkylarene).

Where the precise structure of the reaction product is known, developing a GCN based on precursor or starting ingredient(s) of a reaction would be too ambiguous.

(c) Long descriptive phrases or a list of atoms.

Long descriptive phrases may be too general. For example, referral to a specific chemical ingredient as a “long chain hydrocarbon containing sulphur and nitrogen” gives no indication of whether the hydrocarbon is saturated, unsaturated, branched or linear; does not indicate whether the sulphur and nitrogen only have hydrogen attached to them or something more complex; and does not indicate whether sulphur or nitrogen is the main functional group, such as an amide or imide, or sulfonate or sulfoxide.

4.0 References

1. ChemID, National Library of Medicine, National Institute of Health. Available at: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
2. CRC Handbook of Chemistry and Physics, 96th Edition, Published by CRC Press, Editor(s):William M. Haynes, 2015
3. The Merck Index, 15th Edition, Royal Society of Chemistry, 2013
4. International Union of Pure and Applied Chemistry, (1995) Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure. Pure &App/. Chem., Vol. 67, Nos 819, pp. 1307-1375.

PART 6

Additional Requirements

Part 6 of the *Hazardous Products Regulations* (HPR) sets out additional requirements that relate to the information that must be provided on the safety data sheet (SDS) or label of a hazardous product. Notably, Part 6 requires that safety data sheets and labels always be in both official languages of Canada (English and French). In addition, suppliers must:

- provide information about the hazardous product to a health professional who requests that information for the purpose of making a medical diagnosis of, or rendering medical treatment to, an individual in an emergency.
- disclose the source of information for any toxicological data used in the preparation of an SDS, on the request of an inspector, any person or government to which the hazardous product is sold or any user of the hazardous product.

The following definitions from the *Hazardous Products Act* (HPA) apply in this Part:

Definitions from the HPA (Section 2)

"label" means a group of written, printed or graphic information elements that relate to a hazardous product, which group is designed to be affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged;

"safety data sheet" means a document that contains, under the headings that, by virtue of the regulations made under subsection 15(1), are required to appear in the document, information about a hazardous product, including information related to the hazards associated with any use, handling or storage of the hazardous product in a work place";

"supplier" means a person who, in the course of business, sells or imports a hazardous product.

The following definitions from the HPR apply in this Part:

Definitions from the *Hazardous Products Regulations* (HPR)

"work place" means a place where a person works for remuneration.

"health professionals": For the purposes of Parts 5 and 6, health professionals are

(a) physicians who are registered, and entitled under the laws of a province to practise medicine and who are practising medicine under those laws in that province; and

(b) nurses who are registered or licensed, and entitled under the laws of a province to practise nursing and who are practising nursing under those laws in that province.

Further information about these definitions can be found in the chapters relating to Part 1 (Interpretation), Part 3 (Labelling) and Part 4 (Safety Data Sheet).

Discussion of the *Hazardous Products Regulations* Subsection 6(1)

Communication of information elements – health professionals

6(1) A supplier who sells or imports a hazardous product intended for use, handling or storage in a work place in Canada must provide, as soon as feasible, any information element in respect of the hazardous product that is referred to in subsection 4(1) and is in the possession of the supplier to any health professional who requests that information for the purpose of making a medical diagnosis of, or rendering medical treatment to, an individual in an emergency.

Any information element that is referred to in subsection 4(1) of the HPR, and that is in the possession of the supplier, must be provided by the supplier to a health professional (see above definition of health professional) upon request, provided that the health professional makes the request for the purpose of making a medical diagnosis or rendering medical treatment to an individual in an emergency. The health professional must consider the requested information element to be necessary or useful to make a medical diagnosis or render a medical treatment.

A supplier who receives a request for information from a health professional should understand that there is an emergency situation in which an individual is in need of medical attention, and therefore, reasonable attempts should be made to comply with the request as soon as possible.

If the SDS was duly completed by the supplier, the health professional may only obtain what is actually disclosed on the SDS. However, the health professional may also obtain information that should have been disclosed on the SDS and that may have been omitted or only partially disclosed.

Since the information elements provided on an SDS must be in both official languages of Canada (see section 6.2 of the HPR), the supplier must provide the required information elements as they appear on the SDS (i.e., in both official languages). As per the request of the health professional, the requested information elements may be the English text, the French text or the English and French text, of the SDS.

Finally, it is important to note that the nature and extent of the information required to appear on SDSs of a hazardous product pursuant to paragraph 4(1)(c) (which refers to additional hazard information that is available) may provide health professionals with valuable information for the purpose of making a medical diagnosis or rendering medical treatment to an individual in an emergency.

Discussion of the *Hazardous Products Regulations*
Subsection 6(2)

Confidentiality

6(2) Any information that, by virtue of an exemption under the *Hazardous Materials Information Review Act* or these Regulations, is not required to be provided on the safety data sheet but has nevertheless been provided by a supplier to any health professional who requests that information for the purpose of making a medical diagnosis of, or rendering medical treatment to, an individual in a medical emergency must be kept confidential, except for the purpose for which it was provided, if the health professional has been informed by the supplier that the information is to be kept confidential.

The objective of this provision is to provide a mechanism to preserve the confidentiality of information that is CBI and that was provided to a health professional by a supplier.

This provision addresses situations where a supplier has filed or was granted a claim for CBI under HMIRA, and the supplier receives a request from a health professional, through subsection 6(1) of the HPR, for an information element that is the subject of a claim. When the supplier provides the information, this provision requires that the health professional maintain the confidentiality of the information elements subject to a claim under HMIRA that were provided to the health professional, except for the purpose for which they were provided, so long as the health professional has been informed by the supplier that the information is to be kept confidential.

Discussion of the *Hazardous Products Regulations*
Section 6.1

Communication of source for toxicological data

6.1 Subject to the *Hazardous Materials Information Review Act*, a supplier who sells or imports a hazardous product intended for use, handling or storage in a work place in Canada must disclose, as soon as feasible, the source of information for any toxicological data used in the preparation of a safety data sheet on the request of an inspector, any person or government to which the hazardous product is sold or any user of a hazardous product.

Subject to the provisions of the HMIRA, a supplier who receives a request for the source of information for any toxicological data provided under item 11 (Toxicological Information) of the SDS from an inspector, any person or government to which a hazardous product is sold or any user of a hazardous product, must provide that information to the requester as soon as possible. There is no requirement under the HPR for the recipient of this information to maintain it in confidence.

However, paragraph 11(1)(c) of the HMIRA allows a supplier to file a claim for an exemption from the requirement to disclose, under item 11 of the SDS, the name of any toxicological study that identifies a material or substance that is a hazardous product, or any ingredient in a mixture that is a hazardous product, if the supplier considers this information to be CBI. In the event that a supplier has filed or was granted a CBI claim and receives a request for the source of information for any toxicological data provided under item 11 of the SDS, the supplier is lawfully allowed to refuse to disclose the sought information.

However, an inspector or government may still have access to this CBI through section 46 of the HMIRA which is administered by Health Canada. To access this CBI, the conditions of the exceptions of subsection 46(1.1) or paragraphs 46(2)(c), (c.1), (d) or (e) of the HMIRA (i.e., who is entitled to receive the information and for which purpose) must be met. Anyone who obtains any information element through these provisions must keep the information confidential as per paragraph 46(4) of the HMIRA.

Discussion of the *Hazardous Products Regulations*
Subsection 6.2(1)

Bilingual safety data sheet and label

6.2(1) The information elements provided on a safety data sheet and on a label must be in both official languages of Canada.

Subsection 6.2(1) of the HPR specifies that the information elements provided on an SDS and on a label must be in both official languages of Canada (English and French). It must be noted that this provision is required to fulfill an obligation under the *Official Languages Act*.

It is important to note that under the HCS 2012, the SDS and label must be in English, but OSHA will allow additional languages (see paragraph (f)(2) of the HCS 2012).

Discussion of the *Hazardous Products Regulations* Paragraph 6.2(2)(a)

Bilingual presentation

6.2(2) The information elements referred to in subsection (1) may

(a) in the case of a safety data sheet, appear either on a single bilingual safety data sheet or document in two unilingual parts that constitute one bilingual safety data sheet; and

The following are examples of ways in which the requirement for providing bilingual SDSs could be met:

1. The supplier could provide a single bilingual SDS, that is, an SDS that contains the required information elements, as set out in Part 4 and Schedule 1 of the HPR, in one document. Either the English and French text could be interspersed or all of the English text could appear first and then all of the French text, or *vice versa*.

2. The supplier could provide an SDS that contains the required SDS information elements, as set out in Part 4 and Schedule 1 of the HPR, where the English and French portions of the SDS are separated into two parts - one in English and one in French.

Providing a bilingual SDS

A bilingual SDS must be provided to the purchaser of the hazardous product, either in hard copy (e.g. mail, hand delivered etc.) or by electronic means.

The following are examples of ways in which a bilingual SDS could be provided to a purchaser by electronic means:

1. The supplier could send an email to the purchaser and attach the SDS to the email (in the case where the English and French portions of the SDS are two separate parts, both the English and French parts must be attached to the same email).

2. The supplier could provide the purchaser with a universal serial bus (USB) stick or a compact disc (CD) on which the SDS has been saved (in the case where the English and French portions of the SDS are two separate parts, both the English and French parts must be saved on the same USB stick or CD).

It is important to note that it is not acceptable to provide an SDS by only providing the purchaser of the hazardous product with a website address or hyperlink from which the purchaser may download the SDS for the hazardous product that he purchased.

There is an exception under section 5.11 of the HPR to the obligation to provide an SDS which states that a separate SDS need not accompany every single container of a hazardous product, nor does an SDS need accompany every single shipment of the same hazardous product to the same purchaser, provided that the most recent SDS that was provided to the purchaser remains compliant with the HPR.

Discussion of the *Hazardous Products Regulations*
Paragraph 6.2(2)(b)

Bilingual presentation (continued)

6.2(2)(b) in the case of a label, appear either on a single bilingual label or in a group of information elements in two unilingual parts that constitute one bilingual label.

The following are examples of ways in which the requirement for bilingual labels can be met:

1. A single bilingual label, with the English and French text side by side or one on top of the other, or with the English and French text interspersed.

An example of a side by side label is shown below:

2. The English and French portions of the label could be separated into two parts.
The group of information elements for each part can be:

- affixed to,
- printed on or
- attached to, including attached to same side of

the hazardous product or the container in which the hazardous product is packaged, either side-by-side or one on top of the other or any other configuration which contrasts with any other information on the hazardous product or the container.

3. The English and French portions of the label could be separated into two parts.
The group of information elements for each part can be:

- affixed to,
- printed on or
- attached to, including attached to two different sides of

the hazardous product or the container in which the hazardous product is packaged.
In this scenario, it may not be possible to see both English and French text all at once, if this is the case, the required pictogram(s) would be required to appear on each unilingual part of the label. This repetition would not be considered to contravene section 14.2 of the HPA.

Section 3.4 of the HPR requires that both the English and French portions of the label be placed on a surface that is visible under normal conditions of use (e.g., placing a portion of the label on the bottom of a container is not permitted). For example, if a hazardous product is packaged in a square bottle, the English portion of the label could be attached to one side of the bottle and the French portion, to any other side. The two sides need not be adjacent to one another, provided that each side of the bottle is visible under normal conditions of use, but not necessarily at the same time. As mentioned previously, if the two unilingual parts of the label are located on two sides of the container that are opposed (e.g. not visible all at once), the required pictogram(s) would have to appear on each unilingual part of the label.

Irrespective of which option is chosen, the label must comply with the requirements of Part 3 of the HPR. Requirements with respect to legibility and durability are set out in sections 3.4 and 3.5, respectively.

References

29 CFR 1910.1200, Hazard Communication

Hazardous Products Act, R.S.C., 1985, c. H-3

Hazardous Products Regulations, SOR/2015-17

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

PART 7

Physical Hazard Classes

Introduction

This Part provides an overview of the physical hazard classes and their classification, in general. Detailed guidance on each physical hazard class, as set out in Part 7 of the *Hazardous Products Regulations* (HPR), has been provided to assist suppliers in determining the appropriate hazard classification of a product, mixture, or substance, in relation to the criteria for physical hazards. Physical hazards are based on the physical or chemical properties of the product, such as flammability, reactivity or corrosivity. The physical hazards presented by a product, mixture or substance can cause harm to workers by exposing them to fire or explosion.

Classification in relation to the physical hazard classes is based on available data and no additional testing is required to be undertaken. However, if testing is carried out, then the test method(s) specified in the chapter for a given physical hazard must be applied. All available data must be evaluated against the criteria for each physical hazard class to determine the classification of a product, mixture or substance. It is important to note that the classification of a product, mixture or substance in one physical hazard class does not preclude classification of the same product, substance or mixture in other physical hazard classes.

The list of Physical Hazard classes in Schedule 2 of the *Hazardous Products Act* (HPA) is the following:

1. Explosives[+]
2. Flammable Gases
3. Flammable Aerosols
4. Oxidizing Gases
5. Gases under Pressure
6. Flammable Liquids
7. Flammable Solids
8. Self-reactive Substances And Mixtures
9. Pyrophoric Liquids
10. Pyrophoric Solids
11. Self-heating Substances And Mixtures
12. Substances and Mixtures Which, In Contact With Water, Emit Flammable Gases
13. Oxidizing Liquids
14. Oxidizing Solids
15. Organic Peroxides
16. Corrosive To Metals

17. Combustible Dusts*
18. Simple Asphyxiants*
19. Pyrophoric Gases*
20. Physical Hazards Not Otherwise Classified*

[+] It is important to note that, although Schedule 2 of the HPA refers to a hazard class for "Explosives", the GHS hazard class for Explosives has not been adopted in the HPR. As specified in Schedule 1 of the HPA, explosives, as defined in section 2 of the *Explosives Act*, are excluded from the application of the HPA.

* These hazard classes are not covered by the GHS (5th revised edition, 2013).

The classification criteria for each of these 20 physical hazard classes are addressed by a Subpart of Part 7, set out in the same order as listed in Schedule 2 of the HPA. The hazard classes listed in Schedule 2 of the HPA are consistent with those of the HCS 2012 except for the following:

- The GHS "Explosives" hazard class has been adopted in the HCS 2012, but not in the HPR
- The HCS 2012 addresses combustible dusts, pyrophoric gases and simple asphyxiants, but does not provide distinct criteria for any of these hazards. Furthermore, simple asphyxiants are addressed under health hazards. The HCS 2012 addresses hazards not otherwise classified, but does not provide distinct criteria for physical hazards not otherwise classified.

Physical State

Certain physical hazards are based on physical state: gas, liquid and solid. Physical states are defined by their intrinsic properties. Physical properties such as melting point, boiling point and viscosity may be necessary to identify the physical state of the substance or mixture. In the definitions and classification criteria for the hazard classes set out in Parts 7 and 8, where no mention is made with regard to physical state, it must be understood that the hazard class applies to all physical states. The following physical state definitions are included in subsection 1(1) of Part 1 of the HPR: gas; liquid; and solid.

Physical State and Physical Hazard Class

The physical states that are addressed by the various physical hazard classes are shown in the following table:

Hazard Class	Gas	Liquid	Solid
7.2 Flammable Gases	✓		
7.3 Flammable Aerosols	✓	✓	✓
7.4 Oxidizing Gases	✓		
7.5 Gases Under Pressure	✓		
7.6 Flammable Liquids		✓	
7.7 Flammable Solids			✓
7.8 Self-Reactive Substances and Mixtures		✓	✓
7.9 Pyrophoric Liquids		✓	
7.10 Pyrophoric Solids			✓
7.11 Self-Heating Substances and Mixtures		✓	✓
7.12 Substances and Mixtures which, in contact with water, Emit Flammable Gases		✓	✓
7.13 Oxidizing Liquids		✓	
7.14 Oxidizing Solids			✓
7.15 Organic Peroxides		✓	✓
7.16 Corrosive to Metals		✓	✓
7.17 Combustible Dusts			✓
7.18 Simple Asphyxiants	✓		
7.19 Pyrophoric Gases	✓		
7.20 Physical Hazards Not Otherwise Classified	✓	✓	✓

Types of data that can be used to classify a product, mixture or substance in the physical hazard classes

When classifying a product or substance with respect to the physical hazard classes set out in Part 7 of the HPR, certain types of data are to be used, as specified in subparagraphs 2.1(a)(i) to (iv) and 2.1(b)(i) to (iv) of the HPR.

Data on the product or substance may include any of the following:

- results of testing or studies carried out in accordance with the test methods referred to in Part 7;
- results of testing or studies carried out in accordance with generally accepted standards of good scientific practice;
- conclusions based on established scientific principles; and
- case reports or documented observations.

If data on the product or substance itself are unavailable or are insufficient to evaluate the substance or material in accordance with the applicable criteria, then for each physical hazard class, data of the types listed above for a product or substance with similar properties to the substance or material that is being classified must be considered.

Further guidance is provided in the discussion of section 2.1 in Part 2 of this technical guidance.

When classifying a mixture with respect to the physical hazard classes set out in Part 7 of the HPR, the types of data to be used are the same as those listed above. The data may pertain to the mixture as a whole or a mixture with similar properties, as specified in subsection 2.2(1) of the HPR. Further guidance is provided in the discussion of subsection 2.2(1) in Part 2 of this technical guidance.

Specific consideration that is relevant to the physical hazard classification of a product, mixture, or substance (Section 2.8)

In the case of the physical hazard classes, namely, Flammable Solids (Subpart 7 of Part 7), Pyrophoric Solids (Subpart 10 of Part 7), Self-Heating Substances and Mixtures (Subpart 11 of Part 7), Substances and Mixtures Which, In Contact With Water, Emit Flammable Gases (Subpart 12 of Part 7) and Oxidizing Solids (Subpart 14 of Part 7), the data used for the purposes of classification must relate to the solid in the physical form in which it is sold or imported. If the solid is in some other physical form that is different from the form in which the data was generated then the evaluation must be carried out in that other physical form of the solid because different forms and physical states of a substance or mixture may result in different physical properties and hazards with possible consequences on the classification of the substance or mixture.

In addition to using information on the mixture itself or information on a mixture with similar properties, there are four physical hazard classes which include provisions for classifying mixtures based on information on the ingredients in the mixture.

1. In Subpart 2 of Part 7 (Flammable Gases), subsection 7.2.1 (3) allows the use of a calculation method to determine the flammability of a gas mixture. This method uses data on the ingredients to determine the flammability of the gas mixture.
2. In Subpart 4 of Part 7 (Oxidizing Gases), section 7.4.1 allows the use of a calculation method to determine the oxidizing power of a gas mixture. This method uses data on the ingredients to determine the oxidizing power of the gas mixture.
3. In Subpart 6 of Part 7 (Flammable Liquids), paragraph 7.6.1 (4)(b) also refers to a calculation method which uses data on ingredients to determine the flammability of a liquid mixture.
4. In Subpart 15 of Part 7 (Organic Peroxides), subsection 7.15.1 (4) does not use a calculation method but requires, under certain conditions, that the classification of a mixture of organic peroxides be based on data available on the ingredients (i.e., on the most hazardous organic peroxide in the mixture).

Test Procedures

The physical hazard classes may have specific test procedures associated with them, or a more general test method, or none at all.

Data from scientifically validated methods, developed by the International Organization for Standardization (ISO standard) or ASTM International (ASTM standard) can, and must in certain circumstances, be used for determining classification, as indicated in specific provisions of Part 7 of the HPR.

Subpart 2: Flammable Gases: ISO standard 10156:2010: *Gases and gas mixtures — Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*

Subpart 4: Oxidizing Gases: ISO standard 10156:2010: *Gases and gas mixtures — Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*

Subpart 6: Flammable Liquid: any appropriate closed-cup ISO or ASTM method listed in paragraph 2.6.4.2.5 of the GHS (5th revised edition, 2013) for testing the flash point of a liquid must be used as long as the liquid meets the criteria specified by the method in question.

Certain hazard classes have no test methods associated with them:

Subpart 5: Gases Under Pressure

Subpart 17: Combustible Dusts

Subpart 18: Simple Asphyxiants

Subpart 19: Pyrophoric Gases

Subpart 20: Physical Hazards Not Otherwise Classified.

Test methods may become available in the future.

Many of the physical hazard classifications are based on United Nations Transport of Dangerous Goods criteria and the test procedures come from the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015. The manual contains criteria, test methods and procedures to be used for the classification of dangerous goods according to the provisions of Parts 2 and 3 of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, as well as the classification of chemicals presenting physical hazards according to the GHS. Test procedures found in the Manual of Tests and Criteria are referred to in the following physical hazard classes in Part 7 of the HPR:

Subpart 3: Flammable Aerosols

Subpart 7: Flammable Solids

Subpart 8: Self-reactive Substances and Mixtures

Subpart 9: Pyrophoric Liquids

Subpart 10: Pyrophoric Solids

Subpart 11: Self-heating Substances and Mixtures

Subpart 12: Substances and mixtures which in contact with water, emit flammable gases

Subpart 13: Oxidizing Liquids

Subpart 14: Oxidizing Solids

Subpart 15: Organic Peroxides

Subpart 16: Corrosive to Metals

Acronyms referred to in Part 7 – Physical Hazards

HPA	*Hazardous Product Act*
HPR	*Hazardous Product Regulations*
HCS 2012	U.S. OSHA Hazard Communication Standard 2012
ECHA CLP	ECHA Regulations on the Classification, Labelling and Packaging of Substances and Mixtures
GHS	Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition, 2013
UN TDG	UN Recommendations on the Transport of Dangerous Goods Model Regulations, 19th revised edition, 2015
TDG MTC	Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015
TDGR	*Transportation of Dangerous Goods Regulations*
U.S. DOT	U.S. Department of Transport - Dangerous Goods Regulations

Subpart 1
Explosives

[7.1 reserved]

Subpart 2
Flammable Gases

Definition

7.2 In this Subpart, "flammable gas" means a gas that has a flammable range when mixed with air at 20°C and at the standard pressure of 101.3 kPa.

The flammable range is determined by tests or by use of a calculation method. However, in accordance with subsection 7.2.1(3) of the HPR, test data have priority over data obtained using a calculation method.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.2.1(1)

Exclusions

7.2.1(1) Any product that is classified in a category of the hazard class "Flammable Aerosols" need not be classified in any category of this hazard class.

If a product is classified as a Flammable Aerosol, it need not be classified as a Flammable Gas. The definition of "flammable aerosol" and the criteria for classification in the Flammable Aerosols hazard class are found in sections 7.3 and 7.3.1 of the HPR, respectively.

Classification Criteria for Flammable Gases

Discussion of the *Hazardous Products Regulations*
Subsection 7.2.1(2)

Categories

7.2.1(2) A flammable gas is classified in a category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Flammable Gases — Category 1**	**A gas that** **(a) is ignitable when mixed with air at a concentration ≤ 13.0% by volume; or** **(b) has a flammable range when mixed with air ≥ 12 percentage points, regardless of the lower flammable limit**
2	**Flammable Gases — Category 2**	**A gas that is not classified in the category "Flammable Gases — Category 1" and has a flammable range when mixed with air**

Subsection 7.2.1(2) provides the criteria for classifying a gas in the appropriate category for Flammable Gases (Category 1 or Category 2).
To ignite a flammable gas, three basic conditions have to be met:

- the concentration of the gas must be within the concentration range over which the gas can be ignited, i.e., between the lower and upper flammable limits of the gas;
- an oxidizing gas (e.g., air) must be present; and
- there must be a source of ignition.

The lower flammable limit (LFL) is the minimum concentration (per cent by volume) of a gas in air below which a flame is not propagated when an ignition source is present; (i.e., at any lower concentration the gas is "too lean" to burn). Similarly, the upper flammable limit (UFL) is the maximum concentration above which the gas is "too rich" to burn. (Fire Protection Guide to Hazardous Materials, 2002 Edition, NFPA 325 p. 5)

The flammable range is the range between LFL and UFL. It is measured in percentage points between the UFL and LFL. For example, if a gas is ignitable at a LFL of 20% and a UFL of 30%, then it has a flammable range of 10 percentage points (30-20=10).

To classify a flammable gas under the HPR, test results on its flammability must have been conducted in standard conditions (at 20°C and at the pressure of 101.3 kPa). The necessary data to classify a flammable gas in a category of the class includes the flammable range and information on whether the gas is ignitable at a concentration of 13% gas in air by volume, or less.

A gas that does not have a flammable range under standard conditions must not be classified in the Flammable Gases hazard class.

A gas which has a flammable range under standard conditions must be classified in Flammable Gases — Category 1 if at least one of the two criteria is met:

a) the gas ignites at a concentration of 13% in air by volume, or less, or

b) its flammable range when mixed with air in any proportion is higher than or equal to 12 percentage points. (For example, it could have a flammable range from 60% - 80% or from 14% - 26%)

Otherwise, a gas which has a flammable range under standard conditions must be classified in Flammable Gases — Category 2.

Comparison to HCS 2012 and GHS

The GHS (5th revised edition, 2013, paragraph 2.2.2.2) classifies chemically unstable gases. However, Chemically Unstable Gases were not retained as part of the Flammable Gases hazard class in the HCS 2012 or the HPR. Therefore, WHMIS 2015 and the HCS 2012 are aligned in this respect.

Discussion of the *Hazardous Products Regulations* Subsection 7.2.1(3)

Calculation method

7.2.1(3) Test data have priority over data obtained using a calculation method. If a calculation method is used to establish whether a gas is classified in a category of this hazard class, the calculation method set out in the International Organization for Standardization standard ISO 10156:2010 entitled *Gases and gas mixtures — Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*, as amended from time to time, or any other calculation method that is a scientifically validated method, must be used.

Test data have priority over data obtained using a calculation method. If test results are not available, or if the available data is insufficient for classification, calculation methods can be used as an alternative.

An example of calculation and the criteria are detailed below.

The calculation method described in ISO 10156: 2010, determines only if the mixture is flammable or not. It does not determine a flammability range. Therefore, this calculation method cannot be used to determine if the mixture falls into Category 1 or Category 2 of the Flammable Gases hazard class. So, mixtures determined to be flammable according the calculation method

must be classified as Flammable Gases - Category 1 if no additional information is available. (ECHA Guidance, 2015, paragraph 2.2.4.4)

Other scientifically valid calculation methods may be used and may or may not allow a gas to be classified in a category depending on the results of the calculation. If the result of a calculation allows the determination of a flammability range then the gas may be classified in a category of this hazard class. Otherwise, if the calculation method identifies the gas as being a flammable but does not provide enough information to determine in which category it falls (i.e., Category 1 or 2), the gas must be classified in Category 1.

Hazard Communication

The symbols, signal words, hazard statements, and precautionary statements for "Flammable Gases" are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, p. 308 (Category 1) and p. 309 (Category 2)) subject to paragraphs 3(5)(a) and (b) of the HPR. Note: there is no symbol for Category 2.

Classification of Flammable Gases

Examples

Example 1: Classification of a Substance with Known Data

Available data

A gaseous substance with a boiling point of -42°C and a flammable range between 2.2 – 11 % in air at standard conditions (20 °C and 101.3 kPa).

Classification

The gaseous substance meets the criteria for Flammable Gas - Category 1.

Rationale

1. At 20 °C and 101.3 kPa, the substance ignites when mixed with air at a concentration of less than or equal to 13%, criteria (a) of Category 1 is met.

Example 2: Classification of a Mixture Based on Calculation Method (GHS, 5th revised edition, 2013, paragraph 2.2.5)

Formula for the classification of a flammable gas mixture by calculation according to ISO 10156:2010

The formula for the determination: $\sum_{i}^{n} \frac{\text{Vi (\%)}}{\text{Tci}}$

with = $$Vi(\%) = \frac{\text{Ai}}{\sum_{i}^{n} Ai + \sum_{1}^{p} K_k B_k}$$

where:

Vi (%) = the equivalent content of the i^{th} flammable gas in the mixture, in %;

Tci = the maximum concentration of a flammable gas in nitrogen at which the gas is still not flammable in air, in %;

i = the first gas in the mixture;

n = the number of flammable gases in the mixture;

k = the number of inert gases in the mixture;

A_i = is the molar fraction of the i^{th} flammable gas in the mixture, in %;

K_k = is the coefficient of equivalency of the inert gas k relative to nitrogen;

B_k = is the molar fraction of the k^{th} inert gas in the mixture, in %;

p = is the number of inert gases in the mixture

The criteria for a gas to be flammable is $\sum_{1}^{n} \frac{\text{Vi (\%)}}{\text{Tci}} > 1$

When a gas mixture contains an inert diluent other than nitrogen, the volume of this diluent is adjusted to the equivalent volume of nitrogen using K_k.

The calculation method applies to gas mixtures and can be applied when the Tci for all flammable components and the K_k for all inert components are available. These values are listed for a number for gases in ISO 10156:2010. In the absence of Tci value for a flammable gas, the value of the Lower Flammable Limit (LFL) can be used, and ISO 10156:2010 proposes the value of 1.5 where no K_k value is listed.

It should be noted that ISO 10156:2010 uses molar fractions in some of its equations. For most gases under normal (i.e., non-extreme) conditions, the volume fraction can be assumed to be equal to the molar fraction, which is the same as assuming ideal gas behavior for all gases in the mixture.

For mixtures containing both flammable and oxidizing components, special calculation methods are described in ISO 10156:2010.

Mixture Composition

2% hydrogen (H_2) + 6% methane (CH_4) + 27% argon (Ar) + 65% helium (He)

Assumptions

(1) the equivalency factor (K_k) is 0.5 for the inert gases argon and helium;

(2) the Tci coefficient is 5.7% for hydrogen and is 14.3% for methane.

Calculations

The equivalent mixture using nitrogen as the balance gas for argon and helium is:

$$2\%\ (H_2) + 6\%\ (CH_4) + [27\% \times 0.5 + 65\% \times 0.5](N_2) = 2\%\ (H_2) + 6\%\ (CH_4) + 46\%\ (N_2) = 54\%$$

The adjusted sum of the contents to 100% is:

$$\frac{100}{54} \times [2\%\ (H_2) + 6\%\ (CH_4) + 46\%\ (N_2)] = 3.7\%\ (H_2) + 11.1\%\ (CH_4) + 85.2\%\ (N_2)$$

The flammability of the equivalent mixture is:

$$\sum_1^n \frac{\text{Vi (\%)}}{\text{Tci}} = \frac{3.7}{5.7} + \frac{11.1}{14.3} = 1.42$$

Therefore, the mixture is flammable in air.

Classification

The gas mixture meets the criteria for classification as a Flammable Gas - Category 1.

Rationale

1. The result of the calculation is 1.42 which is >1, therefore the volume of ignitable gas (Vi) is higher than the minimum volume of gas (Tci) which will ignite in nitrogen.
2. The result of the calculation does not allow for a determination of the classification category based on the criteria, therefore by default it is classified in Category 1.

Subpart 3
Flammable Aerosols

Definitions

7.3 The following definitions apply in this Subpart.

"flammable aerosol" means a product that contains one or more flammable components in an aerosol dispenser and that, when dispensed, is liable to ignite, but excludes a product that contains flammable components in an aerosol dispenser at a concentration less than or equal to 1.0% and that has a heat of combustion less than 20 kJ/g.

"flammable component" means a mixture or substance that is classified in a category or subcategory of a hazard class in Subpart 2, 6 or 7 of this Part.

"foam aerosol" means the content that is dispensed from an aerosol dispenser having a spray distance of less than 15 cm and that is in the form of a foam, mousse, gel or paste.

"spray aerosol" means the content that is dispensed from an aerosol dispenser and that is not a foam aerosol.

Discussion – Aerosol and Flammable Aerosol

The definition of "aerosol dispenser" may be found in subsection 1(1) of this document.

The GHS defines aerosols as aerosol dispensers, which refers to "any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state" (GHS, 5th revised edition, 2013, paragraph 2.3.1).

However, the definitions used in the HPR distinguish between the ejected contents and the container. Only the ejected contents are identified as an aerosol and the aerosol container is referred to as an "aerosol dispenser". "Aerosol dispenser" is defined in subsection 1(1) of the HPR, and the aerosol is what is generated by that container or contained within that container.

The definition of "foam aerosol" in the HPR differs slightly from the HCS 2012 and GHS in that the HPR also includes the terms "mousse" and "gel" in order to align with the definition of "aerosol dispenser". This difference is not expected to impact the classification of Flammable Aerosols.

Aerosols are classified in one of the three categories of this hazard class based on the physical properties of their components, the chemical heat of combustion and, if applicable, on the results of the foam test (for foam aerosols), ignition distance test and enclosed space test (for spray aerosols).

As per subsection 7.3.1 of the HPR, the classification of Flammable Aerosols is based on tests described in Part III of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, as amended from time to time, where details on the Ignition Distance Test, Enclosed Space Ignition Test, and Aerosol Foam Flammability Test are provided in sub-sections 31.4, 31.5 and 31.6, respectively.

Discussion – Flammable Components

Flammable aerosols means a product that contains one or more flammable components in an aerosol dispenser and that, when dispensed, the component is liable to ignite. The flammable component could be a substance or mixture that is classified in a category or subcategory of the following hazard classes:

- Flammable Gases (HPR Part 7, Subpart 2),
- Flammable Liquids (HPR Part 7, Subpart 6), or
- Flammable Solids (HPR Part 7, Subpart 7).

Aerosols should be considered for classification in Category 1 or 2 of the Flammable Aerosols hazard class if they contain more than 1% components (by mass) which are classified as flammable.

Notes:

1. Because such components are never used as aerosol contents, flammable components do not include substances and mixtures which are pyrophoric, self-heating or water reactive.
2. Flammable aerosols need not be classified in the Flammable Gases, Flammable Liquids, or Flammable Solids hazard classes. See subsections 7.2.1(1), 7.6.1(1) and 7.7.1(1) of the HPR.

Discussion – Foam Aerosol and Spray Aerosol

The terms “foam aerosol” and “spray aerosol” are not defined in the GHS. However, if testing is being conducted on the aerosol, certain aerosols should be subjected to the foam aerosol test and others to the spray aerosol test. Spray aerosols and foam aerosols can be distinguished by the distance that the aerosol contents travel when ejected. Therefore, these definitions are included in section 7.3 of the HPR (spray aerosol and foam aerosol) to specify what they mean in the classification criteria.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.3.1(1)

Categories

7.3.1(1) A flammable aerosol is classified in a category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Flammable Aerosols — Category 1	An aerosol dispenser that (a) contains ≥ 85.0% flammable components and that generates an aerosol that has a heat of combustion ≥ 30 kJ/g; (b) generates a spray aerosol that has an ignition distance ≥ 75 cm, based on test results from the ignition distance test for spray aerosols performed in accordance with sub-section 31.4 of Part III of the Manual of Tests and Criteria; or (c) generates a foam aerosol that has, based on test results from the aerosol foam flammability test performed in accordance with sub-section 31.6 of Part III of the Manual of Tests and Criteria, either (i) a flame height ≥ 20 cm and a flame duration ≥ 2 s, or (ii) a flame height ≥ 4 cm and a flame duration ≥ 7 s
2	Flammable Aerosols — Category 2	An aerosol dispenser that generates (a) a spray aerosol that does not meet the criteria for the category "Flammable Aerosols — Category 1" and that has (i) a heat of combustion ≥ 20 kJ/g, (ii) an ignition distance ≥ 15 cm, based on test results from the ignition distance test for spray aerosols performed in accordance with sub-section 31.4 of Part III of the Manual of Tests and Criteria, (iii) a time equivalent ≤ 300 s/m^3, based on test results from the enclosed space ignition test performed in accordance with sub-section 31.5 of Part III of the Manual of Tests and Criteria, or (iv) a deflagration density ≤ 300 g/m^3, based on test results from the enclosed space ignition test performed in accordance with sub-section 31.5 of Part III of the Manual of Tests and Criteria; or (b) a foam aerosol that does not meet the criteria for the category "Flammable Aerosols — Category 1" and that has a flame height ≥ 4 cm and a flame duration ≥ 2 s, based on test results from the aerosol foam flammability test performed in accordance with sub-section 31.6 of Part III of the Manual of Tests and Criteria

A flammable aerosol is classified in either Category 1 or Category 2 of the Flammable Aerosol hazard class on the basis of:

- its flammable components and its chemical heat of combustion or,
- if applicable, the results of the foam test (for foam aerosols) or the ignition distance test and enclosed space test (for spray aerosols) in the test procedure specified in subsection 7.3.1(1) of the HPR.

The ignition distance test is the method used to determine the distance from the aerosol dispenser at which the aerosol spray can be ignited. This test is applicable to aerosol products that can spray a distance of 15 cm or more. Ignition at greater distances increases the possibility of contact of the spray with an ignition source during use.

Aerosol products with a spray distance of less than 15 cm, such as dispensing foams, mousses, gels and pastes or that are fitted with a metering valve, are excluded from this test. Aerosol products that dispense foams, mousses, gels or pastes are subject to testing under the aerosol foam flammability test. The aerosol foam flammability test is the method to determine the flammability of an aerosol emitted in the form of a foam, mousse, gel or paste. The enclosed space ignition test is the method used to assess the flammability of products emerging from aerosol dispensers based on their propensity to ignite in an enclosed or confined space.

The heats of combustion are found in literature, calculated or determined by testing. For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta H_c \text{ (product)} = \sum_{i}^{n} [\, w_i\% \times \Delta H_{c(i)}]$$

where:

ΔH_c = chemical heat of combustion (kJ/g)

$w_i\%$ = mass fraction of component i in the product

$\Delta H_{c(i)}$ = specific heat of combustion (kJ/g)of component i in the product

The heats of combustion can be determined by the following tests methods or other scientifically validated methods:

- ASTM D240-02: Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter;
- ISO 13943: 2000: Fire Safety - Vocabulary, First Edition, April 15, 2000, Sections 86.1 to 86.3; and
- NFPA 30B, Code for the Manufacture and Storage of Aerosol Products, 2007 Edition. (GHS, 5th revised edition, 2013, paragraph 2.3.4.2.1)

Discussion of the *Hazardous Products Regulations*
Subsection 7.3.1(2)

Default category

7.3.1(2) A product that contains flammable components in an aerosol dispenser for which there are no test results in accordance with subparagraph 2.1(a)(i) and referred to in subsection (1) must be classified in the category "Flammable Aerosols – Category 1", unless the product contains flammable components at a concentration less than or equal to 1.0% and has a heat of combustion less than 20 kJ/g.

When a product is not tested and it contains flammable components (liquids, gases or solids) in an aerosol dispenser, the product must be classified in Flammable Aerosols — Category 1. The only exception is when the aerosol dispenser contains the flammable components at a concentration ≤ 1.0% and has a heat of combustion of < 20 kJ/g. In that case, the product need not be classified in this hazard class.

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for Flammable Aerosols are provided in in section 3 of Annex 3 of the GHS, 5th revised edition, 2013, p. 311, subject to paragraphs 3(5)(c) and (d) of the HPR.

Classification of Flammable Aerosols

Examples

(GHS, 5th revised edition, 2013, paragraph 2.3.4.2.1)

Example 1:

The following example explains the classification process for a product suspected of being a flammable aerosol when data on flammable components and on the chemical heat of combustion are known.

Available data

The product FA1 is an aerosol with:

- Flammable components: 70% (by mass) butane/propane, 25% (by mass) ethanol
- Non-flammable components: 5%
- The chemical heats of combustion (ΔH_c) for gases in the mixture:
  - ΔH_c (butane/propane) = 43.5 kJ/g
  - ΔH_c (ethanol) = 24.7 kJ/g
  - ΔH_c (other non-flammable components) = 0 kJ/g

Classification

The product FA1 meets the criteria for Flammable Aerosols - Category 1.

Rationale

The heat of combustion (ΔH_c) can be calculated using the formula presented below:

ΔH_c (product) = $\sum_{i}^{n}$ [w_i % x $\Delta H_{c(i)}$]

ΔH_c (FA1) = [w_i% x $\Delta H_{c(i)}$ for butane/propane] + [w_i% x $\Delta H_{c(i)}$ for ethanol] + [w_i% x $\Delta H_{c(i)}$ for the non-flammable components]

ΔH_c (FA1) = [0.70 x 43.5] + [0.25 x 24.7] + [0.5 x 0] = 30.45 + 6.175 + 0 = 36.6

The information gathered is then compared to the classification criteria:

1. Does FA1 contain ≤1% flammable components and does it have a heat of combustion < 20 kJ/g?

   No. It has 95% flammable components and the heat of combustion is 36.6 kJ/g. Therefore it is subject to classification in this hazard class.

2. Does FA1 contain ≥ 85% flammable components and does it have a heat of combustion ≥ 30 kJ/g?

   Yes. It has 95% flammable components and the heat of combustion is 36.6 kJ/g.

Therefore, product FA1 is classified in Flammable Aerosols – Category 1.

Example 2:

In this example, data on flammable components, the chemical heats of combustion and the results of the ignition distance test (for spray aerosols) are known.

Available data

The product FA2 is a spray aerosol with:

- Flammable components: 30% (by mass) butane/propane
- Non-flammable components: 70% (by mass)
- The chemical heats of combustion (ΔH_c) for gases in the mixture:
  - ΔH_c (butane/propane) = 43.5 kJ/g
  - ΔH_c (other non-flammable components) = 0 kJ/g
- Results of the ignition distance test: ignition occurs at less than 75 cm but more than 15 cm.
- Results of enclosed space ignition test: not conducted

Classification

The product FA2 meets the criteria for Flammable Aerosols - Category 2.

Rationale

The heat of combustion (ΔH_c) can be calculated using the formula presented below

ΔH_c (product) = $\sum_{i}^{n}$ [w_i % x $\Delta H_{c(i)}$]

ΔH_c (FA2) = [w_i% x $\Delta H_{c(i)}$ for butane/propane] + [w_i% x $\Delta H_{c(i)}$ for the non-flammable components]

ΔH_c (FA2) = [0.30 x 43.5] + [0.7 x 0] = 13.05 + 0 = 13.1 kJ/g

The information gathered is then compared to the classification criteria:

1. Does FA2 contain ≤ 1% flammable components and does it have a heat of combustion < 20 kJ/g?

   No: it has 30% flammable components and the heat of combustion is 13.1 kJ/g. Therefore it is subject to classification in this hazard class.
2. Does FA2 contain ≥ 85% flammable components and does it have a heat of combustion ≥ 30 kJ/g?

   No: FA2 has 30% flammable components and the heat of combustion is 13.1 kJ/g
3. In the ignition distance test, does ignition occur at a distance ≥ 75 cm?

   No. Ignition occurred at less than 75 cm and more than 15 cm
4. Does FA2 have a heat of combustion < 20 kJ/g?

   Yes. The heat of combustion is 13.1 kJ/g
5. In the ignition distance test, does ignition occur at a distance ≥ 15 cm?

   Yes. The ignition occurs at less than 75 cm but more than 15 cm

Therefore, product FA1 is classified in Flammable Aerosols – Category 2.

Example 3:

In this example, data on flammable components, the chemical heats of combustion and the results of the foam test (for foam aerosols) are known:

Available data

Product FA3 is a foaming aerosol with:

- Flammable components: 4% (by mass) butane/propane
- Non-flammable components: 96%
- The chemical heats of combustion (ΔH_c) for gases in the mixture:
  - ΔH_c (butane/propane) = 43.5 kJ/g
  - ΔH_c (other non-flammable components) = 0 kJ/g
- Results of the foam test: the flame height is less than 4 cm and the flame duration is less than 2 seconds

Classification

The product FA3 does not meet any of the criteria for Flammable Aerosols.

Rationale

The heat of combustion (ΔH_c) can be calculated using the formula presented below:

ΔH_c (product) = $\sum_{i}^{n}$ [w_i % x $\Delta H_{c(i)}$]

ΔH_c (FA3) = [w_i% x $\Delta H_{c(i)}$ for butane/propane] + [w_i% x $\Delta H_{c(i)}$ for the non-flammable components]

ΔH_c (FA3) = [0.04 x 43.5] + [0.96 x 0] = 1.74 + 0 = 1.7 kJ/g

The information gathered is then compared to the classification criteria:

1. Does FA3 contain ≤ 1% flammable components and does it have a heat of combustion < 20 kJ/g?

   No. FA3 has 4% flammable components and the heat of combustion is 1.7 kJ/g.

2. Does FA3 contain ≥ 85% flammable components and does it have a heat of combustion ≥ 30 kJ/g?

   No. FA3 has 4% flammable components and the heat of combustion is 1.7 kJ/g

3. In the foam test, is

   a) the flame height ≥ 20 cm and the flame duration ≥ 2 seconds; or

   b) is the flame height ≥ 4 cm and the flame duration ≥ 7 seconds?

   No. In the foam test, the flame height is less than 4 cm and the flame duration less than 2 seconds.

4. In the foam test, is the flame height ≥ 4 cm and the flame duration ≥ 2 seconds?

   No. In the foam test, the flame height is less than 4 cm and the flame duration less than 2 seconds.

Therefore, product FA3 is not classified in the Flammable Aerosols hazard class.

Subpart 4
Oxidizing Gases

Definition of "oxidizing gas"

7.4 In this Subpart, "oxidizing gas" means a gas that is liable to cause or contribute to the combustion of other material more than air does.

Discussion – Oxidizing Gas and Oxidizer

In general terms, an oxidizer is a chemical that brings about an oxidation reaction. An oxidizing reaction means:

- the oxidizer provides oxygen to the substance being oxidized (in which case the oxidizer has to be oxygen or contain oxygen), or
- the oxidizer receives electrons from the substance being oxidized (e.g., chlorine is a good oxidizer for electron-transfer purposes, even though it contains no oxygen).

Oxidizers can initiate or greatly accelerate the combustion of other materials. The most common oxidizer is atmospheric oxygen. "A gas that is liable to cause or contribute to the combustion of other materials more than air does" means that the gas or gas mixture has an oxidizing power of greater than 23.5%. This value is associated with the quantity of oxygen in air. Oxygen makes up approximately 21% by volume of the composition of air. When a gas has an oxidizing power of greater than 23.5% it exceeds the contribution of air alone and is then considered an oxidizing gas.

Comparison to HCS 2012 and GHS

The definition in the HPR differs slightly from the one in the GHS, 5th revised edition, 2013, paragraph 2.4.1 and the one in the HCS 2012. The words "generally by providing oxygen", which are included in the GHS and the HCS 2012, are not included in the HPR. Providing oxygen is not required in order for a gas to be classified as an oxidizing gas. Therefore, the words "generally providing oxygen" do not limit the definition and are not necessary. The slightly different wording used in the definition of "oxidizing gas" in the HPR as compared to the GHS and the HCS 2012 does not have any impact on classification.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Section 7.4.1

Category

7.4.1 An oxidizing gas is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Oxidizing Gases — Category 1**	**A gas that has an oxidizing power > 23.5% based on one of the methods set out in the International Organization for Standardization standard ISO 10156:2010 entitled *Gases and gas mixtures — Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*, as amended from time to time**

To classify an oxidizing gas, data from tests or calculation methods as described in ISO 10156:2010 "*Gases and gas mixtures – Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets*" must be used.

ISO 10156:2010 specifies methods for determining whether or not a gas or gas mixture is flammable in air, and whether a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The methods are intended to be used for the classification of pure gaseous substances and gas mixtures.

Comparison to HCS 2012

The HCS 2012 refers to the use of the following test methods:

- ISO 10156:1996, "Gases and gas mixtures – Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets" and
- ISO 10156-2:2005, "Gas cylinders, Gases and gas mixtures. Part 2: Determination of oxidizing ability of toxic and corrosive gases and gas mixtures"
- An equivalent validated method to either of the above.

ISO 10156:1996 and ISO 10156-2:2005 have both been revised and replaced by ISO 10156:2010. In comparing ISO 10156:1996 and ISO 10156-2:2005 it was noted that the oxygen index used in the calculation changed from 21% (ISO 10156:1996 and ISO 10156-2:2005) to less than 23.5% (ISO 10156:2010). Consequently, gases having an oxidizing power of 21% and up to 23.5% will be classified in the Oxidizing Gases hazard class under the HCS 2012 will not be required to be classified as such under the HPR. However, any gases having an oxidizing power of more than 23.5% will be classified in the Oxidizing Gases hazard class when following the requirements of the HCS 2012 or the HPR. In addition, it is important to note that Health Canada

would not object to a hazardous product having an oxidizing power between 21% and 23.5% being classified in the Oxidizing Gases hazard class under the HPR.

Hazard Communication

The symbol, signal word, as well as hazard and precautionary statements for "Oxidizing Gases" are specified in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, p. 313).

Classification of an Oxidizing Gas Mixture by Calculation According to ISO 10156:2010

Example

(GHS, 5th revised edition, 2013, paragraph 2.4.4.2)

The method described in ISO 10156:2010 uses the criterion that a gas mixture should be considered as more oxidizing than air if the oxidizing power of the gas mixture is higher than 0.235 (23.5%).

Formula for Calculating Oxidizing Power

The oxidizing power (OP) is calculated as follows:

$$OP = \frac{\sum_{i=1}^{n} X_i C_i}{\sum_{i=1}^{n} X_i + \sum_{k=1}^{p} K_k B_k}$$

Where:

X_i = molar fraction of the i^{th} oxidizing gas in the mixture;

C_i = coefficient of oxygen equivalency of the i^{th} oxidizing gas in the mixture;

K_k = coefficient of equivalency of the inert gas k compared to nitrogen;

B_k = molar fraction of the k^{th} inert gas in the mixture;

n = total number of oxidizing gases in the mixture and i is running from 1 to n;

p = total number of inert gases in the mixture and k is running from 1 to p;

Example mixture: 9% (O_2) + 16% (N_2O) + 75% (He)

Available data

If the coefficient of oxygen equivalency (C_i) for the oxidizing gases in the mixture and the nitrogen equivalency factors (K_k) for the non-flammable, non-oxidizing gases are known, the oxidizing power can be calculated. In this example, the values are:

C_i (N_2O) = 0.6 (nitrous oxide)

C_i (O_2) = 1 (oxygen)

K_k (He) = 0.9 (helium)

The information gathered is then used to complete the calculation:

$$OP = \frac{0.09x1 + 0.16x0.6}{0.09 + 0.16 + 0.75x0.9} = 0.201$$

OP = 0.201 = 20.1%. The oxidizing power of the gas mixture is 20.1%.

Classification

The mixture does not meet the criteria for classification in Oxidizing Gas – Category 1.

Rationale

1. The calculated oxidizing power of the gas mixture is 20.1%, which is less than the value of >23.5% required for classification.

Subpart 5
Gases Under Pressure

Definitions

7.5 The following definitions apply in this Subpart.

"critical temperature" means the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

"gas under pressure" means a product that consists of a gas contained in a receptacle at a gauge pressure of 200 kPa or more at 20°C, or that is liquefied, or liquefied and refrigerated, but excludes any gas that has an absolute vapour pressure of not more than 300 kPa at 50°C or that is not completely gaseous at 20°C and the standard pressure of 101.3 kPa.

Discussion – Gas Under Pressure

Subsection 1(1) of the HPR provides the definition for "gas" which "means a mixture or substance that

a) at 50°C has an absolute vapour pressure of greater than 300 kPa; or

b) is completely gaseous at 20°C and at the standard pressure of 101.3 kPa."

Because the definition of "gas under pressure" refers to a "gas", it excludes any substance or mixture that does not meet the definition of "gas" in the HPR.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations* Section 7.5.1

Categories

7.5.1 A gas under pressure is classified in a category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	Gases Under Pressure — Compressed Gas	A gas that when packaged under pressure is entirely gaseous at -50°C, including all gases with a critical temperature ≤ -50°C
2	Gases Under Pressure — Liquefied Gas	A gas that when packaged under pressure is partially liquid at temperatures > -50°C
3	Gases Under Pressure — Refrigerated Liquefied Gas	A gas that when packaged is partially liquid because of its low temperature
4	Gases Under Pressure — Dissolved Gas	A gas that when packaged under pressure is dissolved in a liquid phase solvent

To classify gases under pressure in this hazard class, the following information is required:

- the vapour pressure at 50 °C,
- the physical state at 20 °C, and at standard pressure (101.3 kPa), and
- the critical temperature.

This data can be found in literature, calculated or determined by testing. In addition, most pure gases are already classified in the UN Recommendations on the Transport of Dangerous Goods, Model Regulations. (GHS, 5th revised edition, 2013, paragraph 2.5.4.2) No test methods are specified in the criteria for the classification of Gases Under Pressure.

Gases under pressure are classified in one of four categories, according to their physical state when packaged, as shown in section 7.5.1. The criteria apply to products that are gases, as defined by the HPR. The classification in one of the categories of the Gases Under Pressure hazard class depends on the characteristics of the gas “when packaged under pressure” or “when packaged”. Classification in this hazard class also requires knowledge of the physical form of the gas (i.e., entirely gaseous, partially liquid due to pressure or low temperature, or dissolved in liquid phase) when packaged. The same gaseous substance or mixture could be classified in a different category (i.e., Compressed Gas, Liquefied Gas, Refrigerated Liquefied Gas OR Dissolved Gas) depending on its packaging.

Note: If the gas is not contained in a receptacle at a pressure of 200 kPa or more at 20°C, or is not liquefied, or is not liquefied and refrigerated, then the gas does not meet the definition of gas under pressure specified in section 7.5 of the HPR and therefore, is not classified in Gases Under Pressure.

Gases under pressure need to be considered for classification in all other hazard classes relevant to gases, such as the physical hazard classes Flammable Gases, Oxidizing Gases and Simple Asphyxiants, where relevant.

Comparison to HCS 2012 and GHS

The GHS, 5th revised edition, 2013 and the HCS 2012 distinguish between liquefied gases that are high pressure liquefied gases and low pressure liquefied gases. The HPR does not distinguish between high pressure and low pressure liquefied gases because there is no difference for hazard classification or hazard communication for high pressure versus low pressure liquefied gases.

Hazard Communication

The symbol, signal word as well as hazard and precautionary statements for "Gases under Pressure" are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013 on p. 314 for Compressed Gas, Liquefied Gas and Dissolved Gas, and p. 315 for Refrigerated Liquefied Gas.

Classification of Gases Under Pressure

Examples

Example 1: A Substance that is Not Classified

Available data

The substance has a vapour pressure of 200 kPa at 50 °C and is not completely gaseous at 20 °C and standard pressure (101.3 kPa).

Classification

The substance does not meet the criterion for classification as a Gas Under Pressure.

Rationale

1. Does the substance meet the definition of a "gas" under the HPR?
   No. The vapour pressure of the gas at 50 °C is 200 kPa which is not greater than 300 kPa, and the gas is not completely gaseous at 20°C and 101.3 kPa.

The gas does not meet the definition of a gas specified in subsection 1(1) of the HPR and therefore is not considered for classification as a gas under pressure.

Example 2: Compressed Gas

Available data

- The substance is a gas.
- The substance is contained in a receptacle at a pressure of >200 kPa at 20 °C.
- The vapour pressure at 50 °C is > 410 kPa.
- When packaged under pressure, the substance is entirely gaseous at -50 °C; and
- The critical temperature is -240.1 °C.

Classification

The gas meets the criterion for classification as a Gases Under Pressure - Compressed Gas.

Rationale

1. Is the substance a gas?
   The substance is described as a gas, although extra information is provided.
2. Does the gas meet the definition of “gas under pressure”?
   Yes. The gas is contained in a receptacle at a pressure of 200 kPa or more at 20 °C, and has a vapour pressure at 50 °C of 410 kPa.
3. Does the gas meet the criterion for Dissolved Gas?
   No. The gas is not dissolved in a liquid solvent under pressure.
4. Does the gas meet the criterion for Refrigerated Liquefied Gas?
   No. The gas is not partially liquid because of its low temperature given that when packaged under pressure, it is entirely gaseous at -50 °C.
5. Does the gas meet the criterion for Liquefied Gas?
   No. The gas is not partially liquid at temperatures above -50 °C given that when packaged under pressure, it is entirely gaseous at -50 °C.
6. Does the gas meet the criterion for Compressed Gas?
   Yes. The gas when packaged under pressure is entirely in gaseous state at -50 °C and has a critical temperature of -240.1 °C. A Compressed Gas is a gas which when packaged under pressure is entirely gaseous at -50 °C including all gases with a critical temperature ≤ -50 °C.

Example 3: Liquefied Gas

Available data

- The substance is a gas with a vapour pressure of 290 kPa at 50 °C.
- The substance is completely gaseous at 20 °C and standard pressure.
- The gas is not entirely gaseous at -50 °C.
- The critical temperature is 75.3 °C.
- The gas is contained in a receptacle at a pressure of 200 kPa or more at 20 °C.

Classification

The gas is meets the criterion to be classified in Gases Under Pressure - Liquefied Gas.

Rationale

1. Does the substance meet the definition for gas?
   Yes. The substance is completely gaseous at 20 °C and 101.3 kPa.
2. Does the gas meet the definition of “gas under pressure”?
   Yes. The gas is contained in a receptacle at a pressure of 200 kPa or more at 20 °C, and has a vapour pressure at 50 °C of 290 kPa.
3. Does the gas meet the criterion for Dissolved Gas?
   No. The gas when packaged under pressure is not dissolved in a liquid solvent under pressure.
4. Does the gas meet the criterion for Refrigerated Liquefied Gas?
   No. The gas when packaged under pressure is not partially liquid because of its low temperature.
5. Does the gas meet the criterion for Compressed Gas?
   No. The gas is not entirely gaseous at -50 °C; and the critical temperature is 75.3 °C which is not ≤ -50 °C.
6. Does the gas meet the criterion for Liquefied Gas?
   Yes. The gas when packed under pressure is not entirely in gaseous state at 50 °C.
   A liquefied gas is a gas which when packaged under pressure is partially liquid at temperatures above -50 °C.

Subpart 6
Flammable Liquids

Definitions

7.6 The following definitions apply in this Subpart.

"appropriate closed-cup method" means the methods listed in paragraph 2.6.4.2.5 of the GHS, as amended from time to time.

"flammable liquid" means a liquid that has a flash point of not more than 93 °C.

Discussion - Appropriate Closed-Cup Method

A "closed-cup method" refers to a method in which a liquid's vapour is enclosed in the space above the liquid being tested, such that the vapour cannot dissipate. (Open-cup techniques, where the vapour can dissipate, tend to yield flash points with values higher than those obtained with closed-cup methods.) The term "appropriate closed-cup methods" used in subsections 7.6.1(3) and (4) of the HPR, currently refers to the 10 methods listed in the GHS, 5th revised edition, 2013, paragraph 2.6.4.2.5, namely:

- The *International Organization for Standardization* (ISO) methods:
  - 1516 - Determination of flash/no flash - Closed cup equilibrium method
  - 1523 - Determination of flash point - Closed cup equilibrium method
  - 2719 - Determination of flash point - Pensky-Martens closed cup method
  - 13736 - Determination of flash point - Abel closed-cup method
  - 3679 - Determination of flash point - Rapid equilibrium closed cup method,
  - 3680 - Determination of flash/no flash - Rapid equilibrium closed cup method

- The *American Society for Testing Materials* (ASTM) methods:
  - D3828-07a - Standard Test Methods for Flash Point by Small Scale Closed Cup Tester
  - D56-05 - Standard Test Method for Flash Point by Tag Closed Cup Tester
  - D3278-96(2004)e1 - Standard Test Methods for Flash Point of Liquids by Small Scale Closed Cup Apparatus
  - ASTM D93-08 - Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.6.1(1)

Exclusions

7.6.1(1) Any product that is classified in a category of the hazard class "Flammable Aerosols" need not be classified in any category of this hazard class.

If a product is classified in the Flammable Aerosol hazard class, it need not be classified in the Flammable Liquid hazard class. The definition of "flammable aerosol" and the criteria for classification in the Flammable Aerosols hazard class are found in sections 7.3 and 7.3.1 of the HPR, respectively.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.6.1(2)

Categories

7.6.1(2) A flammable liquid is classified in a category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Flammable Liquids — Category 1	A liquid that has a flash point < 23°C and initial boiling point ≤ 35°C
2	Flammable Liquids — Category 2	A liquid that has a flash point < 23°C and initial boiling point > 35°C
3	Flammable Liquids — Category 3	A liquid that has a flash point ≥ 23°C and ≤ 60°C
4	Flammable Liquids — Category 4	A liquid that has a flash point > 60°C and ≤ 93°C

Subsection 7.6.1 (2) provides the numeric cut-off criteria for classifying a substance or mixture in one of the four categories of the Flammable Liquids hazard class.

To classify a substance or mixture in the Flammable Liquids hazard class, data, as determined using standardized methods, are needed on:

- flash point and initial boiling point, for classification in Category 1 and Category 2, and
- flash point, for classification in Category 3 and Category 4.

Discussion of the *Hazardous Products Regulations*
Subsection 7.6.1(3)

Determination of flash point - substance

7.6.1(3) In the case of a liquid that is a substance, the flash point must be determined by

(a) tests using an appropriate closed-cup method; or

(b) use of scientific literature that reports a value obtained from an appropriate closed-cup method.

Subsection 7.6.1(3) indicates the relevant information that is appropriate for the determination of the flash point for a substance.

The 10 appropriate closed-cup methods for the determination of the flash point are detailed under the definition “appropriate closed-cup method” in section 7.6. Flash point data reported in the scientific literature and that were obtained by any of the 10 “appropriate closed-cup methods” can also be used in place of experimental determination.

Discussion of the *Hazardous Products Regulations*
Subsection 7.6.1(4)

Determination of flashpoint – mixture

7.6.1(4) In the case of a liquid that is a mixture, the flash point must be determined by

(a) tests using an appropriate closed-cup method; or

(b) use of an applicable calculation method under conditions for which it has been validated according to generally accepted standards of good scientific practice at the time the validation was carried out.

Subsection 7.6.1 (4) indicates the relevant information that is appropriate for the determination of the flash point for a mixture.

The titles of 10 appropriate closed-cup methods for the determination of the flash point are provided under the definition “appropriate closed-cup method” in section 7.6. Also, a calculation method may be used only if the method has been validated for the type of mixture that is being assessed. There is only one validated calculation method currently available for determining the flash point of a mixture. The GHS 5th revised edition, 2013, paragraphs 2.6.4.2.2 and 2.6.4.2.3 outline the requirements and restrictions of this method.

Hazard Communication

The symbols, signal words as well as hazard and precautionary statements for Flammable Liquids Categories 1 to 4 are provided in Section 3 of Annex 3 of the GHS 5th revised edition, 2013 on pp. 316-317.

Classification of Flammable Liquids

Examples

Example 1:

Available data

- Diethyl ether (CAS# 60-29-7): Flash point (closed cup) = -40 °C; initial boiling point = 34.5 °C

Classification

- Meets criteria for classification in Flammable Liquids - Category 1

Rationale

- Flash point is <23°C and the initial boiling point ≤35°C

Example 2:

Available data

- Pentane (CAS# 109-66-0): Flash point (closed cup) < -40 °C; initial boiling point = 36 °C

Classification

- Meets criteria for classification in Flammable Liquids - Category 2

Rationale

- Flash point is <23°C and the initial boiling point >35°C

Example 3:

Available data

- Cyclohexanone (CAS# 108-94-1): Flash point (closed cup) = 47°C

Classification

- Meets criteria for classification in Flammable Liquids - Category 3

Rationale

- Flash point is ≥23°C and ≤60°C

Example 4:

Available data

- 2-Mercaptoethanol (CAS# 60-24-2): Flash point (closed cup) = 67°C

Classification

- Meets criteria for classification in Flammable Liquids - Category 4

Rationale

- Flash point is >60°C and ≤93°C

Subpart 7
Flammable Solids

Definitions

7.7 The following definitions apply in this Subpart.

"flammable solid" means a readily combustible solid or a solid that is liable to cause or contribute to fire through friction.

"readily combustible solid" means a powdered, granular or pasty mixture or substance that can be easily ignited by brief contact with an ignition source and, when ignited, has a flame that spreads rapidly.

Discussion

A solid can have many physical forms (e.g., dusts, particulates, granules, ingots, massive solids) that can differ in the surface area available for chemical reactions. The finer the particle size of a solid, the greater the surface area exposed to air. Since flammability is a reaction with the oxygen in the air, the particle size will greatly influence the ability of a solid to ignite.

Many organic solids meet the criteria to be classified in the Flammable Solids hazard class; however, it is rare for inorganic solids to be classified in the Flammable Solids hazard class. The exception is powders of metals or metal alloys. Metal powders are especially dangerous because normal extinguishing agents such as carbon dioxide or water can increase the hazard when used to extinguish a fire (United Nations Transport of Dangerous Goods, Model Regulations, 2015, paragraph 2.4.2.2.1.2). The classification criteria outlined in the HPR for Flammable Solids assess metal powders separately from other solids.

Classification in the Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.7.1(1)

Exclusions

7.7.1(1) Any product that is classified in a category of the hazard class "Flammable Aerosols" need not be classified in any category of this hazard class.

If a product is classified in the Flammable Aerosols hazard class, it need not also be classified in the Flammable Solids hazard class. The definition of a "flammable aerosol" and the criteria for classification in the Flammable Aerosols hazard class are found in sections 7.3 and 7.3.1 of the HPR, respectively.

Discussion of the *Hazardous Products Regulations*
Subsection 7.7.1(2)

Categories

7.7.1(2) A flammable solid that is a readily combustible solid is classified in a category of this hazard class, based on results from testing performed in accordance with the burning rate test in sub-section 33.2.1 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Flammable Solids – Category 1**	**A solid that is** **(a) other than a metal powder, in respect of which** **(i) the burning time is < 45 s or the burning rate is > 2.2 mm/s, and** **(ii) the wetted zone does not stop the fire or stops the fire for less than 4 min; or** **(b) a metal powder, in respect of which the burning time is ≤ 5 min**
2	**Flammable Solids – Category 2**	**A solid that is** **(a) other than a metal powder, in respect of which** **(i) the burning time is < 45 s or the burning rate is > 2.2 mm/s, and** **(ii) the wetted zone stops the fire for at least 4 min; or** **(b) a metal powder, in respect of which the burning time is > 5 min and ≤ 10 min**

If testing is done, it must be performed using test N.1 of sub-section 33.2.1 of Part III of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, as amended from time to time, where a complete description of the method and analysis of the test results are described. The UN method consists of two tests: a preliminary screening test and a burning rate test (GHS, 5th revised edition, 2013, paragraph 2.7.4). The screening test is performed to determine if, on ignition by a gas flame, propagation by burning with flame or smouldering occurs. If propagation occurs within a specified time then the full test is carried out to determine the rate and vigour of burning. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 33.2.1.3.1)

Classification and categorization for metal powders is determined based on burn time alone. If the reaction spreads over the whole length of the sample in 10 minutes or less, it meets the criteria to be classified in the Flammable Solids hazard class. If the burn time is 5 minutes or less, the metal powder falls into Category 1. If the burn time is more than 5 minutes but not more than 10 minutes, the metal powder is classified in Category 2.

Classification and categorization for all other solids is determined based on burn time as well as the ability or inability of the wetted zone to stop the flame propagation. The burn time must be less than 45 seconds, or the burn rate greater than 2.2 mm/s, to meet the criteria to classify as a Flammable Solid. If the burn time is less than 45 seconds, or the burn rate greater than 2.2 mm/s and the wetted zone is unable to stop the fire or stops the fire for less than 4 minutes, the solid falls into Category 1. If the burn time is less than 45 seconds, or the burn rate is greater than 2.2 mm/s, and the wetted zone stops the fire for 4 minutes or longer, the solid is classified in Category 2.

Comparison to HCS 2012 and GHS

There is a minor difference in the classification criteria between the HPR and the GHS, 5th revised edition, 2013 and HCS 2012. The GHS, 5th revised edition, 2013 and HCS 2012 require that the wetted zone not stop the fire for Flammable Solids – Category 1, and that the wetted zone stops the fire for at least 4 minutes for Flammable Solids - Category 2. The HPR adds the following for a Category 1 classification "the wetted zone does not stop the fire or stops the fire for less than 4 minutes" because there is a possibility that the wetted zone could stop the fire for less than 4 minutes (i.e., between 0 and 4 minutes). It is anticipated that substances and mixtures that classify in the Flammable Solids hazard class according to the HPR, in either Category 1 or Category 2, will classify the same way according to HCS 2012.

Discussion of the *Hazardous Products Regulations*
Subsection 7.7.1(3)

Fire through friction

7.7.1(3) A flammable solid that is a solid that is liable to cause or contribute to fire through friction is classified in the category "Flammable Solids — Category 2".

Comparison to HCS 2012 and GHS

The GHS, 5th revised edition, 2013 and HCS 2012 specify that solids which may cause fire through friction should be classified by "analogy with existing entries (e.g., matches)" until definitive criteria are established (GHS, 5th revised edition, 2013, paragraph 2.7.2.3). The terms "existing entries" refers to classifications under transport regulations. The GHS and HCS 2012 do not specify in what category this type of flammable solid would be classified. However, "matches" are classified for transport as Class 4.1 Packing Group III by U.S. Department of Transport, which would align with Flammable Solids – Category 2.

Subsection 7.7.1(3) of the HPR specifies that any flammable solid that is liable to cause or contribute to fire through friction must be classified in Category 2.

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for Flammable Solids Category 1 and Category 2 are specified in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013 on p. 318.

Classification of Flammable Solids

Example

(ECHA Guidance, 2015, paragraph 2.7.7.1)

Available data

- Substance X is not a metal powder.
- Based on the screening test, Substance X will burn or smoulder when in contact with a flame and is a candidate for classification as a flammable solid and further consideration is required.
- According to test N.1 of sub-section 33.2.1 of Part III of the Manual of Tests and Criteria, 6 runs were performed and the resulting burning times for a distance of 100 mm were obtained (in seconds): 44, 40, 49, 45, 37, 41. The wetted zone stopped the fire without reignition.

Classification

- Substance X meets the criteria to be classified in the Flammable Solids - Category 2 hazard class.

Rationale

- The shortest burning time is less than 45 seconds, therefore Substance X meets one of the criteria specified in the Table to subsection 7.7.1(2) of the HPR.
- The wetted zone stopped the fire completely (meeting the minimum time of 4 minutes), therefore Substance X is classified in Category 2.

Subpart 8
Self-Reactive Substances and Mixtures

Definitions

7.8 The following definitions apply in this Subpart.

"as packaged" means packaged in the form and condition described in test series B, D, G and H of Part II of the Manual of Tests and Criteria.

"explosive properties" means the properties of a self-reactive substance or mixture that, in laboratory testing according to test series A, C or E of Part II of the Manual of Tests and Criteria, make the substance or mixture liable to detonate, deflagrate rapidly or show a violent effect when heated under confinement.

"self-reactive" means, in relation to a thermally unstable liquid or solid product, mixture or substance, liable to undergo a strongly exothermic decomposition, having a heat of decomposition equal to or greater than 300 J/g, even without participation of oxygen.

Discussion – As Packaged

The methodology of the test series (i.e., series B, D, G and H of the Manual of Tests and Criteria) used to classify self-reactive substances and mixtures requires that the substance or mixture be tested in the condition and form in which it is offered for transport or "**as packaged**". (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-sections 22.1, 24.1, 27.1, 28.1)

Discussion - Explosive Properties

The above definition for **explosive properties** is derived from the following statement from the GHS:

> "A self-reactive substance or mixture is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement." (GHS, 5th revised edition, 2013, paragraph 2.8.1.2)

The test methods are included in the definition given in section 7.8 of the HPR because results from these tests are used to conclude whether a substance or mixture has explosive properties for the purposes of this subpart.

Discussion – Self-Reactive

The statement "having a heat of decomposition equal to or greater than 300 J/g" is included to the HPR definition to more clearly define the phrase "strongly exothermic", used in the same definition.

Self-reactive substances and mixtures vary considerably in their properties and formulations. Certain chemical groups, however, are indicative of self-reactive properties (United Nations Transport of Dangerous Goods, Model Regulations, 19th revised edition, 2015, paragraph 2.4.2.3.1.2) and include:

- Aliphatic azo compounds (-C-N=N-C-);
- Organic azides (-C-N_3);
- Diazonium salts (-CN_2+Z-);
- N-nitroso compounds (-N-N=O); and
- Aromatic sulfohydrazides (-SO_2-NH-NH_2).

Note: The above is not an exhaustive list. Substances with other reactive groups, combinations of groups and some mixtures of substances may have similar properties. Additional information on self-reactive properties is given in the Manual of Tests and Criteria, Appendix 6 – *Screening Procedures*. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, Appendix 6, sub-section 5.1)

All self-reactive substances and mixtures undergo strong exothermic decomposition that "…can be initiated by heat, contact with catalytic impurities (e.g., acids, heavy-metal compounds, and bases), friction, or impact. The rate of decomposition increases with temperature and varies with the substance or mixture. Decomposition, particularly if no ignition occurs, may result in the evolution of toxic gases or vapours. For certain self-reactive substances and mixtures, the temperature must be controlled during storage and handling. Some self-reactive substances and mixtures may decompose explosively, particularly if confined. This characteristic may be modified by the addition of diluents or by the use of appropriate packaging. Some self-reactive substances and mixtures burn vigorously." (United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, 19th revised edition, 2015, paragraph 2.4.2.3.1.2)

Other applicable definitions

The following terms are used in this chapter. Its definition appears under Part I, Interpretation of the HPR:

> **"Manual of Tests and Criteria" means the United Nations document entitled *Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria*, as amended from time to time.**

This definition specifies that the document is "amended from time to time", this means that the classification must be based on the test series contained in the most recent version of the document.

"SADT" or "self-accelerating decomposition temperature" means the lowest temperature at which self-accelerating decomposition occurs.

Discussion – SADT

Self-reactive substances or mixtures when held at moderate ambient temperatures for an extended period of time undergo self-heating as a result of slow thermal degradation. This exothermic reaction accelerates with increasing temperature. If the heat does not dissipate into the environment as quickly as it is generated, the resulting increase in temperature will further intensify the rate of decomposition. Unchecked, the temperature can increase exponentially to a point where decomposition cannot be stopped. This reaction creates a dangerous situation known as **self-accelerating decomposition**.

The self-accelerating decomposition temperature (SADT) is the lowest temperature at which a packaged self-reactive substance or mixture will undergo a self-accelerating decomposition. "The SADT is a measure of the combined effect of the ambient temperature, decomposition kinetics, package size and the heat transfer properties of the substance and its packaging." (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.4.1.3)

Four tests are described in the Manual of Tests and Criteria for determining the SADT:

- United States SADT test
- Adiabatic storage test (AST)
- Isothermal storage test (IST)
- Heat accumulation storage test

A detailed description of the test methods is provided in the Manual of Tests and Criteria. These test methods or any other suitable validated test method may be used to determine the SADT.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.8.1(1)

Exclusions

7.8.1(1) The following need not be classified in any category of this hazard class:

(a) mixtures or substances, or mixtures or substances as packaged, that are classified in a category of the hazard class "Organic Peroxides";

(b) liquid or solid mixtures that are classified in a category of the hazard class "Oxidizing Liquids" or "Oxidizing Solids", and contain less than 5.0% of combustible organic substances; and

(c) liquid or solid substances that are classified in a category of the hazard class "Oxidizing Liquids" or "Oxidizing Solids".

Subsection 7.8.1(1) of the HPR details the exclusion criteria for substances and mixtures that do **not** need to be classified in the Self-Reactive Substances and Mixtures hazard class. The exclusion criteria are as follows:

- substances and mixtures that are classified as Organic Peroxides under section 7.15 of the HPR;
- mixtures that are classified as Oxidizing Liquids or Oxidizing Solids under sections 7.13 and 7.14 of the HPR respectively, if they contain <5.0 % of combustible organic substances; and
- substances that are classified as Oxidizing Liquids or Oxidizing Solids under section 7.13 or 7.14 of the HPR respectively.

Discussion of the *Hazardous Products Regulations*
Subsection 7.8.1(2)

Categories

7.8.1(2) Subject to subsection (3), a self-reactive substance or mixture is classified in a category of this hazard class, based on results from testing performed in accordance with test series A to H of Part II of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Self-reactive Substances and Mixtures — Type A	A liquid or solid that, as packaged, is liable to detonate, or deflagrate rapidly
2	Self-reactive Substances and Mixtures — Type B	A liquid or solid that possesses explosive properties and, as packaged, neither detonates, nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package
3	Self-reactive Substances and Mixtures — Type C	A liquid or solid that possesses explosive properties and, as packaged, neither detonates, nor deflagrates rapidly, nor undergoes a thermal explosion in that package
4	Self-reactive Substances and Mixtures — Type D	In laboratory testing, a liquid or solid that (a) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; (b) does not detonate, deflagrates slowly and shows no violent effect when heated under confinement; or (c) neither detonates nor deflagrates, and shows a medium effect when heated under confinement
5	Self-reactive Substances and Mixtures — Type E	In laboratory testing, a liquid or solid that neither detonates nor deflagrates, and shows low or no effect when heated under confinement
6	Self-reactive Substances and Mixtures — Type F	In laboratory testing, a liquid or solid that neither detonates in the cavitated state nor deflagrates and (a) shows low or no effect when heated under confinement, as well as low or no explosive power; or (b) shows no effect when heated under confinement nor any explosive power, and either (i) has a SADT < 60°C when evaluated in a 50 kg package, or (ii) in the case of a liquid mixture, has a diluent that is used for desensitization with a boiling point < 150°C
7	Self-reactive Substances and Mixtures — Type G	In laboratory testing, a liquid or solid that neither detonates in the cavitated state nor deflagrates, shows no effect when heated under confinement nor any explosive power, and either (a) has a SADT of 60°C to 75°C when evaluated in a 50 kg package, or (b) in the case of a liquid mixture, has a diluent that is used for desensitization with a boiling point ≥ 150°C

Self-reactive substances and mixtures are classified into seven categories (Types A to G) according to the degree of danger they present as defined by their ability to detonate, to deflagrate, and to react while heated under confinement. Type A is the most severe hazard category while Type G is the least severe.

The criteria for Types A, B, and C specify that the self-reactive substance or mixture be tested "as packaged" since "stronger packaging may result in more violent reactions when the substance or mixture decomposes" (ECHA Guidance, 2015, paragraph 2.8.4.1). The words "in laboratory testing" in Types D, E, F and G criteria imply that the self-reactive substance or mixture is tested in its non-packaged form. Types F and G have conditional criteria that also require testing in a "50 kg package".

The Manual of Tests and Criteria provides guidance on screening substances and mixtures (Annex 6) before testing and is based on the potential of certain chemical groups to exhibit explosive or self-reactive properties. These chemical groups include:

Chemical groups indicating explosive properties of organic materials:

- C-C unsaturation (e.g., acetylenes, acetylides, 1,2-dienes)
- C-Metal, N-Metal (e.g., Grignard reagents, organo-lithium compounds)
- Contiguous nitrogen atoms (e.g., azides, aliphatic azo compounds, diazonium salts, hydrazines, sulphonyl hydrazides)
- Contiguous oxygen atoms (e.g., peroxides, ozonides)
- N-O (e.g., hydroxylamines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles)
- N-halogens (e.g., chloroamines, fluoroamines)
- O-halogens (e.g., chlorates, perchlorates, iodosyl compounds)

Chemical groups indicating self-reactive properties of organic materials:

- Mutually reactive groups (e.g., aminonitriles, haloanilines, organic salts of oxidizing acids)
- S=O (e.g., sulphonyl halides, sulphonyl cyanides, sulphonyl hydrazides)
- P-O (e.g., phosphites)
- Strained rings (e.g., epoxides, aziridines)
- Unsaturation (e.g., olefins, cyanates)

Desensitization, mentioned in the criteria for Types F and G, refers to the addition of a diluent to a self-reactive substance to increase its stability. The United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, 19th revised edition, 2015, paragraphs 2.4.2.3.5.2, 2.4.2.3.5.3 and 2.4.2.3.5.4 provide specifications for acceptable diluents.

Testing

If testing is done it must be performed using test series A to H as described in sections 20 to 28 of Part II of the Manual of Tests and Criteria, which are designed to answer the questions given in the flowchart (Figure 20.1(a) of the Manual of Tests and Criteria - *Flowchart Scheme for Self-Reactive Substances and Organic Peroxides*) and Decision Logic 2.8 for self-reactive substances and mixtures on p. 78 of the GHS.

The tests are performed in two stages. The first stage uses preliminary small-scale testing to determine the sensitivity of the substance or mixture to mechanical stimuli (impact and friction), and to heat and flame (United Nations Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.3.1). The preliminary testing consists of the following procedures:

a) a falling weight test to determine sensitiveness to impact,

b) a friction or impact test to determine the sensitiveness to friction,

c) a test to assess thermal stability and the exothermic decomposition energy, and

d) a test to assess the effect of ignition.

United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.3.2

The second stage of testing involves testing for classification purposes. Results from test series A to H are used to answer questions in the GHS Decision Logic 2.8 for self-reactive substances and mixtures (p. 78 of the GHS) relating to:

- Propagation of detonation,
- Propagation of deflagration,
- Effect on heating in confinement, and
- Thermal stability.

The sequence of test series A to H is based more on assessing results than on the order in which tests are actually conducted. The recommended sequence of laboratory scale testing is test series E, H, F, C and then A, although some tests may not be required. The package tests of test series B, D, and G only need to be performed if indicated by the results from the corresponding tests in test series A, C, and E. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-sections 20.4.5.1 and 20.4.5.2)

> Note: The test series described in Part II of the Manual of Tests and Criteria are not equivalent to the classification types listed under subsection 7.8.1(2) of the HPR. For example, from the Decision logic 2.8 for self-reactive substances and mixtures in the GHS (p. 78), testing to classify a substance or mixture into hazard category Type A might include results from Test A and Test B or alternatively results from Test A, Test C and Test D. Results from Test A alone are insufficient to classify a substance or mixture into Type A.

Test series H is used to determine the self-accelerating decomposition temperature (SADT). The SADT is used in criteria for Types F and G. The SADT is dependent on the nature of the self-reactive product, and the volume and heat-loss characteristics of the packaging. Therefore, the "SADT is only valid for the substance or mixture as tested and when handled properly. Mixing the self-reactive substances and mixtures with other chemicals, or contact with incompatible materials (including incompatible packaging) may reduce the thermal stability due to catalytic decomposition, and lower the SADT. This may increase the risk of decomposition and has to be avoided." (ECHA Guidance, 2015, paragraph 2.8.4.3.1)

The SADT decreases with increasing package size and with increasing efficiency of the insulation on the package. "The test selected shall be conducted in a manner which is representative, both in size and material, of the package." (GHS, 5th revised edition, 2013, paragraph 2.8.2.3)
An SADT must be determined in order to decide if a substance or mixture:

a) conforms to the requirements of Types F or G, when appropriate, or

b) meets the SADT criterion for self-reactive substances, when appropriate.

(United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.4.1.3)

In addition, a SADT is required to determine if a substance or mixture should be subject to temperature control during transport, storage and handling.

Discussion of the *Hazardous Products Regulations* Subsection 7.8.1(3)

Exclusion after evaluation

7.8.1(3) A mixture or substance with a self-accelerating decomposition temperature greater than 75°C when evaluated in a 50 kg package need not be classified in any category of this hazard class.

This exclusion is listed in paragraph 2.8.2.1(e) of the GHS. See also discussion of subsection 7.8.1(1) of the HPR for information on other exclusions.

Hazard Communication

The symbols, signal words as well as hazard and precautionary statements for "Self-Reactive Substances and Mixtures" are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013) as follows:

- Type A on p. 319,
- Type B on p. 320, and
- Types C to F, on p. 321.
- Type G has no symbol, signal word, hazard or precautionary statement.

Classification of Self-Reactive Substances or Mixtures

Example

A white solid is suspected of being a self-reactive substance and is tested according to the appropriate UN tests.

The test methods for determining the type of self-reactive substance or mixture are performed using the Manual of Tests and Criteria, Part II, Test Series A to H. The tests are designed to provide the information necessary to apply the principles for classification. In the following example, the results of the tests are assessed in alphanumeric order; however, the tests are performed in the order recommended under sub-section 20.4.5 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015.

Available data

- White solid
- Molecular formula: $C_2H_4N_4O_2$
- Apparent density: 945 kg/m^3
- Particle size: < 400 µm

Test results

Test Name	Observation	Result
Test series A - Detonation propagation [BAM 50/60 steel tube test]	30 cm of tube fragmented, unreacted substance remained in the tube	Partial propagation of detonation
Test series B - Detonation as packaged	Not applicable	
Test series C - Deflagration propagation [Time/pressure test]	Test conducted on 5 g of sample three times and the time it took for the pressure to rise from 690 kPa to 2,070 kPA was noted (3.0 s, 2.5 s, 2.7 s). Shortest recorded time (2.5 s) is used for result.	Test result/criteria: Yes, it can propagate a deflagration but slowly, because the time for pressure to rise from 690 kPa to 2,070 kPA is greater than or equal to 30 ms.
Test series C - Deflagration propagation [Deflagration test]	Test conducted two times on 265 cm^3 of sample at 50 °C, and the reaction rate noted for each (0.71 mm/s, 0.65 mm/s). Shortest recorded rate (0.65 mm/s) is used for result.	Yes, it can propagate the deflagration but slowly, because the deflagration rate is less than or equal to 5.0 mm/s and greater than or equal to 0.35 mm/s. Based on both series C tests, it can propagate the deflagration but slowly.
Test series D - Deflagration as packaged	Not applicable	
Test series E - Effect of heating under confinement [Koenen test]	Tested 26.0 g of sample. Limiting diameter of 3.5 mm (time to reaction 19.0 s, duration of reaction 22 s)	Violent effect of heating under confinement because the limiting diameter is greater than or equal to 2.0 mm.
Test series E - Effect of heating under confinement [Dutch Pressure Vessel test]	Tested 10.0 g of sample. Limiting diameter of 10.0 mm (time to reaction 110 s, duration of reaction 4 s)	Violent effect of heating under confinement because rupture of the disc with an orifice of 9.0 mm or greater and a sample mass of 10.0 g. Based on both series E tests the effect of heating under confinement is Violent
Test series F - Explosive Power	Not applicable	
Test series G - (explosion) as packaged [Thermal explosion test in the package]	Tested 25 kg of substance in packaging type 6HG2. Observed fumes only, no fragmentation of the package.	No explosion: No fragmentation or a fragmentation into no more than three pieces shows that the substance does not explode in the package. Chemical is classified as a self-reactive Type C.
Test series H - Thermal stability [United States SADT test]	Not applicable	

Classification

Substance XYZ is classified as Self-Reactive, Type C: Any self-reactive liquid or solid substance or mixture possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive substance Type C.

Rationale

The classification of a self-reactive liquid or solid substance or mixture must be based on the results from testing performed in accordance with test series A to H of the Manual of Test and

Criteria which must be assessed against the criteria in the table to subsection 7.8.1(2) and subsection 7.8.1(3).

Substance XYZ is a solid that possesses explosive properties, which neither detonates nor deflagrates rapidly nor undergoes a thermal explosion as packaged. (item 3 of table to subsection 7.8.1(2).

Subpart 9
Pyrophoric Liquids

Definition of "pyrophoric liquid"

7.9 In this Subpart, "pyrophoric liquid" means a liquid that is liable to ignite within five minutes after coming into contact with air.

Discussion – Pyrophoric Liquid

The adjective "pyrophoric" applies to the ability of a substance or mixture to spontaneously ignite or combust in air, without a supplied spark, flame, or the addition of heat. The reaction is exothermic and almost instantaneous (within minutes) (ECHA Guidance, 2015, paragraph 2.9.1). This instantaneous reaction differentiates pyrophoric substances and mixtures "…from self-heating substances and mixtures, which also react spontaneously with air but only when in larger amounts and after an extended period of time (hours or days)." (ECHA Guidance, 2015, paragraph 2.9.3) For additional information on self-heating substances and mixtures see section 7.11 of the HPR – Self Heating Substances and Mixtures.

Comparison to HCS 2012 and GHS

The definition of pyrophoric liquid given under section 7.9 of the HPR differs slightly from that used in paragraph 2.9.1 of the GHS (5th revised edition, 2013) and in the HCS 2012 which state:

> "A pyrophoric liquid is a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air."

The mention of "even in small quantities" was not included in the HPR so that the definition would not be limited to liquids that are in small quantities. The classification criteria in the HPR are identical to those in the GHS (5th revised edition, 2013) and the HCS 2012.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.9.1

Category

7.9.1 A pyrophoric liquid is classified in the category of this hazard class, based on results from testing performed in accordance with test N.3 of sub-section 33.3.1.5 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Pyrophoric Liquids — Category 1	A liquid that, within 5 min, either (a) ignites when added to an inert carrier and after coming into contact with air, or (b) ignites or chars a filter paper, after coming into contact with air

In the event where data of the types referred in subparagraphs 2.1 (a) (ii), (iii) or (iv) of the HPR is available, such as experience in production or handling showing that the substance or mixture does not seem to ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance seems to be stable at room temperature for prolonged periods of time (days)), this type of data, if feasible, must be assessed against the criteria in the table to section 7.9.1 in order to determine if the liquid meets the criteria to be classified in this hazard class.

However, a liquid known to be pyrophoric based on experience must be considered for classification in the Pyrophoric Liquids hazard class using the criteria in the table to section 7.9.1, as would a liquid that spontaneously ignites upon opening its container.

Certain chemical groups and their derivatives are more likely to be pyrophoric. These chemical groups include:

- organo-metals,
- organo-metalloids,
- organo-phosphines,
- hydrides, and
- haloacetylene derivatives (ECHA Guidance, 2015, paragraph 2.9.1).

More information on pyrophoric substances can be found in *Bretherick's Handbook of Reactive Chemical Hazards, 7th edition*, 2007.

Testing

If testing is done, it must be performed using test N.3: *Test method for pyrophoric liquids* of sub-section 33.3.1.5 of Part III of the Manual of Tests and Criteria (United Nations Transport of Dangerous Goods, Manual of Test and Criteria, 6th revised edition, 2015, sub-section 33.3.1.5).

The procedure consists of two parts. In the first part, 0.5 ml of the liquid is exposed to air to determine if ignition occurs within 5 minutes. If no ignition occurs, the procedure is performed again until a positive result is obtained or a total of six negative attempts have been made.

The second part of the test is only performed if negative results were obtained in the first part of the test. In this part, 0.5 ml test sample is applied to a dry filter paper to see if the liquid will char or ignite the filter paper. The test is repeated for a total of three times using fresh filter paper each time unless a positive result is obtained earlier. Refer to the Manual of Tests and Criteria for a complete description of the method and analysis of the test results.

Note: The mechanism of oxidation is, in general, very complex, and the humidity of air might influence the rate of reaction. Therefore, a false negative may result when performing the tests in an extremely dry environment, and this condition must be avoided when performing the tests for classification for pyrophoricity. (ECHA Guidance, 2015, paragraph 2.9.4.4)

A positive result in either part of the test procedure is sufficient to classify the liquid into Pyrophoric Liquids - Category 1.

Hazard Communication

The symbol, signal word as well as hazard and precautionary statements for “Pyrophoric Liquids” Category 1 are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013) on p. 322.

Subpart 10
Pyrophoric Solids

Definition of "pyrophoric solid"

7.10 In this Subpart, "pyrophoric solid" means a solid that is liable to ignite within five minutes after coming into contact with air.

Discussion – Pyrophoric Solid

The adjective "pyrophoric" applies to the ability of a substance or mixture to spontaneously ignite or combust in air, without a supplied spark, flame, or the addition of heat. The reaction is exothermic and almost instantaneous (within minutes) (ECHA Guidance, 2015, paragraph 2.10.1). This instantaneous reaction differentiates pyrophoric substances and mixtures "…from self-heating substances and mixtures, which also react spontaneously with air but only when in larger amounts and after an extended period of time (hours or days)." (ECHA Guidance, 2015, paragraph 2.10.3) For additional information on self-heating substances and mixtures see section 7.11 of the HPR.

Comparison to HCS 2012 and GHS

The definition of pyrophoric solid given under section 7.10 of the HPR differs slightly from the one used in paragraph 2.10.1 of the GHS (5th revised edition, 2013) and in the HCS 2012, which state:

> "A pyrophoric solid is a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air."

The mention of "even in small quantities" was not included in the HPR so that the definition would not be limited to solids that are in small quantities. The classification criteria in the HPR are identical to those in the GHS (5th revised edition, 2013) and the HCS 2012.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.10.1

Category

7.10.1 A pyrophoric solid is classified in the category of this hazard class, based on results from testing performed in accordance with test N.2 of sub-section 33.3.1.4 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Pyrophoric Solids — Category 1**	**A solid that ignites within 5 min after coming into contact with air**

In the event where data of the types referred in subparagraphs 2.1 (a) (ii), (iii) or (iv) of the HPR is available, such as experience in production or handling showing that the substance or mixture does not seem to ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance or mixture seem to be stable at room temperature for prolonged periods of time (days)), this type of data, if feasible, must be assessed against the criteria in the table to section 7.10.1 in order to determine if the solid meets the criteria to be classified in this hazard class.

However, a solid known to be pyrophoric based on experience must be considered for classification in the Pyrophoric Solids hazard class using the criteria in the table to section 7.10.1, as would a solid that spontaneously ignites upon opening its container.

Certain chemical groups and their derivatives are more likely to be pyrophoric. These chemical groups include:

- organo-metals,
- organo-metalloids,
- organo-phosphines,
- hydrides,
- haloacetylene derivatives,
- complex acetylides, and,
- powders or fine metal particles of metals.

More information on pyrophoric substances can be found in *Bretherick's Handbook of Reactive Chemical Hazards 7th edition*, 2007.

Testing

If testing is done it must be performed using test N.2: *Test Method for pyrophoric solids* of sub-section 33.3.1.4 of Part III of the Manual of Tests and Criteria. The procedure consists of pouring 1 to 2 ml of powder onto a non-combustible surface and observing whether the substance or mixture ignites within 5 minutes. If no ignition occurs, the procedure is performed again until a positive result is obtained or a total of six negative attempts have been made. Refer to the Manual of Tests and Criteria for a complete description of the method and analysis of the test results.

Note: Certain metals will not react in dry air but will react almost instantaneously in moist air. Since the humidity of the air might influence the rate of reaction, false negative results are possible if the test is performed in an extremely dry environment. (ECHA Guidance, 2015, paragraph 2.10.4.4)

A positive result in the test procedure is sufficient to classify the solid into Pyrophoric Solids - Category 1.

Hazard Communication

The symbol, signal word as well as hazard and precautionary statements for “Pyrophoric Solids” Category 1 are specified in Section 3 of Annex 3 of the GHS (5th revised edition, 2013) on p. 323.

Subpart 11
Self-Heating Substances and Mixtures

Definition of "self-heating"

7.11 In this Subpart, "self-heating" means, in relation to a solid or liquid, liable to self-heat by reaction with air and without energy supply.

Discussion – Self-Heating

"Self-heating" is the gradual reaction of a substance or mixture with oxygen in the air to produce heat (i.e., an exothermic reaction). The reaction rate may be very slow initially (induction period). If the heat does not dissipate into the environment as quickly as it is generated, the heat can accumulate, and this accumulation can result in an increase in the temperature of the substance or mixture, leading to self-ignition and combustion. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015)

Comparison to HCS 2012 and GHS

The definition given under section 7.11 of the HPR differs from the one used in the GHS and in the HCS 2012. The GHS definition states:

> "A self-heating substance or mixture is a solid or liquid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days)." (GHS, 5th revised edition, 2013, paragraph 2.11.1)

The HCS 2012 definition is essentially the same as the GHS definition. Unlike GHS and HCS 2012, the definition of self-heating in section 7.11 of the HPR does not mention the exclusion of pyrophoric solids or liquids. These exclusions appear in subsection 7.11.1(1), as discussed below, and are the same as HCS 2012 and GHS. Although the GHS and HCS 2012 definitions mention ignition when in "large amounts (kilograms)" and after "long periods of time (hours or days)", these terms are not included in the HPR because they do not limit the definition.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.11.1(1)

Exclusions

7.11.1(1) The following need not be classified in any category of this hazard class:

(a) a liquid classified in the category of the hazard class "Pyrophoric Liquids"; and

(b) a solid classified in the category of the hazard class "Pyrophoric Solids".

In keeping with the definition given in paragraph 2.11.1 of the GHS, Pyrophoric Solids and Pyrophoric Liquids need not be considered for classification as Self-heating Substances and Mixtures.

Both pyrophoric and self-heating reactions are exothermic and involve spontaneous ignition in the presence of air. However, pyrophoric reactions only require small quantities of a substance or mixture to occur and are almost instantaneous, occurring in minutes. Self-heating reactions require larger amounts (kilograms) and an extended period of time (hours or days) to occur.

Discussion of the *Hazardous Products Regulations* Subsection 7.11.1(2)

Categories

7.11.1(2) Subject to subsection (3), a self-heating substance or mixture is classified in a category of this hazard class, based on results from testing performed in accordance with test N.4 of sub-section 33.3.1.6 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Self-heating Substances and Mixtures — Category 1	A solid or liquid in respect of which a positive result is obtained in a test using a 25 mm sample cube at 140°C and the spontaneous ignition temperature of a 450 l volume of the solid or liquid is ≤ 50 °C
2	Self-heating Substances and Mixtures — Category 2	A solid or liquid in respect of which (a) a positive result is obtained in a test using a 100 mm sample cube at 140°C, a negative result is obtained in a test using a 25 mm sample cube at 140°C and (i) the solid or liquid is packed in packages with a volume > 3 m^3, (ii) a positive result is obtained in a test using a 100 mm sample cube at 120°C and the solid or liquid is packed in packages with a volume > 450 l, or (iii) a positive result is obtained in a test using a 100 mm sample cube at 100°C; or (b) a positive result is obtained in a test using a 25 mm sample cube at 140°C and the spontaneous ignition temperature of a 450 l volume of the solid or liquid is > 50°C

Classification in a Category of the Class

Paragraph 2.11.4.1 of the European Chemicals Agency (ECHA) *Guidance on the Application of CLP Criteria*, version 4.1 June 2015 provides the following guidance:

- Self-heating is a very complex phenomenon which is influenced by many parameters some of them being volume, temperature, particle shape and size, heat conductivity and bulk density. Therefore, self-heating behaviour cannot be predicted by any theoretical models. “In some cases, properties might even differ between producers of seemingly very similar substances or mixtures. Differences in self-heating behaviour are especially to be anticipated where surface treatment occurs in the production process. Hence, all data sources should be carefully evaluated with regard to reliability and scientific validity.” (ECHA Guidance, 2015, paragraph 2.11.4.1)

Note: Substances and mixtures with a temperature of spontaneous combustion higher than 50 °C for a volume of 27 m^3 should not be classified in this hazard class. Substances and mixtures with a self-ignition temperature higher than 50°C for a volume of 450 litres should not be

classified in Category 1 of this hazard class (GHS, 5th revised edition, 2013, paragraph 2.11.2.2 Note 2).

It is important to note that in the event where the data concerning the self-ignition temperature of a 450 L volume of the solid or liquid is not available but a positive result was obtained in a test using a 25 mm sample cube at 140°C, the substance should be classified in Category 1 of this hazard class.

Testing

In many instances, a simple screening test can be used to determine whether self-heating occurs, provided that the results of the test can be adequately correlated with the classification test N.4 of sub-section 33.3.1.6 of Part III of the Manual of Tests and Criteria and that an appropriate safety margin is applied. The GHS (5th revised edition, 2013, paragraph 2.11.4.2) provides the following examples of screening tests:

a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) is designed to determine the relative auto-ignition temperature of a dust sample by heating the same amount of test sample and reference power (graphite) in a hot air stream at a rate of 1°C/min. The surrounding temperature at which the test sample temperature starts to rise faster than that of the inert reference sample is taken as the (relative) auto-ignition temperature of the sample. The classification procedure into a self-heating category may not apply to substances or mixtures with an onset temperature 80 °Kelvin above the reference temperature for a volume of 1 litre.

b) The Bulk Powder Screening Test (Gibson, N., *et al*. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) is used to characterize the thermal decomposition of a powder. The procedure of classification into a self-heating category may not apply to substances or mixtures with an onset temperature 60 °Kelvin above the reference temperature for a volume of 1 litre.

If self-heating behaviour cannot be ruled out by a screening test, then further testing using the classification test N.4 as specified in subsection 7.11.1(2) can be undertaken. This method uses 25 mm or 100 mm cubes of sample at temperatures of 100 °C, 120 °C or 140 °C to see if they undergo spontaneous ignition or dangerous self-heating as indicated by a 60 °C rise in temperature over the oven temperature within 24 hours. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 33.3.1.6)

It is important to note that in the event where the data concerning the self-ignition temperature of a 450 L volume of the solid or liquid is not available but a positive result was obtained in a test using a 25 mm sample cube at 140 °C, the substance should be classified in Category 1 of this hazard class.

Refer to the Manual of Tests and Criteria for a complete description of the method and analysis of the test results.

Comparison to HCS 2012

Subsection 7.11(2) of the HPR specifies that the spontaneous ignition temperature for a volume of 450 L should be known to be able to differentiate between classification in Category 1 or Category 2, based on a positive result using a 25 mm sample cube at 140 °C. However, when a positive result is obtained in a test using a 25 mm sample cube at 140 °C, but the data concerning the self-ignition temperature of a 450 L volume of the solid or liquid is not available, the substance should be classified in Category 1 of this hazard class. It must be noted that HCS 2012 addresses the issue of the auto-ignition temperature in a different manner but the resulting classification is the same. This results in the HPR and HCS 2012 being aligned.

Discussion of the *Hazardous Products Regulations*
Subsection 7.11.1(3)

Exclusion after evaluation

7.11.1(3) A mixture or substance with a temperature of spontaneous combustion higher than 50 °C for a volume of 27 m^3 need not be classified in any category of this hazard class.

This exclusion corresponds to Note 2 of Table 2.11.1 of the 5th revised edition of GHS.

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for “Self-heating Substances and Mixtures” Category 1 and Category 2 are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, p. 324).

Classification of Self-Heating Substances and Mixtures

Example

An inorganic black powder is suspected of being a self-heating substance and is tested according to the Manual of Tests and Criteria, Part III, sub-section 33.3.1.6, Test method N.4: Test method for self-heating substances.

Available data

- Inorganic black powder, transported in packages of 500 liters (0.5 m^3).
- Tested per UN Test method N.4 with the following results:
    - A positive result using a 100 mm sample cube at 140 °C (284 °F).
    - A negative result using a 25 mm sample cube at 140 °C (284 °F).

According to the procedure, if a positive result is obtained at 140 °C (284 °F) in a 100 mm sample cube, but not in a 25 mm sample cube, then an additional test with the substance in a 100 mm sample cube should be performed based on the packaging and quantity being transported. Below are the results of this additional test:

- A positive result using a 100 mm sample cube at 120 °C (248 °F) and the solid is packed in packages of more than 450 liters.

Classification

The chemical meets the criteria for classification for Self-Heating Substances and Mixtures - Category 2.

Rationale

The substance is a powder.

1. Does a 100 mm sample cube undergo self-heating when tested at 140 °C (284 °F)?
   ANSWER: Yes. A positive result was obtained.
2. Does a 25 mm sample cube undergo self-heating when tested at 140 °C (284 °F)?
   ANSWER: No. A negative result was obtained.
3. Is it packaged in more than 3 m^3?
   ANSWER: No. it is transported in packages of 500 liters (0.5 m^3).
4. Does a 100 mm sample cube undergo self-heating when tested at 120 °C (248 °F)?
   ANSWER: Yes. A positive result was obtained.
5. Is it packaged in more than 450 liters?
   ANSWER: Yes. It is transported in packages of 500 liters.

Subpart 12
Substances and Mixtures which, in Contact with Water, Emit Flammable Gases

Interpretation

7.12 In this Subpart, substances and mixtures which, in contact with water, emit flammable gases are liquids and solids that, by interaction with water, are liable to become spontaneously flammable or give off flammable gases in dangerous quantities, that is, in quantities that are equal to or greater than one litre of gas per kilogram of the mixture or substance per hour.

Discussion – Substances and Mixtures which, in Contact with Water, Emit Flammable Gases

Some substances and mixtures at normal ambient temperature (20 °C) and in contact with water or moisture (e.g., damp, humid air) emit gases which might be flammable, toxic, or both. Classification of such substances and mixtures should be considered for both the Physical Hazard Class "Substances and Mixtures which, in Contact with Water, Emit Flammable Gases", Part 7, Subpart 12 and the Health Hazard Class "Acute Toxicity", Part 8, Subpart 1 of the HPR.

This Subpart of the HPR is concerned only with the generation of flammable gases following the contact of a substance or mixture with water. Flammable gases pose a physical hazard to workers by forming explosive mixtures with air that can be easily ignited by ordinary sources of ignition (e.g., sparking hand tools). (United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, 19th revised edition, 2015, paragraph 2.4.4.1)

If contact with water results in the evolution of a toxic gas (e.g., hydrogen chloride) then the substance or mixture might meet the criteria for classification in the Acute Toxicity hazard class. See subsection 8.1.1(2) of the HPR and section 8.1.2 of the HPR for further information.

Comparison to HCS 2012 and GHS

The definition for Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases in the HPR includes the statement that the dangerous quantities mentioned in the definition are equal to or greater than one litre of gas per kilogram of the substance or mixture per hour. This element of the definition is in line with the criteria for classification in this hazard class. The GHS and HCS 2012 do not include in their respective definitions the added information concerning dangerous quantities; however, it is anticipated that substances and mixtures that classify in Category 1, 2 or 3 of this hazard class according to the HPR will classify the same way according to HCS 2012.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.12.1(1)

Exclusions

7.12.1(1) The following liquids or solids need not be classified in any category of this hazard class:

(a) those that have a chemical structure that does not contain metals or metalloids;

(b) those that have been shown, through accumulated experience in production or handling, not to react with water; and

(c) those that are soluble in water to form a stable mixture.

Under subsection 7.12.1(1) of the HPR, the classification procedure for this hazard class does not apply to a substance or mixture:

- whose chemical structure does not contain any metals or metalloids;
- where experience in production or handling shows that it does not react with water (e.g., the chemical is manufactured with water or washed with water and no reactions have occurred); or
- that is soluble in water to form a stable mixture.

If any of the exclusion criteria are met, the substance or mixture need not be assessed under this hazard class.

Comparison to HCS 2012 and GHS

These exclusion criteria are the same as those listed in the GHS and the HCS 2012.

Discussion of the *Hazardous Products Regulations* Subsection 7.12.1(2)

Categories

7.12.1(2) A liquid or solid which, in contact with water, emits flammable gases is classified in a category of this hazard class, based on results from testing performed in accordance with test N.5 of sub-section 33.4.1.4 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases — Category 1	A liquid or solid that (a) reacts with water at ambient temperature and produces a gas that is liable to ignite spontaneously; (b) reacts with water at ambient temperature such that the rate of evolution of flammable gas is ≥ 10 l/kg of liquid or solid over any one minute; or (c) reacts with water at ambient temperature to ignite spontaneously in any step of the test procedure
2	Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases — Category 2	A liquid or solid that reacts with water at ambient temperature such that the maximum rate of evolution of flammable gas is ≥ 20 l/kg of liquid or solid per hour
3	Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases — Category 3	A liquid or solid that reacts with water at ambient temperature such that the maximum rate of evolution of flammable gas is ≥ 1 l/kg of liquid or solid per hour

Subsection 7.12.1(2) of the HPR outlines the requirements to classify a substance or mixture into a category under "Substances and Mixtures which, in Contact with Water, Emit Flammable Gases" and applies to both solids and liquids.

Classification in a Category of the Class

The following types of data should be considered when classifying a substance (ECHA Guidance, 2015, paragraph 2.12.4.1) or mixture in the Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases hazard class:

- chemical structure - check to see if the substance or mixture contains:
    - certain chemical families which are often hazardous in contact with water and could meet the requirements for classification, including:
        - alkali metals (e.g., lithium, sodium)
        - metal hydrides (e.g., sodium hydride, lithium hydride)
        - complex metal hydrides (e.g., lithium aluminum hydride, sodium aluminum hydride)
        - metal phosphides (e.g., aluminum phosphide, calcium phosphide)
        - certain metal powders (e.g., aluminium and magnesium powders, zinc dust)

A comprehensive list of substances that should be considered for classification in this hazard class can be found in *Bretherick's Handbook of Reactive Chemical Hazards, 7th edition*, 2007.

- in the case of solids, the particle size and friability (the ability of a solid to be easily broken down into smaller pieces) – this characterization of physical state is especially important if testing is undertaken.
    - Under the UN test N.5 of sub-section 33.4.1.4 of Part III of the Manual of Tests and Criteria, samples of solids containing particles of less than 500 um diameter and that constitute more than 1% (mass) of the total solid, or of solids that are friable, should be ground to a powder before testing to allow for a reduction in particle size that could occur during handling and transport. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 33.4.1.4.3.5)
- chemical identity and flammability of the emitted gas, which is used to decide whether the evolved gas is flammable or not.

Testing

If testing is done it must be performed using test N.5 of sub-section 33.4.1.4 of Part III of the Manual of Tests and Criteria. This test method can be applied to both solids and liquids and is intended to determine whether the reaction of a substance or mixture with water leads to the development of a dangerous amount of gas which may be flammable. If spontaneous ignition occurs at any stage then no further testing is necessary and the substance or mixture would be classified in Category 1 of this hazard class. Refer to the Manual of Tests and Criteria for a complete description of the method and analysis of the test results. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 33.4.1.4)

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for Substances and Mixtures which, in Contact with Water, Emit Flammable Gases are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, pp. 325-326).

Classification of Substances and Mixtures Which, in Contact with Water, Emit Flammable Gases

Example

A liquid is suspected of being a *chemical which, in contact with water, emits flammable gas*. The liquid is tested to determine whether any gas is evolved, if spontaneous ignition of the gas occurs, and if there is evolution of flammable gas at a rate greater than 1 liter per kilogram of the chemical per hour.

Tests are performed using the Manual of Tests and Criteria, Part III, sub-section 33.3.1.4, Test method N.5: "Test method for substances which in contact with water emit flammable gases."

Available data

- Liquid contains an organometallic.
- The chemical reacts slowly with water and emits a gas known to be flammable which is not liable to ignite spontaneously.
- Chemical was tested for seven hours at ambient temperature per UN Test N.5 "Test method for substances which, in contact with water, emit flammable gases." Test results showed
    - o A maximum rate of evolution of 15 liters per kilogram (L/kg) substance per hour of flammable gas.
    - o The gas did not spontaneously ignite in any step of the test procedure.

Classification

The liquid meets the criteria for Substances and Mixtures which, in contact with water, emits flammable gases - Category 3.

Rationale

1. Does the liquid react with water at ambient temperature and produce a gas that is liable to ignite spontaneously?

   ANSWER: No

2. Does the liquid react with water at ambient temperature such that the rate of evolution of flammable gas is ≥ 10 L/kg of liquid or solid over any one minute?

   ANSWER: No

3. Does the liquid reacts with water at ambient temperature to ingnite spontaneously in any step of the test procedure?

   ANSWER: No

4. Does the liquid react with water at ambient temperature such that the maximum rate of evolution of flammable gas is ≥ 20 L/kg of liquid or solid per hour?

   Answer: No

5. Does the liquid react with water at ambient temperature such that the maximum rate of evolution of flammable gas is ≥ 1 L/kg of liquid or solid per hour?

   Answer: Yes, 15 L/kg of liquid or solid per hour.

The liquid meets the Category 3 criteria: Any chemical which reacts with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.

Subpart 13
Oxidizing Liquids

Definition of "oxidizing liquid"

7.13 In this Subpart, "oxidizing liquid" means a liquid, whether or not combustible, that is liable to cause or contribute to the combustion of other material.

Discussion – Oxidizing Liquids

In general terms, an oxidizer is a chemical that brings about an oxidation reaction. An oxidizing reaction means:

- the oxidizer provides oxygen to the substance being oxidized (in which case the oxidizer has to be oxygen or contain oxygen), or
- the oxidizer receives electrons from the substance being oxidized (e.g., bromine pentafluoride is an oxidizer based on electron-transfer, even though it does not contain oxygen).

Oxidizers can initiate or greatly accelerate the combustion of other materials. The most common oxidizer is atmospheric oxygen.

Comparison to HCS 2012 and GHS

The definition in the HPR differs slightly from the one in paragraph 2.13.1 of the GHS (5th revised edition, 2013) and the one in the HCS 2012. The words "generally by yielding oxygen", which are included in the GHS and the HCS 2012, are not included in the HPR. Yielding oxygen is not required in order for a product to be classified as an oxidizing liquid. Therefore, the words "generally by yielding oxygen" do not limit the definition and are not necessary. The slightly different wording used in the definition of "oxidizing liquid" in the HPR as compared to the GHS and the HCS 2012 does not have any impact on classification.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.13.1(1)

Exclusions

7.13.1(1) The following liquids need not be classified in any category of this hazard class:

(a) any organic liquid that does not contain oxygen, fluorine or chlorine;

(b) any organic liquid that contains oxygen, fluorine or chlorine if those elements are chemically bonded only to carbon or hydrogen; and

(c) any inorganic liquid that does not contain oxygen or halogens.

Under subsection 7.13.1(1) of the HPR, the classification procedure for this class need not be applied to a liquid that is:

- an **organic** substance or mixture:
  a) that does not contain oxygen (O), fluorine (F) or chlorine (Cl), or
  b) that contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon (C) or hydrogen (H).
- an **inorganic** substance or mixture:
  c) that does not contain oxygen or halogen atoms (e.g., fluorine, chlorine, bromine (Br), iodine (I)).

Any substance or mixture that meets the above exclusion criteria can be considered as not having oxidizing properties. Therefore, no testing is needed and the substance or mixture need not be classified as an oxidizing liquid.

Comparison to HCS 2012 and GHS

These exclusion criteria are the same as those listed in paragraphs 2.13.4.2.3 and 2.13.4.2.4 of the GHS, (5th revised edition, 2013), and HCS 2012.

Discussion of the *Hazardous Products Regulations*
Subsection 7.13.1(2)

Categories

7.13.1(2) An oxidizing liquid is classified in a category of this hazard class, based on results from testing performed in accordance with test O.2 of sub-section 34.4.2 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Oxidizing Liquids — Category 1	A liquid that, when tested in a 1:1 mixture, by mass, with cellulose, spontaneously ignites, or exhibits a mean pressure rise time < the mean pressure rise time of a 1:1 mixture, by mass, of 50.0% perchloric acid and cellulose
2	Oxidizing Liquids — Category 2	A liquid that, when tested in a 1:1 mixture, by mass, with cellulose, exhibits a mean pressure rise time ≤ the mean pressure rise time of a 1:1 mixture, by mass, of 40.0% aqueous sodium chlorate solution and cellulose
3	Oxidizing Liquids — Category 3	A liquid that, when tested in a 1:1 mixture, by mass, with cellulose, exhibits a mean pressure rise time ≤ the mean pressure rise time of a 1:1 mixture, by mass, of 65.0% aqueous nitric acid and cellulose

The available data must first be compared against the criteria for exclusion from classification in this class listed in subsection 7.13.1(1) of the HPR. If any of the exclusion criteria are met, the substance or mixture need not be assessed under this class.

If none of the exclusion criteria are met, the available data are assessed against the criteria in table to subsection 7.13.1(2).

It must be noted that a hazard category cannot be assigned based on the chemical structure.

Testing

If testing is done it must be performed using test O.2 of sub-section 34.4.2 of Part III of the Manual of Tests and Criteria. The test measures the time for the pressure to rise between two specific values (690 kPa – 2070 kPa) and compares it to a standard.

Note that the higher the rate of pressure rise (i.e., a shorter time of pressure rise), the stronger the oxidizing capability of the liquid tested.

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for “Oxidizing Liquids” are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013); for Oxidizing Liquids - Category 1 on p. 327, and for Oxidizing Liquids - Category 2 and 3 on p. 328.

Classification of Oxidizing Liquids

Example

Tests are performed using the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 34.4.2, Test Method O.2: "Test for oxidizing liquids."

A liquid suspected of being an oxidizing liquid is tested to determine whether a mixture of the substance and cellulose spontaneously ignites. The mean time taken for the pressure to rise from 690 kPa to 2,070 kPa is compared with those of the reference mixtures. The three reference mixtures are: 50% perchloric acid and cellulose, 40% aqueous sodium chlorate solution and cellulose and 65 % aqueous nitric acid and cellulose. Five trials are performed with the mixture and each of the reference mixtures. The time taken for the pressure rise from 690 kPa to 2,070 kPa is noted. The mean time interval is used for classification.

Available data

- 2.5 g of the liquid to be tested is mixed with 2.5 g of dried cellulose. The mixture did not spontaneously ignite.
- The mixture is heated, and the time taken for the pressure rise from 690 kPa to 2,070 kPa is measured. The mean pressure rise time for 5 trials is 4,210 seconds (s).
    - The test sample exhibited a pressure rise ≥ 2,070 kPa gauge.
    - The mean pressure rise time for the reference mixture containing 50% perchloric acid and cellulose is 3,085 s.
    - The mean pressure rise time for the reference mixture containing 40% aqueous sodium chlorate and cellulose is 4,050 s.
    - The mean pressure rise time for the reference mixture containing 65% aqueous nitric acid and cellulose is 4,767 s.

Classification

The chemical meets the criteria to be classified in Oxidizing Liquids - Category 3.

Rationale

The substance is a liquid.

1. Does a 1:1 mixture, by mass, of substance and cellulose tested, exhibit a pressure rise ≥ 2,070 kPa gauge?

   ANSWER: Yes. The test sample exhibited a pressure rise of ≥ 2,070 kPa gauge.

2. Does a 1:1 mixture, by mass, of substance and cellulose tested, spontaneously ignite or exhibit a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose?

ANSWER: No. Absence of spontaneous ignition and the mean pressure rise time for the liquid test substance is 4,210 s, which is greater than 3,085 s for perchloric acid.

3. Does a 1:1 mixture, by mass, of substance and cellulose tested, exhibit a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate and cellulose?

   ANSWER: No. The mean pressure rise time for the liquid test substance is 4,210 s, which is greater than 4,050 s for 40% aqueous sodium chlorate.

4. Does a 1:1 mixture, by mass, of substance and cellulose tested, exhibit a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose?

   ANSWER: Yes. The mean pressure rise time for the liquid test substance is 4,210 s, which is less than 4,767 s for 65% aqueous nitric acid.

The liquid meets the criteria for Oxidizing Liquids - Category 3 and does not meet the criteria for Category 1 or 2.

Subpart 14
Oxidizing Solids

Definition of "oxidizing solid"

7.14 In this Subpart, "oxidizing solid" means a solid, whether or not combustible, that is liable to cause or contribute to the combustion of other material.

Discussion – Oxidizing Solids

In general terms, an oxidizer is a chemical that brings about an oxidation reaction. An oxidizing reaction means:

- the oxidizer provides oxygen to the substance being oxidized (in which case the oxidizer has to be oxygen or contain oxygen), or
- the oxidizer receives electrons from the substance being oxidized.

Oxidizers can initiate or greatly accelerate the combustion of other materials. The most common oxidizer is atmospheric oxygen.

Comparison to HCS 2012 and GHS

The definition in the HPR differs slightly from the one in paragraph 2.14.1 of the (GHS 5th revised edition, 2013) and the one in the HCS 2012. The words "generally by yielding oxygen", which are included in the GHS and the HCS 2012, are not included in the HPR. Yielding oxygen is not required in order for a product to be classified as an oxidizing solid. Therefore, the words "generally by yielding oxygen" do not limit the definition and are not necessary. The slightly different wording used in the definition of "oxidizing solid" in the HPR as compared to the GHS and the HCS 2012 does not have any impact on classification.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.14.1(1)

Exclusions

7.14.1(1) The following solids need not be classified in any category of this hazard class:

(a) any organic solid that does not contain oxygen, fluorine or chlorine;

(b) any organic solid that contains oxygen, fluorine or chlorine if those elements are chemically bonded only to carbon or hydrogen; and

(c) any inorganic solid that does not contain oxygen or halogens.

Under subsection 7.14.1(1) of the HPR, the classification procedure for this hazard class need not be applied to a solid that is:

- an **organic** substance or mixture:
  a) that does not contain oxygen (O), fluorine (F) or chlorine (Cl), or
  b) that contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon (C) or hydrogen (H).
- an **inorganic** substance or mixture:
  c) that does not contain oxygen or halogen atoms (e.g. fluorine, chlorine, bromine (Br), iodine (I)).

Any substance or mixture that meets the above exclusion criteria can be considered as not having oxidizing properties. Therefore, no testing is needed, and the substance or mixture does not need to be classified as an oxidizing solid.

Comparison to HCS 2012 and GHS

These exclusion criteria are the same as those listed in paragraphs 2.14.4.2.2 and 2.14.4.2.3 of the GHS (5th revised edition, 2013), and HCS 2012.

Discussion of the *Hazardous Products Regulations*
Subsection 7.14.1(2)

Categories

7.14.1(2) An oxidizing solid is classified in a category of this hazard class, based on results from testing performed in accordance with test O.1 of sub-section 34.4.1 of Part III of the Manual of Tests and Criteria or test O.3 of sub-section 34.4.3 of that Part, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Oxidizing Solids — Category 1	A solid that, when tested in a 4:1 or 1:1 mixture, by mass, with cellulose, exhibits a mean burning time < the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose
2	Oxidizing Solids — Category 2	A solid that, when tested in a 4:1 or 1:1 mixture, by mass, with cellulose, exhibits a mean burning time ≤ the mean burning time of a 2:3 mixture, by mass, of potassium bromate and cellulose
3	Oxidizing Solids — Category 3	A solid that, when tested in a 4:1 or 1:1 mixture, by mass, with cellulose, exhibits a mean burning time ≤ the mean burning time of a 3:7 mixture, by mass, of potassium bromate and cellulose

The available data must first be compared against the criteria for exclusion from classification in this class listed in subsection 7.14.1 (1) of the HPR. If any of the exclusion criteria are met, the substance or mixture need not be assessed under this class.

If none of the exclusion criteria are met, the available data are assessed against the criteria in table to subsection 7.14.1 (2).

It must be noted that a hazard category cannot be assigned based on the chemical structure.

Testing

If testing is done it must be performed using test O.1 of sub-section 34.4.1 of Part III of the Manual of Tests and Criteria or test O.3 of sub-section 34.4.3 of that Part. The test measures the time a mixture of the solid substance and cellulose takes to burn as compared to a reference material. The test is repeated several times and an average burning time is recorded.

Note that the faster the burning time, the stronger the oxidizing capability of the solid tested.

The table in subsection 7.14.1 (2) of the HPR shows the criteria for the categories based on Test O.1; however, both Tests O.1 and O.3 are valid methods. Test O.3 was developed due to dangerous reactions that sometimes occur with Test O.1. When using Test O.3, the following table must be used as an equivalency for classification in the proper category.

Category	Criteria using test O.1	Criteria using test O.3
1	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, (by mass), of potassium bromate and cellulose.	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate greater than the mean burning rate of a 3:1 mixture (by mass) of calcium peroxide and cellulose.
2	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met.	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate equal to or greater than the mean burning rate of a 1:1 mixture (by mass) of calcium peroxide and cellulose and the criteria for Category 1 are not met.
3	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.	Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate equal to or greater than the mean burning rate of a 1:2 mixture (by mass) of calcium peroxide and cellulose and the criteria for Categories 1 and 2 are not met.

(GHS, 5th revised edition, 2013, paragraph 2.14.2)

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for Oxidizing Solids are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013); for Oxidizing Solids - Category 1 on p. 329, and for Oxidizing Solids - Category 2 and 3 on p. 330.

Classification of Oxidizing Solids

Example

Tests are performed using the Manual of Tests and Criteria, Part III, sub-section 34.4.1, Test Method O.1: "Test for oxidizing solids."

A solid powder substance suspected of being an oxidizing solid is tested to determine whether the mixture of substance and cellulose ignites and burns, and to compare the mean burning time with those of reference mixtures.

Tests require that the substance in question be mixed with dry fibrous cellulose in ratios of 1:1 and 4:1, by mass, of sample to cellulose.

The burning characteristics of these mixtures are compared with the standard reference mixtures, 3:2, 2:3 and 3:7 ratios, by mass, of potassium bromate to cellulose. Five trials are performed on the test substance in each of the sample to cellulose ratios. Five trials are performed with each reference mixture.

Available data

Test data/results

- The data for the 4:1 and 1:1 ratio of the test mixtures are
    - The mean burn time for the 4:1 ratio of the test mixture to cellulose is 105 s
    - The mean burn time for the 1:1 ratio of the test mixture to cellulose is 340 s
- The data for the standard reference mixtures, 3:2, 2:3 and 3:7 ratios of potassium bromate to cellulose are
    - The mean burn time for the 3:2 ratio of potassium bromate to cellulose is 4 s
    - The mean burn time for the 2:3 ratio of potassium bromate to cellulose is 54 s
    - The mean burn time for the 3:7 ratio of potassium bromate to cellulose is 100 s

Classification

The solid substance does not meet the criteria for oxidizing solids, so it is not classified as an oxidizing solid.

Rationale

The substance is a solid

1. Does a 4:1 or 1:1 sample-to-cellulose ratio, by mass, tested, exhibit a mean burning time less than or equal to the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose?

   ANSWER: No. The mean burn times for both the 4:1 and 1:1 solid substance sample-to-cellulose ratios (105 s, 340 s) are greater than the mean burning time of the 3:2 mixture, by mass, of potassium bromate and cellulose (4 s).

2. Does a 4:1 or 1:1 sample-to-cellulose ratio, by mass, tested, exhibit a mean burning time less than or equal to the mean burning time of a 2:3 mixture, by mass, of potassium bromate and cellulose?

   ANSWER: No. The mean burn times for both the 4:1 and 1:1 solid substance sample-to-cellulose ratios (105 s, 340 s) are greater than the mean burning time of the 2:3 mixture, by mass, of potassium bromate and cellulose (54 s).

3. Does a 4:1 or 1:1 sample-to-cellulose ratio, by mass, tested, exhibit a mean burning time less than or equal to the mean burning time of a 3:7 mixture, by mass, of potassium bromate and cellulose?

   ANSWER: No. The mean burn times for both the 4:1 and 1:1 solid substance sample-to-cellulose ratios (105 s, 340 s) are greater than the mean burning time of the 3:7 mixture, by mass, of potassium bromate and cellulose (100 s).

   Consequently, this solid substance is not classified as an oxidizing solid.

Subpart 15
Organic Peroxides

Definitions

7.15 The following definitions apply in this Subpart.

"as packaged" means packaged in the form and condition described in test series B, D, G and H of Part II of the Manual of Tests and Criteria.

"explosive properties" means the properties of an organic peroxide that, in laboratory testing according to test series A, C or E of Part II of the Manual of Tests and Criteria, make the liquid or solid liable to detonate, deflagrate rapidly or show a violent effect when heated under confinement.

"organic peroxide" means an organic liquid or solid that contains the bivalent -O-O- structure.

Discussion – As Packaged

The methodology of the test series (i.e., series B, D, G and H) used to classify organic peroxides requires that the substance or mixture be tested in the condition and form in which it is offered for transport or "**as packaged**" (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.4.3 paragraph (a)).

Discussion - Explosive Properties

The above definition for **explosive properties** is derived from the following statement from the GHS:

> "An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement." (GHS, 5th revised edition, 2013, paragraph 2.15.1.2)

The test methods are included in the definition given in section 7.15 of the HPR because results from these tests are used to conclude whether a substance or mixture has explosive properties for the purposes of classification in the Organic Peroxides hazard class.

Discussion - Organic Peroxides

Organic peroxides may be solid or liquid organic chemicals (i.e., chemicals containing carbon) that are characterized by a weak oxygen-oxygen (-O-O-) bond (also called a peroxy group or peroxide group). This bond can break or decompose easily, releasing heat (i.e., exothermic

reaction). The rate of decomposition increases with increasing temperature. Decomposition can also be initiated by heat, mechanical shock, friction, or contaminants such as amines, metal ions (by themselves or as a result of contact with metal surfaces), strong acids and bases, and strong reducing and oxidizing agents.

In addition to being thermally unstable, organic peroxides "…may have one or more of the following properties:

(a) be liable to explosive decomposition;

(b) burn rapidly;

(c) be sensitive to impact or friction;

(d) react dangerously with other substances."

(GHS, 5th revised edition, 2013, paragraph 2.15.1.1)

In general, organic peroxides have weak or no oxidizing properties but may be flammable or emit a flammable gas when heated (ECHA Guidance, 2015, paragraph 2.15.3).

Other applicable definitions

The following term is used in this chapter but its definition appears under Part I, Interpretation of the HPR:

"SADT" or "self-accelerating decomposition temperature" means the lowest temperature at which self-accelerating decomposition occurs.

Discussion – SADT

When the oxygen-oxygen bond of an organic peroxide decomposes or breaks, it generates free radicals and heat. If the heat does not dissipate into the environment as quickly as it is generated, the resulting increase in temperature will further intensify the rate of decomposition. Unchecked, the temperature can increase exponentially to a point where decomposition cannot be stopped. This reaction creates a dangerous situation known as **self-accelerating decomposition**.

The self-accelerating decomposition temperature (SADT) is the lowest temperature at which a packaged organic peroxide will undergo a self-accelerating decomposition. "The SADT is a measure of the combined effect of the ambient temperature, decomposition kinetics, package size and the heat transfer properties of the substance and its packaging" (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 28.1).

Test series H of Part II of the Manual of Tests and Criteria can be used to determine the SADT of a substance or mixture that is an organic peroxide.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.15.1(1)

Exclusions

7.15.1(1) An organic peroxide that contains any of the following need not be classified in any category of this hazard class:

(a) not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

The exclusion criteria described in subsection 7.15.1(1) of the HPR are based on the available oxygen content (also called the active oxygen content) of the organic peroxide(s) under consideration and the content of hydrogen peroxide in a mixture.

The available oxygen content is the amount of oxygen contained in an organic peroxide molecule that is available for forming free radicals. One oxygen atom in each peroxide group is considered "active" or available. The concept of available oxygen content is related to the energy content of a formulation. In general, energy content increases with available oxygen content so that the higher the molecular mass of the organic groups, the lower the energy content and, usually, the lower the hazard. The formula for calculating available oxygen content is given in subsection 7.15.1(2) of the HPR.

Discussion of the *Hazardous Products Regulations*
Subsection 7.15.1(2)

Available oxygen content

7.15.1(2) The available oxygen content, in percent, of an organic peroxide mixture referred to in paragraph (1)(a) or (b) is determined by the following formula:

$$16 \times \sum_{i}^{n} \left(\frac{n_i \times c_i}{m_i} \right)$$

where

n_i is the number of peroxygen groups per molecule of organic peroxide *i*;

c_i is the concentration (mass %) of organic peroxide *i*; and

m_i is the molecular mass of organic peroxide *i*.

The exclusion criteria described in subsection 7.15.1(1) of the HPR require that the available oxygen content (also called the active oxygen content) of the organic peroxide (or peroxides) be calculated.

The formula given in subsection 7.15.1(2) of the HPR takes into account:

- the number of peroxide (or peroxygen) groups in a given organic peroxide where each peroxide group is considered to contain one active or available oxygen atom. Using the structural formula of the organic peroxide, the number of peroxide groups (-O-O-) can easily be counted.

  Example 1 – Peroxide (or Peroxygen) groups

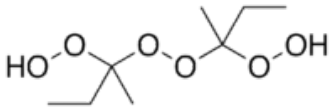
  

  Figure 1. Methyl ethyl ketone peroxide

  From the structural formula given in Figure 1, methyl ethyl ketone peroxide has three (3) peroxide groups.

- the concentration of the organic peroxide as a percentage of the substance or mixture.
- the molecular mass of the organic peroxide.

  Example 2 – Calculation of available oxygen content

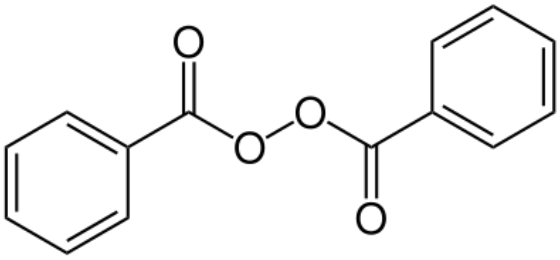
  

  Figure 2. Benzoyl peroxide

  A 25% solution of the organic peroxide benzoyl peroxide does not contain any hydrogen peroxide. To calculate the available oxygen content the following information is required:

  n_i - number of peroxide groups. From figure 2, the number is 1.

  c_i – the concentration of the organic peroxide. In this example, it is a 25% solution.

  m_i - the molecular mass. The molecular mass can be determined from the molecular formula for benzoyl peroxide $C_{14}H_{10}O_4$:

  14(12) + 10(1) + 4(16)

  = 242

  Solve the formula from 7.15.1 (2) using the above numbers:

  16 x (1 x 25)/242

  = 1.65%

The available oxygen content is 1.65%, which is greater than 1% and the solution does not contain any hydrogen peroxide. Based on paragraph 7.15.1(1)(a) of the HPR, this organic peroxide solution does not meet the exclusion criteria and must be given further consideration for classification.

Discussion of the *Hazardous Products Regulations* Subsection 7.15.1(3)

Categories

7.15.1(3) An organic peroxide is classified in a category of this hazard class, based on results from testing performed in accordance with test series A to H of Part II of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Organic Peroxides — Type A	A liquid or solid that, as packaged, is liable to detonate, or deflagrate rapidly
2	Organic Peroxides — Type B	A liquid or solid that possesses explosive properties and, as packaged, neither detonates, nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package
3	Organic Peroxides — Type C	A liquid or solid that possesses explosive properties and, as packaged, neither detonates, nor deflagrates rapidly, nor undergoes a thermal explosion in that package
4	Organic Peroxides — Type D	In laboratory testing, a liquid or solid that (a) detonates partially, but does not deflagrate rapidly and shows no violent effect when heated under confinement; (b) does not detonate, but deflagrates slowly and shows no violent effect when heated under confinement; or (c) neither detonates nor deflagrates, but shows a medium effect when heated under confinement
5	Organic Peroxides — Type E	In laboratory testing, a liquid or solid that neither detonates nor deflagrates, and shows low or no effect when heated under confinement
6	Organic Peroxides — Type F	In laboratory testing, a liquid or solid that neither detonates in the cavitated state nor deflagrates and (a) shows low or no effect when heated under confinement, as well as low or no explosive power; or (b) shows no effect when heated under confinement nor any explosive power, and either (i) has a SADT < 60°C when evaluated in a 50 kg package, or (ii) in the case of a liquid mixture, has a diluent that is used for desensitization with a boiling point < 150°C
7	Organic Peroxides — Type G	In laboratory testing, a liquid or solid that neither detonates in the cavitated state nor deflagrates, shows no effect when heated under confinement nor any explosive power, and either (a) has a SADT of 60°C to 75°C when evaluated in a 50 kg package, or (b) in the case of a liquid mixture, has a diluent that is used for desensitization with a boiling point ≥ 150°C

Organic peroxides are classified into seven categories (Types A to G) according to the degree of danger they present as defined by their ability to detonate, to deflagrate, and to react while heated under confinement. Type A is the most severe hazard category while Type G is the least severe. Additionally, for organic peroxides, their chemical structure (-O-O- bond) and the available oxygen and hydrogen peroxide contents of the mixture (as explained in subsection 7.15.1(1) of the HPR) are also used in classification.

The criteria for Types A, B, and C specify that the organic peroxide be tested "as packaged" since "stronger packaging may result in more violent reactions when the organic peroxide decomposes" (ECHA Guidance, 2015, paragraph 2.15.4.1). The words "in laboratory testing" in Types D, E, F and G criteria imply that the organic peroxide is tested in its non-packaged form. Types F and G have conditional criteria that require testing in a "50 kg package".

Desensitization, mentioned in the criteria for Types F and G, refers to the addition of organic liquids or solids, inorganic solids or water to an organic peroxide to increase the stability of the organic peroxide (United Nations Recommendations on the Transport of Dangerous Goods Model Regulations, volume I, 19th revised edition, 2015, sub-section 2.5.3.5.1). For desensitized organic peroxides, the concentration and type of diluent used are important considerations when classifying. Sub-section 2.5.3.5 of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations, volume I, 19th revised edition, 2015, provides useful information regarding acceptable diluents.

Testing

If testing is done it must be performed using test series A to H as described in sections 20 to 28 of Part II of the Manual of Tests and Criteria, which are designed to answer the questions given in the flowchart (Figure 20.1(a) of the Manual of Tests and Criteria – *Flowchart Scheme for Self-Reactive Substances and Organic Peroxides*) and Decision Logic 2.15 for organic peroxides on p. 104 of the GHS (5th revised edition, 2013).

Prior to performing tests series A to H, small-scale testing should be performed for the safety of laboratory workers. This involves tests for determining the sensitivity of the substance or mixture to mechanical stimuli (impact and friction), and to heat and flame (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.3). The preliminary testing includes:

a) a falling weight test to determine sensitiveness to impact,

b) a friction or impact test to determine the sensitiveness to friction,

c) a test to assess thermal stability and the exothermic decomposition energy, and

d) a test to assess the effect of ignition.

(United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.3.2)

Thereafter, test series A to H (as applicable) are performed and their results are used to answer questions in the GHS Decision Logic 2.15 for organic peroxides (GHS, 5th revised edition, 2013, p. 104) relating to:

- Propagation of detonation,
- Propagation of deflagration,
- Effect on heating in confinement, and
- Thermal stability: SADT.

The sequence of test series A to H is based more on assessing results than on the order in which tests are actually conducted. The recommended sequence of laboratory scale testing is test series E, H, F, C and then A, although some tests may not be required as indicated in the introduction to each test series. The package tests of test series B, D, and G only need to be performed if indicated by the results from the corresponding tests in test series A, C, and E. (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-sections 20.4.5.1 and 20.4.5.2)

> Note: The test series A to H described in Part II of the Manual of Tests and Criteria are not equivalent to the classification of Types A to G as specified under subsection 7.15.1(3) of the HPR. For example, from the Decision logic 2.15 for organic peroxides in the GHS, testing to classify a substance or mixture in hazard category Type A might include results from Test A and Test B or alternatively results from Test A, Test C and Test D. Results from Test A alone are insufficient to classify a substance or mixture in Type A.

Test series H is used to determine the self-accelerating decomposition temperature (SADT). The SADT is used in criteria for Type F and G. The SADT is dependent on the nature of the organic peroxide, and the volume and heat-loss characteristics of the packaging in which the organic peroxide is handled. Therefore, the SADT is only valid for the organic peroxide as tested and when handled properly. Mixing the organic peroxide with other chemicals, or contact with incompatible materials (including incompatible packaging) may reduce the thermal stability due to catalytic decomposition, and lower the SADT. This may increase the risk of decomposition and should be avoided (ECHA Guidance, 2015, paragraph 2.15.4.3.1).

Note that Test Series H does not include the condition of a SADT being less than or equal to 75 °C when transported in a 50 kg package for organic peroxides. Classification based on Test Series H would be consistent with classification expected under the HPR.

The SADT decreases with increasing package size and with increasing efficiency of the insulation on the package. The test selected should be conducted in a manner which is representative, both in size and material, of the package (GHS, 5th revised edition, 2013, paragraph 2.15.2.3).

An SADT must be determined in order to decide if a substance or mixture:

a) conforms to the requirements of Type G, when appropriate, or
b) meets the SADT criterion for organic peroxides, when appropriate.

(United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 20.4.1.3)

In addition, an SADT is required to determine if a substance or mixture should be subject to temperature control during transport, storage and handling.

Comparison with HCS 2012

The HPR includes in the criteria for Organic Peroxide - Type G a temperature limit for the SADT of 75°C. The HCS 2012 does not have an upper temperature limit for the same criteria. This difference may result in fewer organic peroxides being classified as Type G under the HPR than under the HCS 2012. It is important to note that Health Canada would not object to an organic peroxide having an SADT greater than 75°C being classified in Organic Peroxide - Type G under the HPR.

Discussion of the *Hazardous Products Regulations* Subsection 7.15.1(4)

Mixtures

7.15.1(4) A mixture of organic peroxides must be classified in the same category as the most hazardous organic peroxide in the mixture, unless the self-accelerating decomposition temperature of the mixture results in the mixture being classified in a category that represents a more severe hazard.

Testing of a mixture of organic peroxides may be done to determine in which category the mixture will be classified. When testing is not done, the mixture must be classified in the same category as the most hazardous organic peroxide in the mixture. However, if the mixture has an SADT which classifies it in a higher category than the most hazardous organic peroxide in the mixture, that classification takes precedence. In practice, consideration of the SADT applies to Types F and G only.

Comparison to HCS 2012 and GHS

The HCS 2012 guidance and paragraph 2.15.4.2.3 of GHS state the following: “Mixtures of [already classified] organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the self-accelerating decomposition temperature (SADT) of the mixture shall be determined.” (GHS, 5th revised edition, 2013, paragraph 2.15.4.2.3).

Therefore, in a situation where the SADT of a mixture classifies it in a higher category than the most hazardous organic peroxide in the mixture, classification in the higher category would be required under the HPR and allowed under the HCS 2012.

Hazard Communication

The symbol, signal words as well as hazard and precautionary statements for Organic Peroxides are provided in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, pp. 331-333) as follows:

- Type A on p. 331,
- Type B on p. 332,
- Types C to F on p. 333, and
- Type G has no symbol, signal word, hazard or precautionary statement.

Classification of Organic Peroxides

Example

(OSHA Hazard Classification Guidance 2016, pp. 367-370)

A colorless liquid is suspected of being an organic peroxide and is tested according to the tests presented in the Manual of Tests and Criteria, Part II. Organic peroxides, by definition, must contain the molecular structure -O-O-, and must contain a certain level of available oxygen and hydrogen peroxide content.

In the following example, the results of the tests are assessed in alphanumeric order; however, the tests are performed in the order given in sub-section 20.4.5 of the Manual of Tests and Criteria.

Available data

- Colorless liquid.
- Composition: technically pure (97%)
- Molecular formula: not available
- Apparent density: 900 kg/m3
- Available oxygen content: 7.18%

Test results

Test Name	Observation	Result
Test series A - Detonation propagation [BAM 50/60 steel tube test]	Sample conditions: peroxide assay 97% Observations: fragmented part of the tube: 18 cm	Test result/criteria: No propagation of detonation
Test series B - Detonation as packaged	Not applicable	
Test series C - Deflagration propagation [Time/pressure test]	Test conducted on 5 g of sample three times; the time it took for the pressure to rise from 690 kPa to 2,070 kPa was noted. Shortest recorded time (4000 ms) is used for result.	Test result/criteria: Yes, propagates a deflagration slowly, because the time for pressure to rise from 690 kPa to 2,070 kPa is greater than or equal to 30 ms
Test series C - Deflagration propagation [Deflagration test]	Test conducted two times on 265 cm^3 of sample at 25 °C, and the reaction rate noted for each. Shortest recorded rate (0.74 mm/s) is used for result.	Test result/criteria: Yes, propagates a deflagration slowly, because the deflagration rate is less than or equal to 5.0 mm/s and greater than or equal to 0.35 mm/s. Overall result: Yes, propagates a deflagration slowly
Test series D - Deflagration as packaged	Not applicable	
Test series E - Effect of heating under confinement [Koenen test]	Tested 60 mm of sample. Limiting diameter: 2.0 mm fragmentation type “F,” evaluated as “explosion.”	Test result/criteria: Violent effect of heating under confinement because the limiting diameter is greater than or equal to 2.0 mm.
Test series E - Effect of heating under confinement [Dutch Pressure Vessel test]	Tested 10.0 g of sample. Limiting diameter: 6.0 mm (with 10 g)	Test result/criteria: Medium effect of heating under confinement because rupture of the disc with an orifice of 6.0 mm and a sample mass of 10.0 g. Overall result: Violent effect of heating under confinement
Test series F - Explosive Power	Not applicable	
Test series G - Detonation as packaged [Thermal explosion test in the package]	Tested 30-liter packaging. Observations: no fragmentation of the package (N.F.)	Test result/criteria: No fragmentation or a fragmentation into no more than three pieces shows that the substance does not explode in the package.
Test series H - Thermal stability [Heat accumulation storage test; the recommended test for substances transported in packagings, IBCs, or small tanks.]	Tested 380 g of liquid. Half life time of cooling of Dewar vessel with 400 ml DMP: 10.0 hrs (representing substance in package) Observed: Self-accelerating decomposition at 35 °C (95 °F), no self-accelerating decomposition at 30 °C (86 °F). The self-accelerating decomposition temperature (SADT) is 35 °C (95 °F).	Liquid has a SADT of 35 °C (95 °F).

Evaluation of Data

The liquid has 7.18% available oxygen. The liquid is considered for classification as an organic peroxide since the available oxygen is greater than 1%.

1. Does the chemical in question propagate a detonation?
   RESULT (Test series A): No
2. Can the chemical in question propagate a deflagration?
   RESULT (Tests series C): Yes, slowly.
3. What is the effect of heating under confinement?
   RESULT (Tests series E): Violent.
4. Can it detonate as packaged?
   RESULT (Tests series G): No.

Classification

The liquid is classified as an Organic Peroxide - Type C.

Rationale

The criteria for Organic Peroxides – Type C in the Table to subsection 7.15(3) of the HPR are the following: A liquid or solid that possesses explosive properties and, as packaged, neither detonates nor deflagrates rapidly, nor undergoes a thermal explosion in that package.

Based on the results of Test series A and G, the liquid does not propagate a and does not detonate (explode) as packaged. Test series C results showed that the liquid propagates a deflagration slowly (not rapidly). Test series E results demonstrated that the liquid shows a violent effect when heated under confinement. Comparing these results to the criteria for Organic Peroxides – Types A through G, as set out in the Table to subsection 7.15.1(3) of the HPR, it is concluded that the liquid meets the criteria to be classified as an Organic Peroxide – Type C.

The United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations and the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015 recommend the use of temperature control for this substance since the SADT (35 ^{o}C) is less than 50 °C (122 ^{o}F).

Subpart 16
Corrosive to Metals

Definition of "corrosive to metals"

7.16 In this Subpart, "corrosive to metals" means, in relation to a mixture or substance, liable to damage or destroy metal by chemical action.

Discussion - Corrosive to Metals

A substance or mixture that is "corrosive to metals" is defined as the substance or mixture that is liable to undergo an irreversible chemical reaction with metals and leads to significant damage or, in some cases, even full destruction of metals.

Many parameters influence the corrosion properties of a substance or mixture, such as the nature of the chemical or the pH.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.16.1

Category

7.16.1 A mixture or substance that is corrosive to metals is classified in the category of this hazard class, based on results from testing performed in accordance with sub-section 37.4 of Part III of the Manual of Tests and Criteria, in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Corrosive to Metals — Category 1	A mixture or substance that has a corrosion rate on either steel or aluminium surfaces that is > 6.25 mm per year at a test temperature of 55°C

For the purposes of classification, corrosive to metals will only be considered for substances and mixtures that are liable to corrode either steel or aluminium (United Nations Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 37.4). This hazard class does not cover substances or mixtures that have the potential to corrode metals other than steel or aluminium.

A substance or a mixture is classified in Corrosive to Metals - Category 1 if it has a corrosion rate on either steel or aluminium surfaces that is > 6.25 mm per year when tested at a temperature of 55 °C.

It is important to note that where an initial test on either a steel or aluminium surface indicates the substance or mixture being tested is corrosive, the follow-up test on the other metal is not required (GHS, 5th revised edition, 2013, paragraph 2.16.2).

Two types of corrosion phenomena are considered when classifying substances or mixtures as corrosive to metals: the uniform corrosion attack and the localized corrosion (e.g., pitting corrosion, shallow pit corrosion).

Physical State

For classification, the physical state of the substance or mixture is not specified in the HPR. The classification criteria in section 7.16.1 of the HPR is based on the corrosion rate that is measured according to the test method in Part III, sub-section 37.4 of the Manual of Tests and Criteria, Test C.1, "Test for determining the corrosive properties of liquids and solids that may become liquid during transport" (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, sub-section 37.4). Although no guidance is provided on how to define "solids that may become liquid during transport", the test is conducted at 55 °C (which is the temperature required in UN Test C.1), therefore, solids with melting points at or below this temperature must be considered for classification in this hazard class.

Comparison to HCS 2012 and GHS

The GHS (5th revised edition, 2013, paragraph 2.16.2) and the HCS 2012 provide the following criteria for classification in this hazard class, along with an explanatory note:

> "Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55 °C when tested on both materials.
>
> *Note: Where an initial test on either steel or aluminium indicates the substance or mixture being tested is corrosive, the follow-up test on the other metal is not necessary."*

The HPR wording is slightly different from the wording in HCS 2012. In the HPR, the phrase "when tested on both materials" has been omitted from the criteria, but the note to Table 2.16.1 in the GHS (GHS, 5th revised edition, 2013, p. 107) has been included. In this way, it still conveys that, for a substance or mixture to be classified in the Corrosive to Metals hazard class, a positive result is only required for one of the two metals. Therefore, the classification in "Corrosive to Metals" is expected to be the same for HCS 2012 and the HPR.

Testing

If testing is done, it must be performed according to Test C.1 in sub-section 37.4 of Part III of the Manual of Tests and Criteria. This method considers two types of corrosion: uniform corrosion attack and localized corrosion (e.g., pitting corrosion, shallow pit corrosion). Both types of corrosion are determined using 2 mm thick plates of the following materials:

- For the purposes of testing steel, steel types, S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 102.
- For the purposes of testing aluminium, non-clad types 7075-T6 or AZ5GU-T6.

Refer to the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria (6th revised edition, 2015, sub-section 37.4) for a complete description of the method, apparatus used and analysis of the test results.

Although the classification is based on a rate of corrosion that is greater than 6.25 mm over the course of a year, in practice, the corrosion rate is measured over a shorter period of time (usually 1 to 4 weeks) and the data is extrapolated to give an annual rate. If the corrosion rate has not been given in mm/year, the mass loss (for uniform corrosion attack) or minimum intrusion depth (for localized corrosion) values must be used for classification in this hazard class (United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, 6th revised edition, 2015, section 37).

Hazard Communication

As per paragraph 3(1)(c) of the HPR, the symbol, signal word as well as hazard and precautionary statements for Corrosive to Metals - Category 1 are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013, p. 334.

Classification for Corrosive to Metals

Example

For results based on uniform corrosion attack, the mass loss of the most corroded sample is used and compared to Table 37.4.1.4.1 (reproduced below) of the Manual of Tests and Criteria.

Minimum mass loss of specimens after different exposure times

Exposure Time	Mass Loss
7 days	13.5 %
14 days	26.5 %
21 days	39.2 %
28 days	51.5 %

The percentage mass loss values are based on a 6.25 mm/year corrosion rate so that a mass loss of greater than 13.5 % at 7 days represents a corrosion rate of greater than 6.25 mm/year.

Available data

Testing of Substance A on non-clad aluminum 7075-T6 using UN Test C.1 results in a mass loss value of 30.8 % at 14 days.

Classification

Substance A must be classified in Corrosive to Metals - Category 1.

Rationale

Using the above table, any mass loss greater than 26.5 % at 14 days represents a corrosion rate of > 6.25 mm/year; therefore, Substance A meets the criteria to be classified in Corrosive to Metals - Category 1.

Subpart 17
Combustible Dusts

The Combustible Dusts hazard class is not a GHS hazard class. The HCS 2012 includes "combustible dusts" within the definition of "hazardous chemical" but does not contain a hazard class for combustible dusts. In the HPR, unlike HCS 2012, there is a definition for "combustible dust", in addition to classification criteria. OSHA has provided guidance for combustible dusts (Refer to OSHA Hazard Classification Guidance 2016, p.380 for more information).

Definition of "combustible dust"

7.17 In this Subpart, "combustible dust" means a mixture or substance that is in the form of finely divided solid particles that, upon ignition, is liable to catch fire or explode when dispersed in air.

Discussion – Combustible Dusts

Combustible dust hazards involve dusts or other small particles that upon ignition present a fire or explosion hazard when suspended at a sufficient concentration in air or some other oxidizing medium. Under the HPR, products which are sold or imported in dust form and present this physical hazard are included within this hazard class. The Combustible Dusts hazard class, in the HPR, does not apply to products which will be processed downstream to generate dust in the workplace.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Section 7.17.1

Category

7.17.1 A combustible dust is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Combustible Dusts – Category 1**	**A mixture or substance that** **(a) has been shown to, upon ignition, catch fire or explode when dispersed in air or other oxidizing medium; or** **(b) is classified in a category of the hazard class "Flammable Solids" and 5.0% or more of its composition by weight is a flammable solid and has a particle size ≤ 500 µm.**

The experience with use or storage of a substance or mixture may be used to classify it in the Combustible Dusts hazard class, if known. For example, if the supplier knows that a substance or mixture has been involved in a fire or dust explosion incident, the supplier must classify the substance or mixture in Combustible Dusts - Category 1. A substance or mixture which has been shown through testing to catch fire or explode upon ignition when dispersed in air or other oxidizing medium must also be classified in Combustible Dusts – Category 1.

When there is no physical evidence or test results, or if the testing is inconclusive, classification may be based on particle size, if particle size information is available. If the substance or mixture is classified in a category of the Flammable Solids hazard class and 5% or more of its composition by weight has a particle size 500 microns (µm) or less, then it must be classified in Combustible Dusts - Category 1.

Particle size is the average size of the solid particle. It can be measured by passing the solid through a series of standardized mesh sieves. If all of the solid were to pass through a particular sieve then the solid would be described as having a particle size less than or equal to the mesh size of the sieve. There are a number of ways sieve sizes are identified; some are by the size of the particles and others by the number of openings per linear inch (US Sieve Series and Tyler Mesh). For example, a substance or mixture that passes through a U.S. Sieve No. 35 would be considered to have a particle size ≤ 500 µm (OSHA Hazard Classification Guidance 2016, p. 383).

Physical properties

Particle size is an important property as it typically influences the ease of ignition and the severity of a combustible dust explosion. Other factors which influence the explosiveness of dusts include moisture content, ambient humidity, oxygen available for combustion, the shape of dust particles, and the concentration of dust in the air. Physical properties used to measure combustible dusts hazards include the following:

- Minimum ignition energy (MIE), which predicts the ease and likelihood of ignition of a dispersed dust cloud.
- Minimum explosible concentration (MEC), which measures the minimum amount of dust dispersed in air required to spread an explosion. (The MEC is analogous to the Lower Flammable Limit (LFL) or Lower Explosive Limit (LEL) for gases and vapors in air).
- Dust deflagration index (K_{st}), which measures the relative explosion severity compared to other dusts. The severity of an explosion is expected to increase with the value for K_{st} (See Table 1). K_{st} provides the best “single number” estimate of the anticipated behavior of a dust deflagration.

Table 7.17.1 Examples of K_{st} Values for Different Types of Dusts

K_{st} (bar.m/s)	General Characteristic	Typical Substances
0	No explosion	Silica
>0 and = 200	Weak explosion	Powdered milk, charcoal, sulfur, sugar and zinc
>200 and = 300	Strong explosion	Cellulose, wood flour, and poly methyl acrylate
>300	Very strong explosion	Anthraquinone, aluminum, and magnesium
The actual K_{st} value is sample specific and will depend on varying characteristics of the substance or mixture such as particle size or moisture.		

Note: Different dusts of the same substance or mixture can have different ignitability and explosibility characteristics, depending upon physical characteristics such as particle size, shape, and moisture content. Any combustible dust with a K_{st} value greater than zero can be subject to dust deflagration.

Published Test Results

Published literature is available and can be used to aid in classification. For example, the *National Fire Prevention Association* (NFPA) has published several standards, which include lists of test results for the combustible dust characteristics of various substances and materials.

There are also public databases of dust explosibility characteristics that may be consulted, such as the “GESTIS-DUST-EX” database maintained by the Institute for Occupational Safety and Health of the German Social Accident Insurance (Details of website: http://staubex.ifa.dguv.de/?lang=e), available in English, French, German and Dutch.

Testing

If published test results are not available and there is no experience demonstrating a combustible dust hazard, then laboratory testing could be conducted. Reliable test data for a substance or mixture, based on a scientifically validated method, is considered strong evidence for determining whether a substance or mixture presents a combustible dust hazard.

Reliable screening tests, such as the one described in ASTM E1226 (*Standard Test Method for Explosibility of Dust Clouds*), showing a positive normalized rate of pressure rise or dust deflagration index (K_{st}) may be used. The E1515 (*Standard Test Method for MEC of Combustible Dusts*) method may also be used.

Comparison to HCS 2012

Under the HPR, only products that are sold or imported in dust form and that present a combustible dust hazard are required to be labelled. Under the HCS 2012, chemicals that are shipped in dust form and present a combustible dust hazard in that form when used downstream are required to be labelled. Furthermore, chemicals that are shipped in a non-dust form but which, when processed in the workplace, would pose a combustible dust hazard are required to be labelled.

Hazard Communication

Part 1 of Schedule 5 of the HPR specifies the signal word and hazard statement required for Combustible Dusts. A symbol is not required. As per subparagraph 3(1)(d)(ii) of the HPR, the supplier is required to include applicable precautionary statements.

Subpart 18
Simple Asphyxiants

Simple Asphyxiants is not a GHS hazard class. HCS 2012 includes "Simple Asphyxiants" under health hazards. In the HPR, unlike HCS 2012, the Simple Asphyxiants hazard class is included under physical hazards.

Definition of "simple asphyxiant"

7.18 In this Subpart, "simple asphyxiant" means any gas that is liable to cause asphyxiation by the displacement of air.

Discussion

Simple Asphyxiants hazard class is intended to capture any gas that displaces air and causes oxygen deprivation in those who are exposed, leading to unconsciousness and death. The definition specifies that this hazard class applies to gases only, vapours are not included.

Simple asphyxiants are gases that are harmful to the body when they become very concentrated and reduce oxygen in the air to dangerous levels.

Comparison to HCS 2012

The HCS 2012 does not limit the definition of simple asphyxiants to gases. The term "simple asphyxiant" is defined in paragraph 1910.1200(c) as follows "*Simple asphyxiant* means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death." However, the OSHA Hazard Classification Guidance (2015) includes the terms gases and vapors under simple asphyxiants. This difference in definition could result in classification differences between HCS 2012 and the HPR. More products may be classified as simple asphyxiants under the HCS 2012 due to the presence of vapours that have the same action as defined in the HPR for a simple asphyxiant. However, the classification of a product as a simple asphyxiant in Canada, based on the HCS 2012 criteria, would not be considered to violate section 14.2 of the HPA, which prohibits information that is false, misleading or likely to create an erroneous impression. Therefore, HCS 2012 based labels and SDSs would be acceptable in Canada with respect to the Simple Asphyxiants hazard class.

Classification in the Category of the Class

Discussion of the *Hazardous Products Regulations*
Section 7.18.1

Category

7.18.1 A simple asphyxiant is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Simple Asphyxiants — Category 1**	**A gas that is a simple asphyxiant**

A substance or mixture is classified in Simple Asphyxiants – Category 1 if it meets the definition of a simple asphyxiant.

Hazard Communication

Hazard communication for Simple Asphyxiants is provided in Part 2 of Schedule 5 of the HPR. The HPR does not require a symbol for this hazard class. As per subparagraph 3 (1)(d)(ii) of the HPR, suppliers are required to provide appropriate precautionary statements.

Hazard communication for Simple Asphyxiants under the HPR is aligned with the HCS 2012.

Examples

Examples of simple asphyxiants that should be considered for classification in Simple Asphyxiants – Category 1 include:

- the “inert” gases, as well as the “relatively inert” gases like the aliphatic alkanes and the chlorofluorocarbons.
- hydrogen, helium, ethane, ethylene, nitrogen, neon; carbon dioxide, acetylene, argon, methane, propane, propylene.

Subpart 19
Pyrophoric Gases

The Pyrophoric Gases hazard class is not included in the 5th revised edition of GHS. However, Pyrophoric Gases has been included in the Flammable Gases Hazard Class in the 6th revised edition of the GHS. There is no hazard class for pyrophoric gases in the HCS 2012; however, a definition for pyrophoric gases has been included in the standard.

Discussion of the *Hazardous Products Regulations*
Section 7.19

Definition of "pyrophoric gas"

7.19 In this Subpart, "pyrophoric gas" means any mixture or substance in a gaseous state that is liable to ignite spontaneously in air at a temperature of 54°C or less.

The term "pyrophoric" applies to the ability of a substance or mixture to spontaneously ignite in air, without a supplied spark, flame, heat or other ignition source. The reaction is exothermic and almost instantaneous (within minutes).

It is important to note that spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay (GHS 6th revised edition, 2015, paragraph 2.2.2.2). Spontaneous means that an event occurs without apparent external energy and in the context of this hazard the dispersion of the gas in air is enough to cause the reaction. Spontaneity is not associated with a time factor.

Classification in a Category of the Class

Discussion of the *Hazardous Products Regulations*
Subsection 7.19.1

Category

7.19.1 A pyrophoric gas is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Pyrophoric Gases — Category 1**	**A gas that is a pyrophoric gas**

A substance is classified in Pyrophoric Gases - Category 1 if it meets the definition of pyrophoric gas.

A gas is not classified in the Pyrophoric Gases hazard class when experience in production or handling shows that the gas does not ignite spontaneously when it comes into contact with air at normal temperatures. Flammable gas mixtures that contain more than 1% pyrophoric components should be classified in Pyrophoric Gases unless available data supports non-classification (GHS, 6th revised edition, 2015, paragraph 2.2.2.2, note 2).

Test Methods

The HPR does not include a specific test method for classifying a gas in the Pyrophoric Gases hazard class. The following test methods are appropriate, although other scientifically validated methods may also be used:

- IEC 60079-20-1 ed 1.0 (2010-01): Explosive Atmospheres – Part 20-1: Material characteristics for gas and vapour classification - Test methods and data
- DIN 51794: Determining the ignition temperature of petroleum products.

  (GHS, 6th revised edition, 2015, paragraph 2.2.4.4.2)

Hazard Communication

The symbol, signal word and hazard statement for Pyrophoric Gases - Category 1 are provided in Part 3 of Schedule 5 of the HPR. As per subparagraph 3 (1)(d)(ii) of the HPR, suppliers must provide applicable precautionary statements.

Examples

Some examples of pyrophoric gases are: diborane, phosphine and silane (OSHA Hazard Classification Guidance 2016, p. 322).

Subpart 20
Physical Hazards Not Otherwise Classified

Physical Hazards Not Otherwise Classified is not a GHS hazard class. HCS 2012 defines "hazards not otherwise classified" (HNOC) but does not contain a hazard class for such hazards. In the HPR, unlike HCS 2012, HNOCs are classified in Physical Hazards Not Otherwise Classified (Subpart 20 of Part 7 of the HPR) or Health Hazards Not Otherwise Classified (Subpart 12 of Part 8 of the HPR), depending on the hazard presented.

Discussion of *Hazardous Products Regulations* Section 7.20

Definition of "physical hazard not otherwise classified"

7.20 In this Subpart, "physical hazard not otherwise classified" means a physical hazard presented by a product, mixture, material or substance that is different from any other physical hazard addressed by any other Subpart in this Part, and that has the characteristic of occurring by chemical reaction and resulting in the serious injury or death of a person at the time the reaction occurs.

The Physical Hazards Not Otherwise Classified (PHNOC) hazard class is intended to capture physical hazards which are not already covered by any of the other physical hazard classes addressed in Part 7 of the HPR. Therefore, this hazard class does not include effects that are considered under any of the existing physical hazard classes and that did not meet the criteria (e.g., an organic peroxide that did not meet the requirements for classification into any of the Organic Peroxide hazard class categories (types)). In addition, PHNOC does not include products that fall into a GHS hazard category that has not been adopted in the HPR (e.g., Flammable Aerosols - Category 3).

The expression "the characteristic of occurring by chemical reaction" used in section 7.20 in the context of injury or death means that the injury or death may occur as a secondary effect of the hazard, and that the hazard exists regardless of the exposure of a person to the product, mixture, material or substance. Guidance for health hazards of this type (i.e., Health Hazards Not Otherwise Classified), which require exposure to exert their effect, is provided in the chapter of this technical guidance that discusses Subpart 12 of Part 8 of the HPR. The expression also excludes radiological hazards and electrical conductivity.

The expression "resulting in serious injury or death" excludes minor hazards; however, it includes incidents where only property damage occurs, but if a person is present, it would result in a serious injury or death.

Classification in the Category of the Class

Discussion of the *Hazardous Products Regulations* Section 7.20.1

Category

7.20.1 A product, mixture, material or substance is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Physical Hazards Not Otherwise Classified — Category 1**	**A product, mixture, material or substance that presents a physical hazard not otherwise classified.**

A product, mixture, material or substance is classified in PHNOC – Category 1 if it meets the definition of a physical hazard not otherwise classified.

Hazard Communication

Hazard communication requirements for PHNOC are provided in Part 4 of Schedule 5 of the HPR.

Any pictogram found in Schedule 3 of the HPR that is applicable to the hazard, the signal word "Danger" and hazard statement(s) appropriate to the hazard (i.e. wording that describes the nature of the hazard) must be provided. Under item 2(a) of the safety data sheet, the hazard classification or a description of the hazard identified is required. As per subparagraph 3 (1)(d)(ii) of the HPR, suppliers are required to provide appropriate precautionary statements.

VARIANCE with HCS 2012: Label requirements for PHNOC and HNOC

HPR

A supplier must provide on the label a pictogram that is applicable to the hazard. The pictograms from which the supplier may choose are found in Schedule 3 of the HPR. The signal word (i.e., "Danger") is found in Schedule 5 of the HPR. In addition, paragraph 3(1)(d) and Schedule 5 of the HPR specify that appropriate hazard and precautionary statements must also be provided on the label.

HCS 2012

No label elements are required for HNOC; however, the hazards identified may be included on the label as supplemental information.

Examples

Example 1:

As per subsection 2(3) of the HPR, there are several substances and mixtures listed as PHNOC – Category 1 in Schedule 4 of the HPR "Prescribed Classification".

Example 2:

Vigorous polymerization is one example of a PHNOC. Polymerization is a chemical reaction in which many small molecules (monomers) join together to form a large molecule (polymer). Often the reaction produces heat and pressure. Industry carries out these processes under closely monitored conditions. Other chemicals (catalysts and initiators) and controlled amounts of heat, light and pressure are often involved. Vigorous polymerization is potentially hazardous because the reaction may get out of control. Once started, the reaction is accelerated by the heat that it produces. The uncontrolled build-up of heat and pressure can cause a fire or an explosion, or can rupture closed containers. Depending on the product, temperature increases, sunlight, ultraviolet (UV) radiation, X-rays or contact with incompatible chemicals can trigger such reactions.

Many substances (i.e., uninhibited) can undergo vigorous polymerization quite easily by themselves when they are heated slightly or exposed to light. The following examples of substances should be considered for classification in PHNOC – Category 1 if they meet the criteria for this hazard class.

- acrylic acid
- acrylonitrile
- cyclopentadiene
- diketene
- ethyl acrylate
- hydrocyanic acid
- methacrylic acid
- methyl acrylate
- vinyl acetate

(Details on website: https://www.ccohs.ca/oshanswers/chemicals/reactive/react.html).

PART 8

Health Hazard Classes

Introduction

This Part provides guidance to assist suppliers in determining the appropriate hazard classification of a substance, material or mixture in relation to the health hazard classes set out in Part 8 of the *Hazardous Products Regulations* (HPR). Health effects can either be acute (for example, Acute Toxicity, Specific Target Organ Toxicity – Single Exposure) or chronic (for example, Carcinogenicity, Reproductive Toxicity). Classification in relation to the health hazard classes is based on existing data and no additional testing is required to be undertaken. All available data must be evaluated against the criteria for each health hazard class to determine the health hazard classification of a substance, material or mixture.

The list of Health Hazard classes in Schedule 2 of the *Hazardous Products Act* (HPA) is the following:

1. Acute Toxicity
2. Skin Corrosion/Irritation
3. Serious Eye Damage/Eye Irritation
4. Respiratory or Skin Sensitization
5. Germ Cell Mutagenicity
6. Carcinogenicity
7. Reproductive Toxicity
8. Specific Target Organ Toxicity — Single Exposure (STOT-SE)
9. Specific Target Organ Toxicity — Repeated Exposure (STOT-RE)
10. Aspiration Hazard
11. Biohazardous Infectious Materials (BIM)[+]
12. Health Hazards Not Otherwise Classified (HHNOC)[+]

[+] These hazard classes are not covered by the GHS (5th revised edition, 2013)

The U.S. OSHA Hazard Communication Standard 2012 (HCS 2012) does not include a hazard class for biohazardous infectious materials since these materials in the workplace are not regulated by the HCS 2012. The HCS 2012 addresses “Hazards Not Otherwise Classified”, but does not provide distinct criteria for physical and health hazards not otherwise classified.

Types of data that can be used to classify a substance, material or mixture in the health hazard classes

When classifying a substance or material with respect to the health hazard classes set out in Part 8 of the HPR, certain types of data are to be used, as specified in subparagraphs 2.1(a)(i) to (iv) and 2.1(b)(i) to (iv) of the HPR.

Data on the substance or material may include any of the following:

- results of testing or studies carried out in accordance with the test methods referred to in Part 8;
- results of testing or studies carried out in accordance with generally accepted standards of good scientific practice;
- conclusions based on established scientific principles; and
- case reports or documented observations.

If data on the substance or material itself are unavailable or are insufficient to evaluate the substance or material in accordance with the applicable criteria, then, for each health hazard class except for Subparts 2 and 3 of Part 8 (Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation, respectively), data of the types listed above for a substance or material with similar properties to the substance or material that is being classified must be considered. Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation are excluded because these hazard classes provide a sequential approach to the determination of classification that already incorporates the consideration of different types of data, beginning with data on the substance itself and then other types of data, such as pH, followed by data on similar substances.

Further guidance is provided in the discussion of section 2.1 in Part 2 of this technical guidance.

When classifying a mixture with respect to the health hazard classes set out in Part 8 of the HPR, the types of data to be used are the same as those listed above. The data may pertain to the ingredients of the mixture, the mixture as a whole or a mixture with similar properties, as specified in subsection 2.2(2) of the HPR. Further guidance is provided in the discussion of subsection 2.2(2) in Part 2 of this technical guidance.

Considerations that are relevant to the health hazard classification of a substance, material or mixture

The following considerations may apply to the classification of a substance, material or mixture in any health hazard class. There is no specific reference to these provisions within the respective Subparts of Part 8; however, they must always be considered as part of the classification process.

Animal data – not relevant to humans

Subsection 2(9) of the HPR specifies that animal data for which it has been conclusively demonstrated, based on established scientific principles, that the mechanism or mode of action of the substance or mixture in animals is not relevant to humans must not be used for the purpose of classifying a substance or mixture in any of the health hazard classes referred to in Subparts 1 to 10 and 12 of Part 8. This provision does not apply Subpart 11 of Part 8 (BIM). Further guidance is provided in the discussion of subsection 2(9) in Part 2 of this technical guidance.

Biological availability

Section 2.9 of the HPR specifies that a substance, material or mixture need not be classified in any health hazard class if it can be shown by conclusive experimental data from scientifically validated methods that the substance, material or mixture is not biologically available. Further guidance is provided in the discussion of section 2.9 in Part 2 of this technical guidance.

Classification of mixtures in the health hazard classes: order of provisions

When classifying a mixture with respect to the health hazard classes, there is a "tiered" approach that must be followed. This means that the order of provisions for the classification of mixtures, as set out in each health hazard class, must be followed (as specified in subsection 2.2(2) of the HPR). This procedure will generally (but not always) require the following sequential steps:

1. Where test data are available for the mixture as a whole, the classification of the mixture will be based on that data.

2. Where test data are not available for the mixture as a whole, then the applicable bridging principles, as set out in subsections 2.3(3) to 2.3(8) of the HPR, must be used. In order to apply the bridging principles, sufficient test data must be available for similar mixtures and for individual ingredients of the mixture to be classified.

3. If test data are not available for the mixture as a whole, and sufficient data to allow the application of bridging principles are also not available, then the method(s) described in each Subpart for determining the hazards based on the ingredients of the mixture must be applied to classify the mixture (e.g., application of cut-off values/concentration limits/ calculation methods).

In the case of Subparts 5, 6 and 7 of Part 8 (Germ Cell Mutagenicity, Carcinogenicity and Reproductive Toxicity, respectively), the order of provisions is different from the above. The first step in the classification of mixtures is the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified as germ cell mutagens, carcinogens, or reproductive toxicants, respectively. However, if there are test data for the mixture as a whole, these data may be used to classify the mixture, instead of data on the individual ingredients. As a final step, applicable bridging principles may be used to classify the mixture.

For Subpart 11 of Part 8 (BIM), the classification of mixtures follows the same procedure as for the classification of substances. Bridging principles do not apply to this hazard class.

For Subpart 12 of Part 8 (HHNOC), the first step in the classification of mixtures is the evaluation of available test data for the mixture as a whole. Where test data are not available for the mixture as a whole, then classification is based on available test data for the individual ingredients of the mixture using a concentration cut-off value for the ingredients classified as HHNOC. Bridging principles do not apply to this hazard class.

Further guidance is provided in the discussion of subsection 2.2(2) in Part 2 and in the discussion of each Subpart of Part 8 of this technical guidance.

Classification of mixtures in the health hazard classes: in general, classification stops at the first provision that permits the classification of a mixture

As specified in subsection 2.2(3) of the HPR, except in the case of Subparts 1, 4, 7 and 8 of Part 8 (Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity and STOT-SE, respectively), the first provision that results in a mixture being classified in a category or subcategory of a health hazard class concludes the process of classification with regard to that particular health hazard class. No further evaluation of the mixture in relation to the remaining provisions for the classification of mixtures in that health hazard class is necessary.

Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity and STOT-SE are different because, for these health hazard classes, it is possible for a mixture to be classified in more than one category. These health hazard classes contain more than one classification table and it is necessary to evaluate the data for a mixture against the criteria in each classification table. For example, in Subpart 7 of Part 8 (Reproductive Toxicity), it is possible for a mixture to be classified in:

- Reproductive Toxicity — Category 1;
- Reproductive Toxicity — Category 2;
- Reproductive Toxicity — Effects on or via Lactation;
- both Reproductive Toxicity — Category 1 and Reproductive Toxicity — Effects on or via Lactation; or
- both Reproductive Toxicity — Category 2 and Reproductive Toxicity — Effects on or via Lactation.

Further guidance is provided in the discussion of subsection 2.2(3) in Part 2 and in the discussion of each Subpart of Part 8 of this technical guidance.

Classification of mixtures in the health hazard classes: bridging principles

The following summary table indicates which bridging principles are applicable to each of the health hazard classes set out in Part 8 of the HPR.

Summary Table – Application of the Bridging Principles to the Health Hazard Classes of the HPR

Health Hazard Class	Dilution	Production Batches	Increase in concentration of hazardous ingredient	Interpolation	Substantially similar mixtures	Aerosols
Acute Toxicity	✓ (see note 1 below)	✓	✓	✓	✓	✓
Skin Corrosion/ Irritation	✓ (see note 1 below)	✓	✓ (see note 2 below)	✓	✓	✓
Serious Eye Damage / Eye Irritation	✓ (see note 1 below)	✓	✓ (see note 3 below)	✓	✓	✓
Respiratory or Skin Sensitization	✓	✓	✓	✓	✓	✓
Germ Cell Mutagenicity	✓	✓			✓	
Carcinogenicity	✓	✓			✓	
Reproductive Toxicity	✓	✓			✓	
STOT-SE	✓	✓	✓	✓	✓	✓
STOT-RE	✓	✓	✓	✓	✓	✓
Aspiration Hazard	✓	✓	✓	✓	✓	
BIM	Bridging principles do not apply to this health hazard class.					
HHNOC	Bridging principles do not apply to this health hazard class.					

Notes:

1. Special rules apply; please refer to the discussion of paragraph 2.3(3)(a) of the HPR
2. Special rules apply; please refer to the discussion of paragraph 2.3(5)(b) of the HPR
3. Special rules apply; please refer to the discussion of paragraph 2.3(5)(c) of the HPR

Further guidance is provided in the discussion of subsections 2.3(1) to 2.3(8) in Part 2 of this technical guidance.

Considerations that are relevant to the classification of a mixture in the health hazard classes when classification is based on ingredient data

The following considerations may apply to the classification of a mixture in any health hazard class, unless otherwise specified, when classification is based on the evaluation of available test data for the individual ingredients of the mixture. There is no specific reference to these

provisions within the respective Subparts of Part 8; however, they must always be considered as part of the classification process.

Synergistic Effects (subsection 2.4(1) of the HPR)

All data available on the potential occurrence of synergistic effects among the ingredients of the mixture must be used in the evaluation.

Antagonistic Effects (subsection 2.4(2) of the HPR)

If data that show antagonistic effects among the ingredients of the mixture are used, this data must be conclusive and must be based on established scientific principles. Otherwise, data showing antagonistic effects must not be used for the purpose of classifying the mixture.

Concentration Limits — Lower Concentration (subsection 2.5(1) of the HPR)

When classifying a mixture in a particular category or subcategory of any health hazard class except for Subpart 11 of Part 8 (BIM), based on data available for the ingredients of the mixture, if there are data showing that an ingredient still presents the hazard at a concentration which is lower than the applicable concentration limit (cut-off value), then the mixture must be classified in that category or subcategory of that hazard class. This provision takes precedence over the concentration limit rule.

Concentration Limits — Equivalent or Higher Concentration (subsection 2.5(2) of the HPR)

When classifying a mixture in a particular category or subcategory of any health hazard class except for Subpart 11 of Part 8 (BIM), based on data available for the ingredients of the mixture, this provision may be applied if there is appropriate supporting evidence. The provision specifies that, if an ingredient is present in a mixture at a concentration that is equal to or higher than the concentration limit for a particular category or subcategory of a health hazard class, but there are scientifically valid data showing that, based on established scientific principles, the ingredient does not present the hazard at that concentration, then the mixture need not be classified in that category or subcategory of that hazard class due to the presence of that specific ingredient.

Maximum Concentration (section 2.6 of the HPR)

If a mixture contains a hazardous ingredient that is not always present at the same concentration, the maximum concentration at which the ingredient could be present in the mixture must be used for the purposes of establishing whether the mixture is classified in a category or subcategory of any health hazard class.

This provision is intended to ensure that the most conservative approach is taken when classifying a mixture that contains ingredients that could be present at varying concentrations.

Further guidance with regard to these provisions is provided in the discussion of the relevant section or subsection in Part 2 of this technical guidance.

Acronyms referred to in Part 8 – Health Hazards include the following:

ECHA CLP	ECHA Regulations on the Classification, Labelling and Packaging of Substances and Mixtures
GHS	Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition, 2013
HCS 2012	U.S. OSHA Hazard Communication Standard 2012
HPA	*Hazardous Product Act*
HPR	*Hazardous Product Regulations*

Subpart 1
Acute Toxicity

Discussion – Acute Toxicity

Acute toxicity refers to adverse effects occurring following oral or dermal administration of a single dose of a substance or mixture, or multiple doses given within 24 hours, or an inhalation exposure to a substance or mixture of four hours or of a duration that is converted to four hours.

For the Acute Toxicity hazard class, classification of a substance or mixture must be considered for each applicable route of exposure (oral, dermal and inhalation), and it is possible for a substance or mixture to be classified in a different category for each relevant route of exposure (i.e., in more than one category at once). For example, a substance could be classified in Acute Toxicity (Oral) - Category 1, Acute Toxicity (Dermal) - Category 2, and Acute Toxicity (Inhalation) - Category 4, if the substance meets the criteria to be classified in each of these categories. Further guidance is provided below in the discussion of subsection 8.1.1(1) of the HPR.

Discussion of the *Hazardous Products Regulations*
Section 8.1

Definitions

8.1 The following definitions apply in this Subpart.

"acute toxicant" means a mixture or substance that is liable to cause acute toxicity, or a mixture or substance that, upon contact with water, releases a gaseous substance that is liable to cause acute toxicity.

"acute toxicity" refers to adverse effects occurring following

(a) oral or dermal administration of a single dose of a mixture or substance, or multiple doses given within 24 hours; or

(b) an inhalation exposure to a mixture or substance of four hours or of a duration that is converted to four hours in accordance with subsection 8.1.1(4).

"dust" means solid particles that are suspended in a gas, usually air.

"mist" means liquid droplets that are suspended in the air.

In addition to the terms defined in section 8.1 of the HPR, the following terms, which are used in this Subpart, are defined in subsection 1(1) of the HPR.

- ATE,
- $LC_{50,}$
- $LD_{50,}$

- gas, and
- vapour.

Discussion related to these terms is found in Part 1 of this technical guidance.

Discussion – Dust and Mist

Dust is generally formed through mechanical processes whereas mist is generally formed through condensation of supersaturated vapours or by physical shearing of liquids. Dusts and mists generally have sizes ranging from less than 1 to about 100 µm (GHS, 5th revised edition, 2013, note (e) to Table 3.1.1).

Discussion – Acute Toxicity Point Estimate

The two terms "acute toxicity estimate" and "acute toxicity point estimate" do not have the same meaning under the HPR. The term "acute toxicity estimate" (ATE) could apply to:

(i) a hazardous product that is a substance;

(ii) a hazardous product that is a mixture; or

(iii) an ingredient in a hazardous product that is a mixture.

The ATE could include any of the following:

- an LD_{50} value;
- an LC_{50} value;
- an acute toxicity point estimate; or
- a calculated value, for a mixture, that is determined using the mathematical formula in section 8.1.5 or 8.1.6 of the HPR.

Acute toxicity point estimate (ATPE) is a term that is not defined under the HPR. However, an ATPE is a numerical value that can be determined in accordance with the table to section 8.1.7 of the HPR. The ATPE serves as an indicator of acute toxicity, i.e., it is a conservative approximation of the lethal dose (LD_{50}) or lethal concentration (LC_{50}), of a substance or an ingredient in a mixture. The ATPE must be established when the supplier does not know the LD_{50} or LC_{50} value of the ingredient, but knows either:

(i) the experimentally obtained acute toxicity range within which the LC_{50} or LD_{50} value for the substance or ingredient falls; or

(ii) the acute toxicity hazard category into which the substance or ingredient falls.

Where there is no specific LD_{50} or LC_{50} value available for an ingredient in a mixture, determining the ATPE allows an acute toxicity value for this ingredient to be used in the calculation of the ATE of the mixture, according to section 8.1.5 or 8.1.6 of the HPR.

Note: As with LC_{50} and LD_{50} values, the lower the ATPE value, the more hazardous the ingredient.

Discussion – Test Species

The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity (GHS, 5th revised edition, 2013, paragraph 3.1.2.3). When experimental data for acute toxicity are available in several animal species, the most appropriate LD_{50} or LC_{50} value must be selected from among scientifically validated tests.

Although preferred species are mentioned here, it does not mean that these species take precedence over other species. Available data of the types referred to in paragraph 2.1(a) or (b) of the HPR pertaining to species other than the preferred test species mentioned above are also acceptable, provided that the mixture or substance can be concluded as being acutely toxic from the available data. For example, if there is dermal toxicity data from a well-conducted study in rat and mouse, and the mouse LD_{50} value is lower than the rat LD_{50} value, it is appropriate to use the mouse LD_{50} value, despite the rat being the preferred species.

Classification in a Category of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Subsection 8.1.1(1)

LD_{50} or LC_{50} – associated range

8.1.1(1) An acute toxicant that is a substance is classified, with respect to each applicable route of exposure, in a category of this hazard class in accordance with the tables to subsection (3) if it has an LD_{50} by the oral or dermal exposure route, or an LC_{50} by the inhalation exposure route, that falls into one of the ranges indicated in the applicable table to that subsection.

An acute toxicity classification is assigned on the basis of evident lethality (e.g., an LD_{50} or LC_{50} value) or where potential to cause lethality can be concluded from evident toxicity (e.g., from a test performed according to OECD Test Guideline No. 420: Acute Oral Toxicity – Fixed Dose Procedure) (ECHA Guidance, 2015, paragraph 3.1.1).

The Acute Toxicity hazard class is unique because classification in this hazard class must be considered for each applicable route of exposure, as follows:

- Acute Toxicity (Oral)
- Acute Toxicity (Dermal)
- Acute Toxicity (Inhalation)

This requirement means that a substance could be classified in more than one acute toxicity hazard category by the applicable route of exposure. For example, a substance could be classified in each of Acute Toxicity (Oral) - Category 1, Acute Toxicity (Dermal) - Category 2, and Acute Toxicity (Inhalation) - Category 4.

Available data of the type referred to in paragraph 2.1 (a) or (b) of the HPR is used to classify substances in this hazard class. Subsection 8.1.1(1) refers to LD_{50} (oral or dermal) or LC_{50} (inhalation) values. If an LD_{50} or LC_{50} value is available, a substance must be classified in the appropriate category of this health hazard class by referring to the criteria set out in the three tables to subsection 8.1.1(3). These tables provide the ranges of LD_{50} and LC_{50} values and acute toxicity point estimates that correspond to classification in Acute Toxicity (Oral), Categories 1 through 4, Acute Toxicity (Dermal), Categories 1 through 4, and Acute Toxicity (Inhalation), Categories 1 through 4.

Acute Toxicity (Oral, Dermal, Inhalation) Category 5 from the GHS (5th revised edition) was not adopted in the HPR. OSHA's Hazard Communication Standard (HCS) 2012 also did not adopt Acute Toxicity (Oral, Dermal, Inhalation) Category 5 from the GHS.

Discussion of the *Hazardous Products Regulations*
Subsection 8.1.1(2)

Contact with water - gaseous substance

8.1.1(2) In addition to subsection (1), an acute toxicant that is a substance is classified with respect to the inhalation route of exposure in a category of this hazard class in accordance with Table 3 to subsection (3) if upon contact with water, it releases a gaseous substance that has an LC_{50} that falls into one of the ranges indicated in that table, unless that substance is already classified in a category of this hazard class for the inhalation route of exposure that represents a more severe hazard.

Subsection 8.1.1(2) provides requirements with respect to substances that release toxic gas(es) upon contact with water at ambient temperature. These substances, when dry, do not emit gases with toxic properties, but can react vigorously with water to produce gases which can be harmful, toxic or fatal at low airborne concentrations. Subsection 8.1.1(2) of the HPR requires that the LC_{50} value of the emitted gaseous substance be taken into consideration in the classification process. The LC_{50} value of the emitted gaseous substance may be different from that of the emitting substance.

In addition, paragraph 3(1)(f) of the HPR prescribes supplemental information elements for water activated toxicants (substances and mixtures that, upon contact with water, release a gaseous substance that falls into one of the ranges indicated in Table 3 to subsection 8.1.1(3)). The supplemental hazard statements required are based solely on the category into which the emitted gaseous substance falls, and are as follows:

For Categories 1 and 2, “In contact with water, releases gases which are fatal if inhaled”,

For Category 3, “In contact with water, releases gases which are toxic if inhaled”, and

For Category 4, “In contact with water, releases gases which are harmful if inhaled”.

VARIANCE with HCS 2012: Supplemental Hazard Statement for Water Activated Toxicants

HPR

A supplemental hazard statement is required on the label and SDS for substances which, upon contact with water, release a toxic gas.

HCS 2012

A supplemental hazard statement is not required on the label if substances which, upon contact with water, release a toxic gas are present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency. However, this information is required on the SDS, under section 10.

For example, consider a substance that is classified in Acute Toxicity (Inhalation) - Category 1 and which, upon contact with water, emits a gaseous substance that has an LC_{50} /four hours of 650 ppmV. The emitted gaseous substance is, therefore, classified in Acute Toxicity (Inhalation) - Category 3, based on the criteria set out in Table 3 to subsection 8.1.1(3) of the HPR. In this example, the classification in Acute Toxicity (Inhalation) - Category 1 must be retained, because it represents the more severe hazard. However, the supplemental information element for the emitted gaseous substance as mentioned in paragraph 3(1)(f) of the HPR for Category 3 is required on the label and SDS.

The hazard statements required in this example are the following:

Fatal if inhaled; and

In contact with water, releases gases which are toxic if inhaled.

Discussion of the *Hazardous Products Regulations*
Subsection 8.1.1(3)

LD_{50} or LC_{50} – not available

8.1.1(3) If an LD_{50} by the oral or dermal exposure route or an LC_{50} by the inhalation exposure route is not available, an acute toxicity point estimate must be established in accordance with the table to section 8.1.7, and the acute toxicant must be classified based on that acute toxicity point estimate, with respect to each applicable route of exposure, in a category of this hazard class in accordance with the following tables:

TABLE 1
ORAL EXPOSURE ROUTE

	Column 1	Column 2
Item	Category	Ranges for LD_{50} or for Acute Toxicity Point Estimates (mg/kg body weight (bw))
1	Acute Toxicity (Oral) — Category 1	≤ 5
2	Acute Toxicity (Oral) — Category 2	> 5 and ≤ 50
3	Acute Toxicity (Oral) — Category 3	> 50 and ≤ 300
4	Acute Toxicity (Oral) — Category 4	> 300 and ≤ 2000

TABLE 2
DERMAL EXPOSURE ROUTE

	Column 1	Column 2
Item	Category	Ranges for LD_{50} or for Acute Toxicity Point Estimates (mg/kg bw)
1	Acute Toxicity (Dermal) — Category 1	≤ 50
2	Acute Toxicity (Dermal) — Category 2	> 50 and ≤ 200
3	Acute Toxicity (Dermal) — Category 3	> 200 and ≤ 1000
4	Acute Toxicity (Dermal) — Category 4	> 1000 and ≤ 2000

TABLE 3
INHALATION EXPOSURE ROUTE

	Column 1	Column 2	Column 3	Column 4
Item	Category	Ranges for LC_{50} or for Acute Toxicity Point Estimates		
		Gases (ppmV)	Vapours (mg/l)	Dusts and Mists (mg/l)
1	Acute Toxicity (Inhalation) — Category 1	≤ 100	≤ 0.5	≤ 0.05
2	Acute Toxicity (Inhalation) — Category 2	> 100 and ≤ 500	> 0.5 and ≤ 2	> 0.05 and ≤ 0.5
3	Acute Toxicity (Inhalation) — Category 3	> 500 and ≤ 2500	> 2 and ≤ 10	> 0.5 and ≤ 1
4	Acute Toxicity (Inhalation) — Category 4	> 2500 and ≤ 20 000	> 10 and ≤ 20	> 1 and ≤ 5

Tables 1, 2 and 3 to subsection 8.1.1(3) provide the numeric cut-off criteria for classifying a substance in the acute toxicity hazard categories for each route of exposure based on LD_{50}, LC_{50} or ATPE values.

Values for vapours, dusts and mists are expressed in milligrams/ litre (mg/l). Values for gases are expressed in parts per million by volume (ppmV). The formula for converting mg/l to ppmV is:

$$mg/_l = \frac{ppmV \times MW}{24{,}450}$$

where MW is molecular weight.

When an exact LD_{50} or LC_{50} value is not available for the substance itself or for a substance with similar properties, subsection 8.1.1(3) specifies that an ATPE must be established according to the table to section 8.1.7 of the HPR. Use of this table provides a single value. To establish an APTE, information about the acute toxicity hazard category in which the substance is classified (for example, based on information obtained from an upstream supplier) or the range of values within which the LC_{50} or LD_{50} falls is required.

Using the ATPE or the exact LC_{50} or LD_{50} value, the substance is then classified for each applicable route of exposure using the criteria in the tables to subsection 8.1.1(3). For example, the available data for substance X is an LD_{50} (oral) range of 60 to 85 mg/kg bw. Using the table to section 8.1.7, the ATPE for this substance is 100 mg/kg bw because 60-85 mg/kg falls within the range of 50 ≤ 300 mg/kg bw, which converts to an ATPE of 100 mg/kg bw. Since the ATPE is between 50 and 300 mg/kg bw, the substance is classified in Acute Toxicity (Oral) – Category 3.

Discussion of the *Hazardous Products Regulations*
Subsection 8.1.1(4)

One-hour exposure period

8.1.1(4) For the purposes of Table 3 to subsection (3), the LC_{50} is based on a four-hour exposure period. If existing acute inhalation toxicity data have been generated according to a one-hour exposure period, the LC_{50} for gases and vapours must be divided by two, and the LC_{50} for dusts and mists must be divided by four.

LC_{50} values are based on a four-hour exposure period. Where an LC_{50} is obtained in an animal assay using an exposure duration other than four hours, the LC_{50} can be converted to a four hour exposure duration equivalent by using the following formulae:

a) for a gas or vapour, LC_{50} at four hours = LC_{50} at Y hours x $(\text{Y hours})^{1/2}/2$
b) for dust, mist or fume, LC_{50} at four hours = LC_{50} at Y hours x (Y hours)/4

Note: Y = actual number of hours of exposure duration, with maximum number of hours of exposure being 24 hours. Data with exposure period above 24 hours should not be used because above this threshold it will no longer be considered as an acute exposure.

These formulae assume a simple linear relationship between duration of exposure and concentration of dust, mist or fume in the animal chamber and a "square root" function for gas and vapour. The conversions provided in subsection 8.1.1(4) of the HPR are based on the above formulae, but can only be used to convert from one hour to four hour exposures.

Example

If the LC_{50} for a substance (gas) based on 1 hour exposure is 250 ppmV, then:

LC_{50} at four hours = 250 ppmV/2 = 125 ppmV

Therefore, the substance is classified in Acute Toxicity (Inhalation) - Category 2.

If the LC_{50} for a substance (gas) based on 10 hours exposure is 575 ppmV, then:

LC_{50} at four hours = $\sqrt{(575 \times 10)}/2$ = 37.9 ppmV

Therefore, the substance is classified in Acute Toxicity (Inhalation) - Category 1.

Classification in a Category in the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Subsections 8.1.2(1) and (2)

Order of provisions

8.1.2(1) The classification of a mixture as an acute toxicant in a category of this hazard class must proceed in accordance with the order of sections 8.1.3 to 8.1.6.

Concentrations for the purpose of classification

(2) Only ingredients present at concentrations equal to or greater than the concentration limit of 1.0% — w/w for solids, liquids, dusts, mists and vapours and v/v for gases — must be considered for the purpose of classification.

There is a "tiered" approach for classifying mixtures for acute toxicity, meaning that the procedures described in sections 8.1.3 to 8.1.6 must be followed in the order in which these sections appear in the HPR.

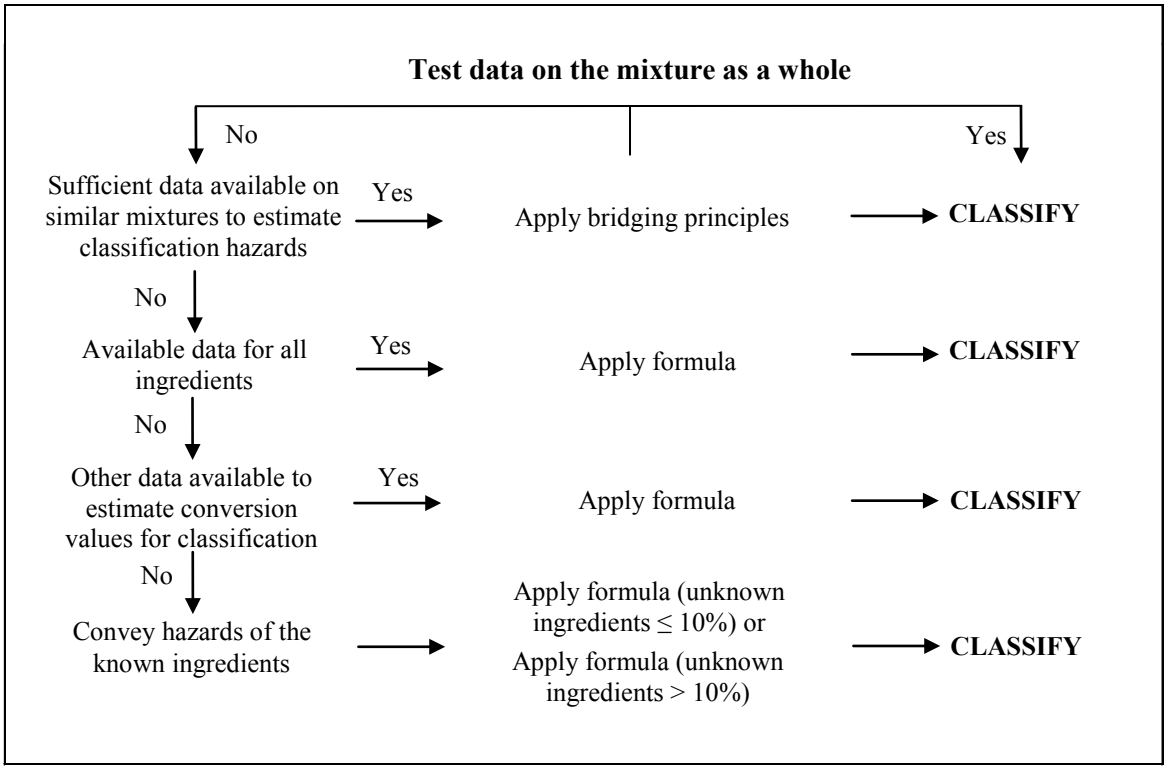
Classification of mixtures for acute toxicity is dependent on the amount of information available for the mixture itself and for its ingredients. In the tiered approach, test data available on the complete mixture (i.e., the mixture as a whole) is considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, additivity formula based on the hazard information on ingredients (Figure 1).

In situations where a mixture is classified according to the calculations specified in section 8.1.5 and 8.1.6, subsection 8.1.2(2) of the HPR specifies which ingredients in the mixture must be taken into consideration. In general, only ingredients which are present at concentrations ≥ 1.0%

(weight/weight for solids, liquids, dusts, mists and vapours and volume/volume for gases) need to be included in the calculation of an ATE of a mixture. However, as described in subsection 2.5(1) of the HPR, where an ingredient is present in a mixture at a lower concentration than the concentration cut-off for a particular category or subcategory of a health hazard class, but still presents the hazard at that concentration, the mixture must be classified in that category or subcategory. In the case of the Acute Toxicity hazard class, the provision described in subsection 2.5(1) would apply to situations where an ingredient is present in a mixture at a concentration of less than 1.0%, but the ingredient still presents an acute toxicity hazard at that concentration. In such situations, the ingredient must be included in the calculations specified in sections 8.1.5 and 8.1.6.

This "relevant ingredient" approach is aligned with the GHS and HCS 2012. Paragraph 3.1.3.3 of the GHS and A.1.3.3 of the HCS 2012 both state that the "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration < 1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2 (GHS, 5th revised edition, 2013, paragraph 3.1.3.3(a)).

Figure 1: Tiered approach to classification of mixtures for acute toxicity



Discussion of the *Hazardous Products Regulations* Section 8.1.3

Data available for mixture as a whole

8.1.3 If data of the types referred to in subparagraphs 2.1(a)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as an acute toxicant in accordance with section 8.1.1.

As the first step in the tiered approach, if data of the types referred to in subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is exactly the same as for substances, and is carried out in accordance with section 8.1.1. Guidance for subparagraphs 2.1(a)(i) to (iv) of the HPR is found in section 2.1 of Part 2 of this technical guidance. The discussion sections of the technical guidance corresponding to subsections 8.1.1(1) through 8.1.1(4), as well as the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. The data available on the mixture as a whole must be compared to the classification criteria within each hazard category for each relevant route of exposure. If the available data meets the criteria, then the mixture must be classified in the category(ies) for which the criteria are met.

Discussion of the *Hazardous Products Regulations* Section 8.1.4

Data available for use of bridging principles

8.1.4 If data are available to enable the characterization of the mixture as an acute toxicant, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in a category of this hazard class in accordance with those subsections.

Section 8.1.4 of the HPR describes the second step in the tiered approach for the classification of mixtures for acute toxicity.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance. All of the bridging principles are applicable to the Acute Toxicity hazard class, namely: dilution, production batches, increase in concentration of hazardous ingredient, interpolation, substantially similar mixtures, and aerosols.

Discussion of the *Hazardous Products Regulations*
Section 8.1.5 and 8.1.6

Data available for all ingredients

8.1.5 If data are available for all ingredients in the mixture, the mixture must be classified as an acute toxicant in accordance with section 8.1.1 using the ATE of the mixture that is determined in respect of each applicable route of exposure by the following formula:

$$ATE_{mix} = \frac{100}{\left[\sum_{n} \frac{C_i}{ATE_i} \right]}$$

where

ATE_{mix} is the ATE of the mixture determined using this formula;

C_i is the concentration of ingredient i;

n is the number of ingredients and i is running from 1 to n;

ATE_i is the ATE of ingredient i, which is either

- **(a) the LD_{50} or the LC_{50} based on or converted to a four-hour exposure period, for i, or**
- **(b) if the LD_{50} or the LC_{50} is unavailable, the acute toxicity point estimate established for i in accordance with the table to section 8.1.7; and**

i is each ingredient in the mixture with

- **(a) an ATE within the ranges set out in the applicable table to subsection 8.1.1(3),**
- **(b) an oral or dermal LD_{50} greater than 2000 mg/kg bw but less than or equal to 5000 mg/kg bw, or**
- **(c) an LC_{50} based on or converted to a four-hour exposure period within a range having an amplitude comparable to the one in paragraph (b).**

Data not available for all ingredients

8.1.6 If the ATE is not available for one or more ingredients of the mixture, the mixture must be classified as an acute toxicant in accordance with section 8.1.1 using the ATE of the mixture that is determined in respect of each applicable route of exposure according to the following:

(a) if data permit the ATE to be estimated for each of those ingredients in accordance with established scientific principles, the formula in section 8.1.5 must be used;

(b) if data do not permit the ATE to be estimated for an ingredient in accordance with established scientific principles, and the concentration of the ingredient in the mixture is equal to or greater than the concentration limit of 1.0%, the mixture is classified based only on the ingredients having an ATE, such that

(i) if the total concentration of all ingredients with unknown acute toxicity is less than or equal to 10.0% of the mixture, the formula in section 8.1.5 must be used, or

(ii) if the total concentration of all ingredients with unknown acute toxicity is greater than 10.0% of the mixture, the following formula must be used:

$$ATE_{mix} = \frac{100 - (\sum C_{unknown} \text{ if} > 10\%)}{\left[\sum_{n} \frac{C_i}{ATE_i} \right]}$$

where

ATE_{mix} is the ATE of the mixture determined using this formula,

C_i is the concentration of ingredient i,

$C_{unknown}$ is the concentration of ingredients i with unknown ATE values,

n is the number of ingredients and i is running from 1 to n,

ATE_i is the ATE of ingredient i, which is either

(a) the LD_{50} or the LC_{50} based on or converted to a four-hour exposure period, for i, or

(b) if the LD_{50} or the LC_{50} is unavailable, the acute toxicity point estimate established for i in accordance with the table to section 8.1.7, and

i is each ingredient in the mixture with

(a) an ATE within the ranges set out in the applicable table to subsection 8.1.1(3),

(b) an oral or dermal LD_{50} greater than 2000 mg/kg bw but less than or equal to 5000 mg/kg bw, or

(c) an LC_{50} based on or converted to a four-hour exposure period within a range having an amplitude comparable to the one in paragraph (b).

When there is no data for the mixture as a whole and the bridging principles cannot be applied, then classification of the mixture must be based on information for the ingredients in the mixture using additivity formulas. There are two different additivity formulas set out in sections 8.1.5 and 8.1.6 of the HPR, which allow for the calculation of the ATE of the mixture.

Considerations

There are some important concepts to consider when applying the additivity formulas:

a) If an LD_{50} (oral or dermal) or an LC_{50} (inhalation) is available for an ingredient, it must be used in the calculation.

b) If an LD_{50} (oral or dermal) or LC_{50} (inhalation) value is not available for an ingredient in a mixture and an LD_{50} or LC_{50} range or the ingredient's acute toxicity classification is available, then an ATPE must be determined for the ingredient in accordance with the table to section 8.1.7 of the HPR. This ATPE is then used in the applicable formula.

c) If an ATPE cannot be determined for the ingredient, but there are data available that permit an ATE to be estimated in accordance with established scientific principles, then the ATE for the ingredient may be estimated accordingly. Determination of the ATE may include evaluation of:

   (i) extrapolation between oral, dermal and inhalation acute toxicity values. When mixtures contain ingredients that do not have acute toxicity data for each route of exposure, acute toxicity estimates may be extrapolated from the available data and applied to the appropriate routes. Such an evaluation would require appropriate pharmacodynamic and pharmacokinetic data;

   (ii) evidence from human exposure that indicates toxic effects but does not provide lethal dose data. For example, methanol, where toxicity in humans is known but the animal LD_{50}/LC_{50} values are greater than the cut-off values in the table to section 8.1.7 of the HPR;

   (iii) evidence from any other toxicity tests/assays available on the ingredient that indicates toxic acute effects but does not necessarily provide lethal dose data; or

   (iv) data from closely analogous substances using structure-activity relationships.

   This approach generally requires substantial supplemental technical information to reliably estimate acute toxicity (GHS, 5th revised edition, 2013, paragraph 3.1.3.6.2.1). If an ATE for the ingredient can be determined, it is then used in the applicable formula.

d) The additivity formula calculations must be done for each relevant route of exposure (oral, dermal and inhalation), as appropriate. The results of each calculation must be compared to the criteria in the three tables to subsection 8.1.1(3) of the HPR, to determine the classification.

   For acute inhalation toxicity of a product that is a mixture, the calculation must be conducted separately for each relevant physical form (i.e., gas, vapour, and/or dust/mist) if there are sufficient data available. The results of each calculation must be compared to the corresponding criteria to subsection 8.1.1(3) to determine the classification. In case of different outcomes, the most severe classification applies.

e) Only relevant ingredients are included in the calculations. To determine which ingredients in a mixture are "relevant" to include in the calculation of the ATE of the mixture, consider the following:

   (i) As specified in subsection 8.1.2(2), with some exceptions, only ingredients which are present at concentrations equal to or greater than 1.0% (weight/weight for solids, liquids, vapours, dusts and mists and volume/volume for gases) need to be included in the calculation of an ATE of a mixture;

   (ii) Ingredients with an ATE that falls within any of the ranges set out in Table 1, 2 or 3 to subsection 8.1.1(3) of the HPR (i.e., ingredients that classify into Acute Toxicity Category 1, 2, 3 or 4 for the route of exposure for which the calculation is being done) must be included;

   (iii) Ingredients with an oral or dermal LD_{50} greater than 2000 mg/kg bw but less than or equal to 5000 mg/kg bw (i.e., ingredients that classify into GHS Acute Toxicity (Oral or Dermal) - Category 5) must be included in the oral and dermal calculations*. This is aligned with the HCS 2012, which includes ingredients which fall into any of the five GHS Acute Toxicity categories for oral and dermal acute toxicity;

   (iv) Ingredients with an LC_{50} based on or converted to a four-hour exposure period within a range comparable to an oral or dermal LD_{50} greater than 2000 mg/kg bw but less than or equal to 5000 mg/kg bw (i.e., ingredients that are classified in GHS Acute Toxicity (Inhalation) - Category 5) must be included* (GHS, 5th revised edition, 2013, paragraph 3.1.3.6.1(a)). This is aligned with the HCS 2012, which also includes ingredients which fall into any of the five GHS Acute Toxicity categories for inhalation toxicity;

   (v) Ingredients that are presumed not acutely toxic (e.g., water, sugar) should **not** be included. Note that ingredients that are not biologically available could be also considered as "presumed not acutely toxic". Guidance pertaining to biological availability is found in the discussion of section 2.9 of the HPR in Part 2 of this technical guidance; and

   (vi) Ingredients for which data are available from a limit dose test at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table 1, 2 or 3 of subsection 8.1.1(3), and the data do not show acute toxicity should **not** be included.

   * Ingredients which fall within GHS Acute Toxicity (Oral, Dermal or Inhalation) – Category 5 should only be included in mixture calculations when actual toxicity data (i.e., an LD_{50} or LC_{50} value) is available, and not when there is only a Category 5 classification available.

f) Where a classified mixture is used as an ingredient of another mixture, the actual or calculated ATE for the already classified mixture must be used when determining the classification of the new mixture (GHS, 5th revised edition, 2013, paragraph 3.1.3.3(b)) using either the formula in section 8.1.5 or the formula in section 8.1.6, as applicable.

The formula set out in section 8.1.5 is used in the following two situations:

(i) when there are data available for all relevant ingredients in the mixture; and

(ii) when there are no data available for one or more relevant ingredients and the total concentration of the relevant ingredient(s) with unknown acute toxicity is less than or equal to 10.0%.

The formula set out in section 8.1.6 is used when data are not available for one or more ingredients and the total concentration of the relevant ingredient(s) with unknown acute toxicity is greater than 10.0%. This formula incorporates a correction to adjust for the percentage of the unknown ingredient(s).

Note that, with regard to the classification of mixtures for the inhalation route of exposure, the formulas set out in sections 8.1.5 and 8.1.6 of the HPR are intended to be used to determine the classification of mixtures with regard to acute inhalation toxicity in the absence of contact with water (that is, these formulas are not intended to be used to evaluate mixtures with regard to water-activated toxicity (WAT) hazard). In the case of a mixture which reacts with water to release a gaseous substance, the procedure set out in subsection 8.1.1(2) of the HPR must be used to evaluate the WAT hazard of the mixture. The acute inhalation toxicity of the mixture in the absence of contact with water must be evaluated separately. If there are no data available for the mixture as a whole and bridging principles do not apply, then classification must be determined using the formula in either section 8.1.5 or 8.1.6 of the HPR.

To apply either of these formulas, one must know the ATE and the concentration of each relevant ingredient. In the case of the ingredient which reacts with water to release a gaseous substance, the LC_{50} of the emitted gaseous substance would not be used as an ATE value. Instead, the ATE and the concentration of the ingredient itself would be used in the calculation according to the formula set out in either section 8.1.5 or 8.1.6 of the HPR.

Ingredients of Unknown Acute Toxicity – Supplemental Label Statement

If a hazardous product is classified in Acute Toxicity (Category 1, 2, 3 or 4) based on ingredient(s) for which the acute toxicity is known and the hazardous product contains ingredients of unknown acute toxicity, a prescribed supplemental label element is required.

As specified in paragraph 3(1)(e) of the HPR, the supplemental label element required is as follows:

“[Insert the total concentration in percentage of ingredients with unknown acute toxicity] % of the mixture consists of an ingredient or ingredients of unknown acute toxicity”

The route of exposure should be included in the statement. For example, if a hazardous product is classified in Acute Toxicity – Oral – Category 1 based on ingredient(s) for which the acute oral toxicity is known and the hazardous product contains, at a concentration of 5%, ingredients of unknown acute oral toxicity, then the following supplemental label element is required:

5% of the mixture consists of ingredient(s) of unknown acute oral toxicity

The supplemental label element is required only for the route(s) of exposure with respect to which the hazardous product is classified. It could apply more than once in the situation where a mixture ends up being classified for more than one route of exposure based on ingredients of known acute toxicity.

For example, if a mixture is classified as acutely toxic through inhalation and oral routes based on ingredient(s) of known acute toxicity, and 2% of this mixture consists of ingredients of unknown acute oral toxicity and 10% of the same mixture consists of ingredients of unknown acute inhalation toxicity, then the following statements must appear on the label of the hazardous product:

2 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

10 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity

or

2% and 10% of the mixture consists of ingredients of unknown acute oral and inhalation toxicity, respectively.

This supplemental label element is also required by the HCS 2012 and the GHS (5th revised edition, 2013, paragraph 3.1.3.6.2.2).

Discussion of the *Hazardous Products Regulations*
Section 8.1.7

Conversion from range to point estimate

8.1.7 If a formula in section 8.1.5 or 8.1.6 is used, an acute toxicity point estimate must be determined, in accordance with the following table, for each ingredient for which only that ingredient's classification category or experimentally obtained acute toxicity range is available:

TABLE

	Column 1	Column 2	Column 3
Item	Exposure Routes	Classification Category and Associated Experimentally Obtained Acute Toxicity Range Minimum and Maximum Values	Converted Acute Toxicity Point Estimate
1	Oral (mg/kg bw)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2000	0.5 5 100 500
2	Dermal (mg/kg bw)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1000 1000 < Category 4 ≤ 2000	5 50 300 1100
3	Inhalation (gases) (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2500 2500 < Category 4 ≤ 20 000	10 100 700 4500
4	Inhalation (vapours) (mg/l)	0 < Category 1 ≤ 0.5 0.5 < Category 2 ≤ 2.0 2.0 < Category 3 ≤ 10.0 10.0 < Category 4 ≤ 20.0	0.05 0.5 3 11
5	Inhalation (dust/mist) (mg/l)	0 < Category 1 ≤ 0.05 0.05 < Category 2 ≤ 0.5 0.5 < Category 3 ≤ 1.0 1.0 < Category 4 ≤ 5.0	0.005 0.05 0.5 1.5

As mentioned in subsection 8.1.1(3), in situations where only a range of LD_{50} (oral or dermal) or LC_{50} (inhalation) values is available for an ingredient, or only the classification category into which the ingredient falls is known, an acute toxicity point estimate (ATPE) must be determined for the ingredient according to the table in this section. This table provides a single value to be used in the calculation of the ATE for a mixture. The values presented in the table are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

For example:

1. The available data for substance X indicate that it is only toxic via the oral route and the only available data is an LD_{50} range of 60 to 150 mg/kg bw. Using the table in section 8.1.7, the ATPE for substance X would be 100 mg/kg bw. This value is then used in the calculation of the ATE of the mixture.
2. The available data for substance Y, a gas, indicate that it falls into Acute Toxicity (Inhalation) - Category 3. Using the table in section 8.1.7, the ATPE for substance Y is 700 ppmV. This value is then used in the calculation of the ATE of the mixture.

Corrosion of the Respiratory Tract

For substances and mixtures that are classified in Acute Toxicity (Inhalation) – Category 1, 2, 3 or 4, if data are available that indicate that the mechanism of toxicity is corrosivity of the substance or mixture, the data should be evaluated to determine whether the substance or mixture is corrosive to the respiratory tract. Corrosion of the respiratory tract is defined as destruction of the respiratory tract tissue after a single, limited period of exposure analogous to skin corrosion; this includes destruction of the mucosa. The corrosivity evaluation could be based on expert judgment using such evidence as: human and animal experience, existing (*in vitro*) data, pH values, information from similar substances or any other pertinent data (GHS, 5th revised edition, 2013, paragraph 3.1.2.6.5).

If data are available that indicate acute inhalation toxicity with corrosion of the respiratory tract that leads to lethality, then, in addition to the hazard communication elements specified in Section 3 of Annex 3 of the GHS (5th revised edition) for the category in which the substance or mixture is classified, the corrosion pictogram, as shown in item 4 of Schedule 3 of the HPR, may be added to the label, along with the hazard statement: “corrosive to the respiratory tract”.

If data are available that indicate acute inhalation toxicity with corrosion of the respiratory tract and the effect does not lead to lethality, then the hazard would be addressed under the Specific Target Organ Toxicity – Single Exposure or Repeated Exposure hazard class (Subpart 8 or 9, respectively, of Part 8 of the HPR).

This approach to respiratory corrosion is aligned with the HCS 2012 and its associated guidance documents.

Hazard Communication

The symbols, signal words, hazard statements and precautionary statements are specified in in Section 3 of Annex 3 of the GHS (5th revised edition) for:

Acute Toxicity (Oral) – pp. 335-337;

Acute Toxicity (Dermal) – pp. 339-341; and

Acute Toxicity (Inhalation) – pp. 343-345.

Note that item 11(d) ("numerical measures of toxicity") of Schedule 1 of the HPR can include LD_{50}, LC_{50} and calculated acute toxicity estimates. In all cases, an ATE can be calculated for a mixture. Therefore, an ATE_{mix} must be disclosed rather than only disclosing the ATE for ingredients in the mixture. Furthermore, the specific route of exposure (oral, dermal, inhalation) for which the ATE_{mix} has been calculated must also be disclosed on the safety data sheet.

Hazard communication elements involving multiple routes of exposure

When there is relevant evidence of toxicity by multiple routes of exposure, then classification of a substance or mixture is to be conducted for all appropriate routes of exposure. For example, a substance could be classified in each of Acute Toxicity (Oral) - Category 1, Acute Toxicity (Dermal) - Category 2, and Acute Toxicity (Inhalation) - Category 4. If more than one hazard category is assigned, the most severe hazard category must be used to assign the pictogram and signal word. All relevant hazard statement(s) and precautionary statement(s) for each applicable route of exposure and hazard category are still required. Therefore, in the above example, the following hazard communication elements are required on the label and SDS:

Pictogram (for label) or symbol (for SDS):	Skull and crossbones
Signal word:	DANGER
Hazard statements:	Fatal if swallowed. Fatal in contact with skin. Harmful if inhaled.
Precautionary statements:	A combination of all applicable precautionary statements for Acute Toxicity (Oral) - Category 1, Acute Toxicity (Dermal) -Category 2 and Acute Toxicity (Inhalation) - Category 4 as listed in section 3 of Annex 3 of the GHS (5th revised edition).

Supplemental Label Statements

1. Substances which, in contact with water, emit a toxic gas that has an LC_{50} that falls into one of the ranges indicated in Table 3 to subsection 8.1.1(3) of the HPR require a supplemental element on their label and SDS. This requirement is set out in paragraph 3(1)(f) and paragraph 2(b) of Schedule I of the HPR.

As noted in the discussion of subsection 8.1.1(2), this requirement is a variance from the HCS 2012, which does not require any supplemental element on the label for WAT.

The wording of the supplemental element is as follows:

- in the case of Categories 1 and 2, "In contact with water, releases gases which are fatal if inhaled",
- in the case of Category 3, "In contact with water, releases gases which are toxic if inhaled", and
- in the case of Category 4, "In contact with water, releases gases which are harmful if inhaled".

In accordance with paragraph 2(b) of Schedule 1 of the HPR, the above-mentioned information is required to be mentioned under section 2 of the SDS. However, the information could also be mentioned under section 10 of the SDS, since this section provides information on the stability and reactivity of the hazardous product.

2. When an ingredient for which there is no LD_{50} or LC_{50} data, nor any information that permits the determination of an ATPE, is present in a mixture at a concentration of 1% or more, it is concluded that the mixture cannot be attributed a definitive ATE. In this situation, the mixture must be classified based on the known ingredients only, and, as specified in paragraph 3.(1)(e) and paragraph 2(b) of Schedule I of the HPR, a supplemental statement indicating that x percent of the mixture consists of ingredient(s) of unknown toxicity is required on the label and SDS. The wording of the supplemental statement is:

"[Insert the total concentration in percentage of ingredients with unknown acute toxicity] % of the mixture consists of an ingredient or ingredients of unknown acute toxicity".

As noted in the discussion of sections 8.1.5 and 8.1.6 of the HPR, this supplemental statement could apply more than once, in the situation where a mixture ends up being classified for more than one route of exposure based on the known ingredients only.

Classification of Acute Toxicity for Substances

Examples

Example 1: Evaluation of the acute oral toxicity of a substance in rats (ECHA Guidance, 2015, paragraph 3.1.6.1.3)

Available data

The substance is a corrosive, volatile liquid.

In an acute oral toxicity study in rats, the following results were observed:

- At a test dose of 200 mg/kg bw:
    - no mortality;
    - only transient symptoms; and
    - no necropsy findings.
- At a test dose of 500 mg/kg bw:
    - 100% mortality;
    - signs of toxicity: poor general state; and
    - necropsy findings: hyperemia in stomach (due to local irritation/corrosivity), no other organs affected.

Classification

Acute Toxicity (Oral) - Category 3

Rationale

Based on this information, the LD_{50} is somewhere between 200 and 500 mg/kg bw. This is a range that can be used to establish an ATPE using the Table to section 8.1.7. However, 200 mg/kg bw is within the range for Category 3 and 500 mg/kg bw is within the range for Category 4. In such a situation, the substance should be classified in the most severe category. Therefore, the ATPE is 100 mg/kg bw.

In accordance with subsection 8.1.1(3) of the HPR, this ATPE value is used to classify the substance based on the criteria set out in Table 1 to subsection 8.1.1(3). Since the value of 100 mg/kg bw falls between 50 and 300 mg/kg bw, the substance classifies in Acute Toxicity (Oral) - Category 3.

Example 2: Evaluation of the acute dermal toxicity of a substance in rabbits (ECHA Guidance, 2015, paragraph 3.1.6.1.4)

Available data

The following test data results were reported:

- At the dose level of 50 mg/kg bw: no mortality was observed.
- At 200 mg/kg bw: 100% mortality was observed.

Classification

Acute Toxicity (Dermal) - Category 2.

Rationale

The dermal LD_{50} is greater than 50 mg/kg bw and less than 200 mg/kg bw. According to Table 2 to subsection 8.1.1(3), this range corresponds to Acute Toxicity (Dermal) - Category 2.

Classification of Acute Toxicity for Mixtures

Examples

Example 1: Evaluation of the acute toxicity of a mixture for which the dermal route of exposure is relevant.

Available data

No test data is available for the whole mixture. Bridging principles are not applicable since no test data on similar mixtures are available. Therefore, classification is based on ingredients. The dermal LD_{50} values of each ingredient are as follows:

Ingredient	% (weight/weight)	LD_{50} (dermal, rat)
Ingredient 1	45	400 mg/kg bw
Ingredient 2	30	300 mg/kg bw
Ingredient 3	25	2,300 mg/kg bw

Classification

Acute Toxicity (Dermal) - Category 3.

Rationale

The additivity formula set out in section 8.1.5 is used because information is available for all ingredients.

ATE_{mix}= 100 divided by (45/400 + 30/300 + 25/2300)

ATE_{mix} = 100/0.223 = 448 mg/kg bw.

According to Table 2 to subsection 8.1.1(3), this value corresponds to Acute Toxicity (Dermal) - Category 3.

Example 2: Evaluation of the acute toxicity of a mixture for which the oral route of exposure is relevant.

Available data

No test data are available for the whole mixture.

Classification via the application of bridging principles is not possible since no test data on similar mixtures are available. Therefore, classification is based on ingredient data.

The oral LD_{50} value and the classification of each ingredient are as follows:

Ingredient	% (weight/weight)	Acute Toxicity Classification	Oral LD_{50}
Ingredient 1	4	Oral Category 3	125 mg/kg bw
Ingredient 2	92	Not classified	No data available
Ingredient 3	3.1	Oral Category 4	1500 mg/kg bw
Ingredient 4	0.9	Not classified	No data available

Classification

Acute Toxicity (Oral) - Category 3

Rationale

The additivity formula set out in subparagraph 8.1.6(b)(ii) is used because the total concentration of ingredients with unknown acute toxicity is 92% (the concentration of ingredient 2), which is above 10%. Ingredient 4 is present below the concentration limit of 1% for relevant ingredients, and the provision in subsection 2.5(1) of the HPR does not apply. Therefore, ingredient 4 it is not used in the calculation.

$ATE_{mix} = (100 – 92)/(4/125 + 3.1/1500) = 235$ mg/kg bw.

According to Table 2 to subsection 8.1.1(3), this value corresponds to Acute Toxicity (Oral) – Category 3.

As required by paragraph 3(1)(e) and paragraph 2(b) of Schedule I of the HPR, the following supplemental statement must be provided on the label and SDS:

92% of the mixture consists of an ingredient of unknown acute oral toxicity.

Example 3: Evaluation of the acute toxicity of a mixture for which the oral route of exposure is relevant.

Available data

No test data are available for the whole mixture. Classification via the application of bridging principles is not possible since no test data on similar mixtures are available. Therefore, classification is based on ingredient data.

The oral LD_{50} value and the classification of each ingredient are as follows:

Ingredient	%(weight/ weight)	Acute Toxicity Classification	Oral LD_{50}
Ingredient 1	75	Oral Category 4	1600 mg/kg bw
Ingredient 2	5	Unknown	Acute toxicity range estimate: 200 mg/kg bw < oral LD_{50} < 2000 mg/kg bw
Ingredient 3	20	Not classified under the HPR, but according to the GHS, would classify in Oral Category 5	3000 mg/kg bw

Classification

Acute Toxicity (Oral) - Category 4

Rationale

The additivity formula set out in section 8.1.5 is used because information is available for all ingredients. For ingredients 1 and 3, the oral LD_{50} values are known, so these LD_{50} values are used as the ATEs of ingredients 1 and 3.

For ingredient 2, the oral LD_{50} falls between 200 and 2000 mg/kg bw. The experimentally-obtained acute toxicity range estimate of 200 mg/kg bw < oral LD_{50} < 2000 mg/kg bw does not match up with the ranges provided in the table in section 8.1.7. This range falls between the ranges for Acute Toxicity (Oral) - Category 3 and Acute Toxicity (Oral) - Category 4. The acute toxicity point estimate for an Acute Toxicity (Oral) - Category 3 ingredient is 100. Given that this point estimate is lower than the experimentally-obtained value of > 200 mg/kg, it does not make sense to use it in the formula. In this situation, one should apply a conservative approach based on the known information and use 200 mg/kg bw as the acute toxicity point estimate for ingredient 2, since it is known that the LD_{50} of ingredient 2 could be just over 200 mg/kg bw.

ATE_{mix}= 100 divided by (75/1600 + 5/200 + 20/3000)

ATE_{mix} = 100/0.07854 = 1273.2 mg/kg bw.

According to Table 2 to subsection 8.1.1 (3), this value corresponds to Acute Toxicity (Oral) - Category 4.

Subpart 2
Skin Corrosion / Irritation

Definitions

8.2 The following definitions apply in this Subpart.

"skin corrosion" means the production of irreversible damage to the skin, namely, visible necrosis through the epidermis and into the dermis, and includes ulcers, bleeding, bloody scabs and, within a 14-day observation period, discoloration due to blanching of the skin, complete areas of alopecia, and scars.

"skin-corrosive" means, in relation to a mixture or substance, liable to cause skin corrosion.

"skin-irritant" means, in relation to a mixture or substance, liable to cause skin irritation.

"skin irritation" means the production of reversible damage to the skin.

Discussion – Skin Corrosion vs Skin Irritation

Skin corrosion and skin irritation both refer to the production of local damage to the skin. Severity of the damage and the reversibility of the lesions are assessed. Skin corrosion is irreversible damage. Skin irritation is reversible and the affected sites are repaired within the observation period of the test (normally 14 days).

The definitions for skin corrosion and skin irritation found in HCS 2012 and the GHS (GHS, 5th revised edition, 2013, paragraph 3.2.1.1) include the phrase: "following the application of a test substance for up to four hours". This phrase was not included in the definitions of the HPR to enable the use of human data from occupational incidents, as well as animal data where the exposure may be more than four hours.

Classification in a Category or Subcategory of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Section 8.2.1

Order of provisions

8.2.1 The classification of a skin-corrosive substance or a skin-irritant substance in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.2.2 to 8.2.7, unless, after applying subsections 8.2.2(1) to (3), the substance is not classified further to subsection 8.2.2(4).

There is an order in which all data must be considered for the purpose of classification in this hazard class. This order applies to the classification of both substances and mixtures. The steps to consider are listed, in order, below. More detail on each step is provided in the discussion of section 8.2.2 to 8.2.7 of the HPR.

1. Positive human data meeting classification criteria outlined in subsection 8.2.2(1) are used to classify a substance in Skin Corrosion – Category 1.
2. Positive animal data (derived from a study specifically designed to test skin corrosion and/or irritation) that meet classification criteria outlined in subsection 8.2.2(2) are used to classify a substance in Skin Corrosion – Category 1, with further classification in subcategory 1A, 1B or 1C (if possible).
3. Positive human data or positive animal data (derived from a study specifically designed to test skin corrosion and/or irritation) that meet classification criteria outlined in subsection 8.2.2(3) are used to classify a substance in Skin Irritation – Category 2.
4. Negative human data or negative animal data (derived from a study specifically designed to test skin corrosion and/or irritation) are used to determine that the substance does not meet classification criteria for this hazard class. If the conditions outlined in subsection 8.2.2(4) are met, progression to subsequent steps is not required. However, progression through the subsequent steps is necessary if there is no or insufficient negative data available.
5. Positive animal data derived from a dermal exposure study that was not specifically designed to test skin corrosion and/or irritation (e.g., acute or subchronic dermal toxicity), but that otherwise meets classification criteria outlined in section 8.2.2 are used to classify a substance in Skin Corrosion – Category 1 or Skin Irritation – Category 2, as appropriate.
6. Positive *in vitro* or *ex vivo* data that meet classification criteria outlined in section 8.2.4 are used to classify a substance in Skin Corrosion – Category 1 or Skin Irritation – Category 2, as appropriate.
7. Substances with pH extremes (≤2.0 or ≥11.5), as outlined in section 8.2.5, are considered and, if criteria are met, are classified in Skin Corrosion – Category 1.

8. Positive structure-activity data that meet classification criteria outlined in subsection 8.2.6(1) or 8.2.6(2) are used to classify a substance in Skin Corrosion – Category 1 or Skin Irritation – Category 2, as appropriate.
9. Finally, all the available evidence must be considered together, as described in section 8.2.7, to determine if classification in Skin Corrosion – Category 1 (with further classification into subcategory 1A, 1B or 1C, if possible) or Skin Irritation – Category 2 is warranted.

If, following step 9, a classification has not been determined, it can be concluded that the substance does not meet the criteria for classification in the Skin Corrosion/Irritation hazard class.

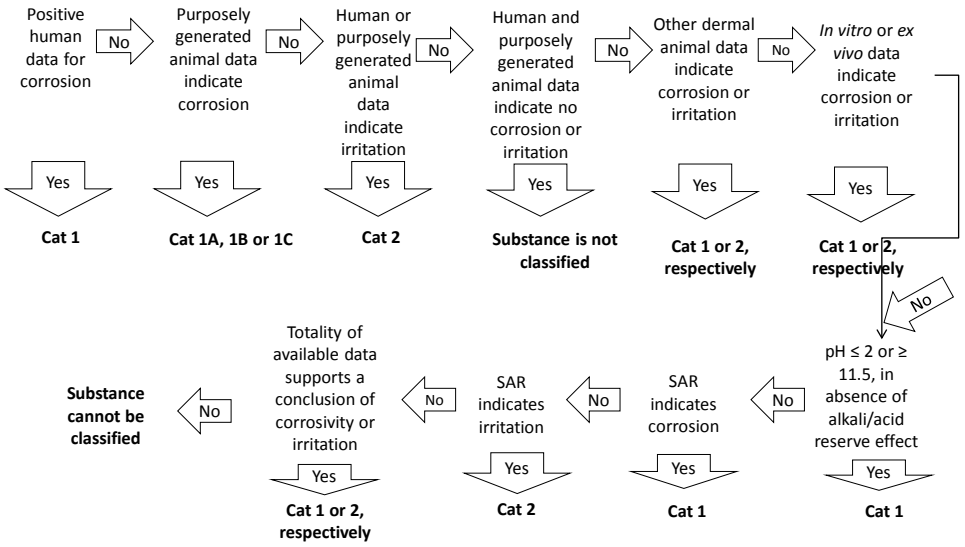


Figure 1: Evaluation sequence for skin corrosion and irritation potential

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.2(1)

Human data – skin corrosion

8.2.2(1) A substance for which human data demonstrate that it is a skin-corrosive substance is classified in the category "Skin Corrosion — Category 1".

Human data demonstrating skin corrosion are considered first. Data which meet the criteria for skin corrosion result in the classification of a substance in Skin Corrosion – Category 1. Positive human data that are insufficient to meet the criteria for skin corrosion are evaluated again, as follows:

- in the assessment for skin irritation – refer to paragraph 8.2.2(3)(a) of the HPR, or
- in the final step of evaluation – refer to section 8.2.7 of the HPR.

Negative results are taken into consideration in a later step – refer to subsection 8.2.2(4) of the HPR.

Note: There is no stipulation on the exposure time for human data used as the basis of classification of a substance in Skin Corrosion – Category 1.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.2(2)

Animal data – skin corrosion

8.2.2(2) A substance for which purposely generated animal data demonstrate that it is a skin-corrosive substance is classified in the category "Skin Corrosion — Category 1" and is, if the applicable data are available, further classified in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Subcategory**	**Criteria**
1	**Skin Corrosion — Category 1A**	**A substance that, according to animal data acquired from a scientifically validated method, produces irreversible damage to the skin after an exposure of three minutes or less, and within one hour of observation, in at least one of three animals**
2	**Skin Corrosion — Category 1B**	**A substance that, according to animal data acquired from a scientifically validated method, produces irreversible damage to the skin after an exposure of more than three minutes and up to and including one hour, and within 14 days of observation, in at least one of three animals**
3	**Skin Corrosion — Category 1C**	**A substance that, according to animal data acquired from a scientifically validated method, produces irreversible damage to the skin after an exposure of more than one hour and up to and including four hours, and within 14 days of observation, in at least one of three animals**

Animal data demonstrating skin corrosion is the second step of the evaluation. Data must be derived from "purposely generated animal data", which means data obtained from an animal study designed specifically to test skin corrosion and/or irritation. Acute dermal toxicity, skin sensitization, subchronic dermal toxicity or other studies that permit observation of skin reactions but are not specifically designed to study skin corrosion and/or skin irritation are considered in a later step – refer to section 8.2.3 of the HPR.

Skin Corrosion - Category 1 has three subcategories: 1A, 1B and 1C. If the data do not permit sub-categorization, the substance would simply be classified in Category 1. For example, it is possible that a three minute (or less) exposure could result in irreversible damage to the skin **after** more than a one hour observation period. In this case, the substance must be classified in Skin Corrosion - Category 1 without further sub-categorization.

In all cases of sub-categorization, a positive result for at least one of the three tested animals is required for classification.

Negative results from purposely generated animal studies are taken into consideration in a later step – refer to subsection 8.2.2(4) of the HPR.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.2(3)

Human or animal data – skin irritation

8.2.2(3) A substance for which there are human data or purposely generated animal data with respect to skin irritation is classified in the category "Skin Irritation — Category 2" in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Skin Irritation — Category 2**	**A substance** **(a) that, according to human data, is skin-irritant; or** **(b) in respect of which animal data reveal** **(i) in the case of data acquired from a test performed in accordance with the OECD Guideline for the Testing of Chemicals, No. 404, entitled *Acute Dermal Irritation/Corrosion*, as amended from time to time, a** **mean score of ≥ 2.3 and ≤ 4.0 for erythema and eschar or for edema in at least two of three animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from gradings on three consecutive days after the onset of skin reactions,** **(ii) in the case of data acquired from a scientifically validated method, inflammation, namely, local alopecia, hyperkeratosis, hyperplasia and scaling, that persists to the end of the observation period specified by the method in at least two animals, or** **(iii) in the case of data acquired from a scientifically validated method, evidence of severe skin irritation in only one animal**

When human or animal data is available but insufficient to meet classification criteria for skin corrosion, the data must also be evaluated for skin irritation. Reversibility of skin lesions is taken into consideration when evaluating irritant responses.

Animal data acquired from a test performed in accordance with OECD TG 404 - *Acute Dermal Irritation/Corrosion*, as amended from time to time, are evaluated based on scoring values specified in that test. The mean scores per animal for erythema and eschar, or edema are calculated separately. For each test animal, the average scores for three consecutive days (24, 48 and 72 hours) are determined. Where three animals have been tested, if two of the animals meet or exceed the cut-off value of 2.3/4.0 for erythema and eschar, or for edema the substance must be classified in Skin Irritation - Category 2.

Where more than three animals have been tested, scores for each animal are calculated in the same manner as described above and applied according to the number of animals tested, as follows:

6 rabbits tests: mean score of ≥ 2.3 and ≤ 4.0 for erythema and eschar or for edema in at least **4** out of 6 animals

5 rabbits tests: mean score of ≥ 2.3 and ≤ 4.0 for erythema and eschar or for edema in at least **3** out of 5 animals

4 rabbits tests: mean score of ≥ 2.3 and ≤ 4.0 for erythema and eschar or for edema in at least **3** out of 4 animals (GHS, 5th revised edition, 2013, paragraphs 3.2.5.3.3-3.2.5.3.5)

The substance must be classified in Skin Irritation - Category 2 when:

- the criteria in b(i) of the Table to subsection 8.2.2(3) of the HPR are met; or
- scores are insufficient to meet the criteria in b(i) of the Table to subsection 8.2.2(3) or are not provided, and inflammation persists in two or more tested animals to the end of the observation period specified by the scientifically validated method used to generate the data. Signs of inflammation are alopecia (hair loss) in a limited area, hyperkeratosis, hyperplasia and scaling (see criteria b(ii) of the Table to subsection 8.2.2(3)).

Note that complete areas of alopecia, blanching, scars, and visible necrosis are indicators of corrosion and a Skin Corrosion - Category 1 classification may be more appropriate.

Sometimes, only one animal is tested for substances that are suspected corrosives. In this case, as well as cases where more than one animal is tested but only one animal exhibits severe skin irritation and no animals exhibit skin corrosion, the substance is classified in Skin Irritation - Category 2 if criteria as outlined in subparagraph 8.2.2(3)(b)(iii) are met.

Only positive results from human or animal data are considered. Negative results are considered in the classification step detailed in subsection 8.2.2(4) of the HPR.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.2(4)

No classification

8.2.2(4) A substance that meets the following conditions need not be classified in any category or subcategory of this hazard class:

(*a*) there are human data or purposely generated animal data on the substance, acquired from a scientifically validated method, with respect to skin corrosion or skin irritation;

(*b*) the substance is not classified further to subsection (1), (2) or (3); and

(*c*) the data referred to in paragraph (a) demonstrate that it is neither a skin-corrosive substance nor a skin-irritant substance.

In this step, negative human data or negative animal data derived from a skin corrosion and/or skin irritation study can be used to determine that the substance is not a skin corrosive or skin irritant.

In the case of a purposely-generated animal study, at least three test animals have to be assessed and all the conditions of subsection 8.2.2(4) must be met in order to conclude that the substance is not a skin corrosive or skin irritant.

If all the conditions of subsection 8.2.2(4) of the HPR are met, the substance can be considered as not classified under this hazard class and there is no requirement to progress further in the evaluation process for this endpoint. However, progression through the subsequent steps is necessary if no data or insufficient negative data are available.

Discussion of the *Hazardous Products Regulations*
Section 8.2.3

Other skin data from animals

8.2.3 A substance for which there are animal data on dermal exposure, acquired from a scientifically validated method, that have not been purposely generated and that demonstrate that the substance is skin-corrosive or skin-irritant is classified, respectively, in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2".

Animal data from studies other than those specifically designed to test for skin corrosion and/or skin irritation must be evaluated if it has not been conclusively established that the substance is not a skin corrosive or skin irritant according to subsection 8.2.2(4) of the HPR. These data include, for example, acute dermal (LD_{50}) toxicity studies, sub-chronic dermal toxicity studies, and skin sensitization studies, which also permit observation of skin reactions to topically applied test substances. Only positive results from such studies are considered for the classification of the substance.

Discussion of the *Hazardous Products Regulations*
Section 8.2.4

***In vitro* or *ex vivo* data**

8.2.4 A substance for which the data, *in vitro* or *ex vivo*, acquired from a scientifically validated method for the evaluation of skin corrosion or skin irritation demonstrate that the substance is skin-corrosive or skin-irritant is classified, respectively, in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2".

Once *in vivo* human and animal data have been evaluated, *in vitro* and/or *ex vivo* data must be evaluated for skin corrosion and skin irritation. Only positive results can be considered for the classification at this step.

Examples of scientifically validated test methods for **Skin Corrosion - Category 1** include:

- OECD TG 430 – Transcutaneous Electrical Resistance (TER) Test: Using rat skin, the test substance is determined to be corrosive to skin if:

  (a) the mean TER value is ≤ 5 kΩ (kiloohm) and the skin discs are obviously damaged; or

  (b) the mean TER value is ≤ 5 kΩ, and the skin discs show no obvious damage, but the mean disc dye content is ≥ the mean disc dye content of the 10M HCl positive control obtained concurrently.

- OECD TG 431 – Human Skin Model (HSM) Tests. Four possible prediction models are used: EpiSkin™, EpiDerm™ SCT, SkinEthic™ RHE, and epiCS®. Table 1 below summarizes how the classification criteria apply to each test.

  Table 1. Application of Human Skin Model Test Results

Prediction Model	Viability	Classification
EpiSkin™	< 35% after 3 minute exposure	Category 1 (1A optional)
	≥ 35% after 3 minute exposure **and** < 35% after 60 minutes	Category 1 (1B and 1C optional)
	≥ 35% after 60 minute exposure **and** < 35% after 240 minutes	Category 1 (1B and 1C optional)
EpiDerm™ SCT and SkinEthic™ RHE	< 50% after 3 minute exposure	Category 1 (1A optional)
	≥ 50% after 3 minute exposure **and** < 15% after 60 minutes	Category 1 (1B and 1C optional)
epiCS®	< 50% after 3 minute exposure	Category 1
	≥ 50% after 3 minute exposure **and** < 15% after 60 minutes	Category 1

- OECD TG 435 – *in vitro* Membrane Barrier Test Method (e.g., Corrositex): According to the established time parameters for each sub-category outlined in subsection 8.2.2(2) of the HPR, the time (in minutes) elapsed between application of the test substance to the membrane barrier and barrier penetration is used to classify the test substance. Therefore, this test allows for sub-categorization into Category 1A, 1B or 1C. Table 2 summarizes how the test results apply to the classification criteria. This method is mostly applicable to acids and bases and may not be suitable for solutions with pH values between 4.5 and 8.5.

  Table 2. Application of the *in vitro* Membrane Barrier (Corrositex) Test Method Results

	Corrositex Corrosivity	
	Exposure	**Observation**
Skin Corrosion – Category 1A	≤ 3 minutes	≤ 1 hour
Skin Corrosion – Category 1B	> 3 minutes ≤ 1 hour	≤ 14 days
Skin Corrosion – Category 1C	> 1 hour ≤ 4 hours	≤ 14 days

An example of a scientifically validated *in vitro* test method for **Skin Irritation - Category 2** is:

- OECD TG 439 – Reconstructed Human Epidermis (RHE) Test Method. The test substance is classified in Skin Irritation - Category 2 if the tissue viability after exposure and post-treatment incubation is ≤ 50%.

(Details on test methods from website: OECD Guidelines for Testing of Chemicals, Section 4 – Health Effects)

Discussion of the *Hazardous Products Regulations* Section 8.2.5

pH

8.2.5 A substance for which the pH is less than or equal to two or equal to or greater than 11.5 is classified in the category "Skin Corrosion — Category 1", unless an assessment of alkali or acid reserve performed in accordance with established scientific principles supports the conclusion that it need not be classified as a skin-corrosive substance on the basis of its pH.

A pH of ≤ 2.0 or ≥ 11.5 for a substance is sufficient to trigger its classification in Skin Corrosion – Category 1 under section 8.2.5 of the HPR, unless data available from an assessment of alkali or acid reserve supports the conclusion that the substance need not be classified based on its pH. The acid or alkaline reserve is a measure of the buffering capacity of substances. In general, the higher the buffering capacity, the higher the potential for corrosivity.

Note: At the time of writing this guidance, there is no validated and internationally accepted method for assessing acid or alkaline reserve (buffering capacity).

If the pH of a substance is ≤ 2.0 or ≥ 11.5 but an assessment of alkali or acid reserve supports the conclusion that the substance need not be classified based on its pH, it is necessary to proceed to the next step in the classification procedure (section 8.2.6 of the HPR).

Discussion of the *Hazardous Products Regulations*
Subsections 8.2.6(1) and (2)

Structure-activity relationship – skin corrosion

8.2.6(1) A substance for which a structure-activity relationship, established in accordance with established scientific principles, supports the conclusion that the substance must be classified in the category "Skin Corrosion — Category 1" is classified in that category.

Structure-activity relationship – skin irritation

8.2.6(2) A substance for which a structure-activity relationship, established in accordance with established scientific principles, supports the conclusion that the substance must be classified in the category "Skin Irritation — Category 2" is classified in that category.

If none of the criteria in section 8.2.2 through section 8.2.5 of the HPR have been met, then a structure-activity relationship (SAR) must be considered as potential evidence in support of classification. The SAR can be used to conclude that the substance is a skin corrosive or a skin irritant, but cannot be used to conclude that the substance is **not** a skin corrosive or skin irritant.

Discussion of the *Hazardous Products Regulations*
Section 8.2.7

Totality of available data

8.2.7 A substance for which an evaluation of the totality of available data, performed in accordance with established scientific principles, supports the conclusion that the substance is skin-corrosive or skin-irritant is classified, respectively, in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2".

As a final step in determining the classification of a substance in this hazard class, all available information must be considered. Evidence that, at some or all of the previous steps in the evaluation, were insufficient to lead to classification must be considered together. If, when considered together, the evidence warrants the classification of the substance as a skin corrosive or skin irritant, the substance must be classified accordingly.

If, following this evaluation, it is determined that there is insufficient data to support classification of a substance as a skin corrosive or skin irritant, the substance is not classified in this hazard class.

Classification in a Category or Subcategory of the Class

Classification of mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.2.8

Order of provisions

8.2.8 The classification of a mixture as skin-corrosive or as skin-irritant in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.2.9 to 8.2.11.

There is a "tiered" approach for classifying mixtures for skin corrosion or skin irritation, which means that the procedures described in sections 8.2.9 to 8.2.11 must be followed in the order in which these sections appear in the HPR. As specified in subsection 8.2.9(1), if there are test data for the mixture as a whole, these data may be used to classify the mixture, unless, according to subsection 8.2.2(4), the mixture need not be classified. As specified in subsection 8.2.9(2), if test data are available for the mixture as a whole, but the mixture cannot be classified, then the procedures described in sections 8.2.10 and 8.2.11 must be followed.

Section 8.2.10 specifies which bridging principles may be applied to this hazard class. Finally, according to section 8.2.11, if there are no test data available for the mixture as a whole and bridging principles cannot be applied, then the classification of mixtures for skin corrosion or skin irritation is based on the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.9(1)

Data available for mixture as a whole

8.2.9(1) If data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) are available for the mixture as a whole, the mixture must be classified in accordance with the order of sections 8.2.2 to 8.2.7, unless under subsection 8.2.2(4) the mixture need not be classified.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is the same as for substances, and is carried out in accordance with the order of section 8.2.2 to section 8.2.7 of the HPR. Therefore, the discussions corresponding to these sections and the discussion corresponding to Part 2 of the HPR are relevant to the classification of mixtures if there are data available for the mixture as a whole.

If data meet the criteria found in sections 8.2.2 through 8.2.7, then the mixture must be classified within the category whose criteria are met.

For example, if there are no human or animal test data (*in vivo* or *in vitro*) available for the mixture as a whole, however, the pH of the mixture can be measured and meets the criteria outlined in section 8.2.5 (pH ≤ 2.0 or ≥ 11.5), the mixture must be classified in Skin Corrosion - Category 1. Evaluation of the mixture can stop at this point and there is no need to assess bridging principles (section 8.2.10) or evaluate information available on individual ingredients of the mixture (section 8.2.11).

Likewise, if there are data on the mixture as a whole that meet the criteria of subsection 8.2.2(4) (i.e., human or purposely generated animal data indicating that the tested substance is not a skin corrosive or skin irritant), then there is no requirement to progress further in the evaluation process. The mixture is not classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.9(2)

Data available for mixture as a whole – sections 8.2.10 and 8.2.11

8.2.9(2) If data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) are available for the mixture as a whole, but the mixture cannot be classified further to subsections 8.2.2(1) to (3) or sections 8.2.3 to 8.2.7, its classification in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.2.10 and 8.2.11.

If, following the evaluation process outlined in subsection 8.2.9(1) of the HPR, the mixture as a whole cannot be classified, and the mixture cannot be excluded from classification based on applicable negative data (subsection 8.2.2(4)), then the classification must proceed through, in order, section 8.2.10 and section 8.2.11.

Discussion of the *Hazardous Products Regulations*
Section 8.2.10

Data available for use of bridging principles

8.2.10 If data are available to enable the characterization of the mixture as a skin-corrosive mixture or a skin-irritant mixture, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in a category or subcategory of this hazard class in accordance with those subsections.

Section 8.2.10 of the HPR describes the second step in the tiered approach for the classification of mixtures for skin corrosion/irritation.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

All of the bridging principles are applicable to the Skin Corrosion/Irritation hazard class, namely: dilution, production batches, increase in concentration of hazardous ingredient, interpolation, substantially similar mixtures, and aerosols.

If the bridging principles cannot be applied to classify as Skin Corrosion – Category 1 or Skin Irritation – Category 2, then it is necessary to proceed to the third step in the tiered approach for the classification of mixtures.

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.11(1)

Data available for ingredients

8.2.11(1) Subject to subsection (3), a mixture that contains one or more ingredients that are classified in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2" is classified in a category or subcategory of this hazard class in accordance with subsection (2), subject to the following:

(*a*) ingredients that are classified in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2" and are present in the mixture at a concentration equal to or greater than the concentration limit of 1.0% must be included in the calculation of the sum of concentrations of ingredients; and

(*b*) ingredients that are classified in the category "Skin Corrosion — Category 1" or the category "Skin Irritation — Category 2" and are present in the mixture at a concentration of less than the concentration limit of 1.0% must be included in the calculation of the sum of concentrations of ingredients only if there is evidence that, at the concentration at which they are present, the ingredients are skin-corrosive substances or skin-irritant substances.

If a classification for the mixture has not been determined following the application of sections 8.2.9 and 8.2.10 of the HPR, then data available for the ingredients of the mixture must be considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

Application of this section considers as "relevant ingredients", ingredients that are present in concentrations at or above 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) unless there is an indication that an ingredient present at < 1% has corrosive or irritant properties at that concentration. Paragraph 8.2.11(1)(b) builds on the concept found in subsection 2.5(1), where it is stated that the mixture is classified based on ingredients present

below the concentration limit that still present the hazard of the hazard class. These ingredients must be considered as part of the additivity approach to determine the classification of the mixture.

The concentrations of all relevant ingredients are summed according to the rules outlined in subsection 8.2.11(2), unless the mixture contains ingredients for which the additivity approach cannot be applied. The approach for mixtures with one or more particular ingredients for which the additivity approach does not apply is discussed in subsection 8.2.11(3).

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.11(2)

Classification - mixture

8.2.11(2) A mixture is classified in a category of this hazard class in accordance with the following:

(*a*) if the sum of concentrations of ingredients classified in the category "Skin Corrosion — Category 1" is equal to or greater than 5.0%, the mixture is classified in the category "Skin Corrosion — Category 1";

(*b*) if the sum of concentrations of ingredients classified in the category "Skin Corrosion — Category 1" is equal to or greater than 1.0% but less than 5.0%, the mixture is classified in the category "Skin Irritation — Category 2";

(*c*) if the sum of concentrations of ingredients classified in the category "Skin Irritation — Category 2" is equal to or greater than 10.0%, the mixture is classified in the category "Skin Irritation — Category 2"; or

(*d*) if the sum of the results of the following subparagraphs is equal to or greater than 10.0%, the mixture is classified in the category "Skin Irritation — Category 2":

(i) 10 times the sum of concentrations of ingredients classified in the category "Skin Corrosion — Category 1", and

(ii) the sum of concentrations of ingredients classified in the category "Skin Irritation — Category 2".

The order of precedence for applying additivity is from paragraph 8.2.11(2)(a) through paragraph 8.2.11(2)(d) of the HPR. For this subsection, what is considered a "relevant ingredient" is identified in subsection 8.2.11(1).

If the sum of all relevant ingredients classified in Skin Corrosion - Category 1 totals 5.0% or more, the mixture is classified in Skin Corrosion - Category 1.

If the sum of all relevant ingredients classified in Skin Corrosion - Category 1 is ≥ 1.0% but < 5.0%, the mixture is classified in Skin Irritation - Category 2.

If the mixture contains relevant Skin Irritation - Category 2 ingredients, the concentrations of those ingredients are summed, and if the sum is 10.0% or more, the mixture is classified in Skin Irritation - Category 2.

If the mixture contains relevant Skin Corrosion - Category 1 ingredients, and relevant Skin Irritation - Category 2 ingredients, a weighting factor of 10 is applied to the Category 1 ingredients. Ten times the sum of concentrations for Category 1 ingredients added to the sum of concentrations of Category 2 ingredients must total 10.0% or more for the mixture to be classified in Skin Irritation - Category 2.

Table 1. Concentration of ingredients of a mixture classified in Skin Corrosion - Category 1 or Skin Irritation – Category 2 that triggers classification of the mixture in Skin Corrosion - Category 1 or Skin Irritation – Category 2

Sum of ingredients classified in:	**Concentration triggering classification of a mixture in:**	
	Skin Corrosion	**Skin Irritation**
	Category 1	**Category 2**
Skin Corrosion - Category 1	≥ 5%	≥ 1% but < 5%
Skin Corrosion - Category 2		≥ 10%
(10 × Skin Corrosion - Category 1) + Skin Irritation Category 2		≥ 10%

(GHS, 5th revised edition, 2013, Table 3.2.3)

Discussion of the *Hazardous Products Regulations*
Subsection 8.2.11(3)

Mixtures containing particular ingredients

8.2.11(3) A mixture is classified in a category of this hazard class in accordance with the following table if it contains one or more substances such as acids, bases, inorganic salts, aldehydes, phenols or surfactants, which could be corrosive or irritant at concentrations below the concentration limits set out in subsection (2) and at least one ingredient with a concentration that is above the concentration limits set out below:

TABLE

	Column 1	Column 2	Column 3
Item	**Category**	**Ingredient**	**Concentration Limits**
1	**Skin Corrosion — Category 1**	**Acid with pH ≤ 2**	**≥ 1.0%**
2	**Skin Corrosion — Category 1**	**Base with pH ≥ 11.5**	**≥ 1.0%**
3	**Skin Corrosion — Category 1**	**Other ingredients classified in the category "Skin Corrosion — Category 1"**	**≥ 1.0%**
4	**Skin Irritation — Category 2**	**Other ingredients classified in the category "Skin Irritation — Category 2", including acids and bases**	**≥ 3.0%**

The additivity approach explained in subsection 8.2.11(2) of the HPR might not apply for certain types of substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants given that many such substances could be corrosive or irritant at concentrations less than those established for the additivity approach.

Therefore, subsection 8.2.11(3) specifies that a mixture must be classified in Skin Corrosion – Category 1 or Skin Irritation – Category 2 based on a single ingredient of the types indicated in Column 2 of the Table in subsection 8.2.11(3) that exceeds the concentration limits listed in Column 3 of the same table.

Hazard Communication

The required symbols, signal words, hazard statements and precautionary statements for Skin Corrosion/Irritation Categories 1 and 2 are specified in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, pp. 347-348), subject to paragraphs 3(5)(e),(f) and (g) of the HPR. These paragraphs specify that if the hazardous product is classified in:

- Skin Corrosion – Category 1, the information elements specified in the GHS for Skin Corrosion/Irritation – Category 1A apply;
- Skin Corrosion – Category 1A, 1B or 1C, the information elements specified in the GHS for Skin Corrosion/Irritation – Category 1A to 1C apply; and

- Skin Irritation – Category 2, the information elements specified in the GHS for Skin Corrosion/Irritation – Category 2 apply.

Note: Substances classified in Skin Corrosion - Category 1 do not also have to be labelled for Serious Eye Damage – Category 1, even if they meet the criteria for classification in that category, because:

1) according to subsection 3.6(2) , if there is a requirement to provide the hazard statement "Causes severe skin burns and eye damage" any requirement to provide the hazard statement "Causes serious eye damage" does not apply;

2) the required signal word and symbol are the same for both hazard classes; and

3) the precautionary statements for Skin Corrosion —Category 1 include the precautionary statements for Serious Eye Damage — Category 1.

Classification of Skin Corrosion/Irritation for Substances

Examples

Example 1: Standard OECD TG 404 with three test animals (ECHA Guidance, 2015, p. 296)

Available data

1) Human data: not available
2) Animal data: No necrosis was observed. The scoring results following a 4-hour application are:

Rabbit No.	Erythema:						Edema:					
	1h	24h	48h	72h	7d	14d	1h	24h	48h	72h	7d	14d
1	3	3	3	2	0		1	2	2	2	0	
2	3	3	3	3	0		1	2	2	1	0	
3	1	1	1	0	0		1	1	1	1	0	

Classification

Skin Irritation - Category 2

Rationale

The mean erythema and edema scores, respectively, for each rabbit over the time periods 24, 48 and 72 hours are:

Rabbit 1= **2.7** and 2.0

Rabbit 2 = **3** and 1.7

Rabbit 3 = 0.66 and 1

Two of the three rabbits have a mean score for erythema that exceeds the cut-off of 2.3 as specified in the Table to subsection 8.2.2(3) of the HPR.

Example 2: OECD TG 404 test with more than three test animals (ECHA Guidance, 2015, p. 297)

Available data

1) Human data: not available
2) Animal data: No necrosis was observed. The scoring results following a four-hour application are:

Rabbit No.	Erythema:						Edema:					
	1h	24h	48h	72h	7d	14d	1h	24h	48h	72h	7d	14d
1	3	3	2	2	1	0	2	3	2	2	1	0
2	3	2	2	2	1	0	2	2	2	2	1	0
3	2	2	1	1	1	0	2	2	2	2	1	0
4	2	2	1	1	1	0	2	2	2	2	1	0

Classification

Not classified

Rationale

The mean erythema and edema scores, respectively, for each rabbit over the time periods 24, 48 and 72 hours are:

Rabbit 1= **2.3** and **2.3**

Rabbit 2 = 2 and 2

Rabbit 3 = 1.3 and 2

Rabbit 4 = 1.3 and 2

The mean erythema and edema scores for only one of the four animals reached the cut-off score of 2.3. When four rabbits are tested, results for three of the four animals need to meet or exceed the cut-off value for classification in Skin Irritation - Category 2.

Classification of Skin Corrosion/Irritation for Mixtures

Example

Classification based on the classified ingredients (ECHA Guidance, 2015, p. 298)

Available data

Data for the mixture as a whole is not available other than the pH which was measured as 9.0-10.0. There is insufficient information available to apply the bridging principles. Therefore, classification is based on the classified ingredients.

Ingredient	Skin Corrosion/Irritation Classification	Concentration (%w/w)
Substance A	Skin Irritation - Category 2	1.8
Substance B	Not classified	0.5
Substance C	Skin Irritation - Category 2	5.4
Substance D	Not classified	4
Acid	Skin Corrosion - Category 1A	2
Water	Not classified	86.3

Classification

Skin Irritation - Category 2

Rationale

1) The pH of the mixture does not meet the criteria specified in section 8.2.5 of the HPR.
2) Substance B, substance D and water can be disregarded as they are not classified for skin-corrosion or skin-irritation.
3) The mixture contains 2% Acid as the only Skin Corrosion - Category 1 ingredient. The acid is present at 2%, which is less that the 5.0% cut-off established for Category 1 ingredients in subsection 8.2.11(2)(a) of the HPR. The concentration of the acid does, however, meet the cut-off values (≥ 1% but < 5%) established for Category 1 ingredients in subsection 8.2.11(2)(b) of the HPR. Therefore, the mixture must be classified in Skin Irritation - Category 2.

Note that, in this example, ingredients A and C do not impact the overall classification of the mixture in Skin Irritation - Category 2.

Subpart 3
Serious Eye Damage / Eye Irritation

Definitions

8.3 The following definitions apply in this Subpart.

"eye irritation" means the production of changes in the eye that are fully reversible within an observation period of 21 days.

"serious eye damage" means the production of tissue damage in the eye or serious physical decay of vision

(*a*) for which data demonstrate that it is irreversible; or

(*b*) that is not fully reversible within an observation period of 21 days.

Discussion – Eye Irritation vs Serious Eye Damage

Eye irritation refers to the production of reversible changes in the eye. Serious eye damage refers to eye tissue that is damaged or serious physical decay of vision and the effects are either not reversible or not fully reversible within 21 days.

The use of the term "physical" to describe decay of vision excludes neurological damage that affects vision. This hazard class assesses physical damage to the eye, rather than neurological damage. Neurological damage that affects the processing or transmission of information from the eye is not included in this hazard class, but could be considered for classification under STOT-SE or STOT-RE.

The GHS (5th revised edition, 2013, paragraph 3.3.1.1) and the HCS 2012 both specify "following application of a test substance to the anterior surface of the eye" in the definition of eye irritation and serious eye damage. This phrase was not included in the definitions of the HPR to enable the use of human data that may have been acquired through means other than the intentional application of a test substance, as appropriate.

Classification in a Category or Subcategory of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Section 8.3.1

Order of provisions

8.3.1 The classification of a substance that causes serious eye damage or eye irritation in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.3.2 to 8.3.7, unless, after applying subsections 8.3.2(1) to (4), the substance is not classified further to subsection 8.3.2(5).

All data must be considered in a specific order for the purpose of classification in this hazard class. This order applies to the classification of both substances and mixtures. The evaluation steps are listed in order below. More detail on each step is provided in the discussion of section 8.3.2 to section 8.3.7 of the HPR:

1. Positive human data or positive animal data as derived from a study designed to evaluate serious eye damage that meets the classification criteria outlined in subsection 8.3.2(1) are used to classify a substance in Serious Eye Damage – Category 1.
2. Positive human data that meet the classification criteria outlined in subsection 8.3.2(2) are used to classify a substance in Eye Irritation – Category 2.
3. Positive animal data as derived from a study designed to evaluate eye irritation that meet the classification criteria outlined in subsection 8.3.2(3) are used to classify a substance in Eye Irritation – Category 2, with further classification in subcategory 2A or 2B (if possible).
4. Positive human data or positive animal data derived from a study designed to evaluate skin corrosion that meet the classification criteria outlined in subsection 8.3.2(4) (i.e., Skin Corrosion – Category 1) are used to classify a substance in Serious Eye Damage – Category 1.
5. Negative human data or negative animal data as derived from a study designed to evaluate serious eye damage or eye irritation is used to determine that a substance does not meet classification criteria for this hazard class. If the conditions outlined in subsection 8.3.2(5) are met, progression to subsequent steps is not required. However, progression through the subsequent steps is necessary if there is no or insufficient negative data available.
6. Positive animal data derived from other eye or skin exposure studies which meet the classification criteria outlined in section 8.3.3 are used to classify a substance in Serious Eye Damage – Category 1, or Eye Irritation – Category 2, with further classification into sub-category 2A or 2B (if possible).
7. Positive *in vitro* or *ex vivo* data that meet the classification criteria outlined in subsection 8.3.4(1) or 8.3.4(2) are used to classify a substance in Serious Eye Damage – Category 1, or Eye Irritation – Category 2, with further classification into sub-category 2A or 2B (if possible).

8. Substances with pH extremes (≤2.0 or ≥11.5), as outlined in section 8.3.5, are considered and, if criteria are met, are classified in Serious Eye Damage – Category 1.
9. Positive structure-activity data that meet the criteria outlined in subsection 8.3.6(1) or 8.3.6 (2) are used to classify a substance in Serious Eye Damage – Category 1 or Eye Irritation – Category 2, with further classification into sub-category 2A or 2B (if possible).
10. Finally, all the available evidence must be considered together as described in section 8.3.7, to determine if classification in Serious Eye Damage – Category 1, or Eye Irritation – Category 2, with further classification in sub-category 2A or 2B (if possible) is warranted.

If, following step 10, a classification has not been determined, it can be concluded that the substance does not meet the criteria for classification criteria in the Serious Eye Damage/Eye Irritation hazard class.

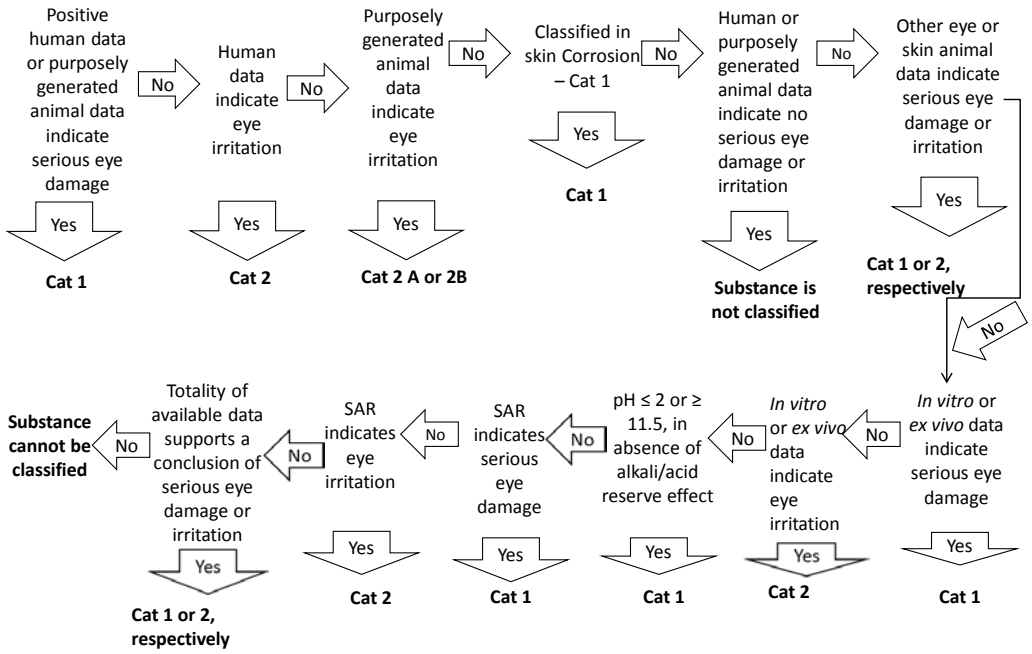


Figure 1: Evaluation sequence for serious eye damage and eye irritation potential

Discussion of the *Hazardous Products Regulations*
Subsection 8.3.2(1)

Human or animal data – serious eye damage

8.3.2(1) A substance for which there are human data or purposely generated animal data with respect to serious eye damage is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Serious Eye Damage — Category 1**	**A substance** **(*a*) that, according to human data, causes serious eye damage;** **(*b*) that, according to animal data acquired from a scientifically validated method from at least one animal, produces effects on the cornea, iris or conjunctiva** **(i) that are irreversible as demonstrated by data, or** **(ii) that are not fully reversible within an observation period of 21 days; or** **(*c*) in respect of which animal data acquired from tests performed in accordance with the OECD Guideline for the Testing of Chemicals, No. 405, entitled *Acute Eye Irritation/Corrosion*, as amended from time to time, demonstrate a positive response in at least two of three animals, and the mean score calculated following gradings at 24, 48 and 72 hours after instillation of the substance, is** **(i) in the case of corneal opacity, ≥ 3, or** **(ii) in the case of iritis, > 1.5**

Human or animal data demonstrating serious eye damage are considered first. Human data that meet the criteria for serious eye damage results in classification of a substance in Serious Eye Damage – Category 1. Positive human data that are insufficient to meet the criteria for serious eye damage are evaluated again, as follows:

- in the assessment for eye irritation – refer to subsection HPR 8.3.2(2) of the HPR, or
- in the final step of evaluation – refer to section 8.3.7 of the HPR.

Negative results are taken into consideration at a later step – refer to subsection 8.3.2(5) of the HPR.

Animal data must be data from an animal study designed specifically to test serious eye damage and/or eye irritation. Data from other studies that permit observations of eye reactions but are not specifically designed to study serious eye damage and/or eye irritation are considered at later steps – refer to subsection 8.3.2(4) and section 8.3.3 of the HPR.

Serious eye damage includes observation of animals with grade 4 corneal lesions in a study conducted and scored according to OECD Test Guideline 405, and other severe reactions (e.g., destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair physical vision (GHS, 5th revised edition, 2013, paragraph 3.3.2.1.1).

The criteria for evaluation of effects on the cornea, iris or conjunctiva, based on purposely generated animal data, are reversibility and severity of damage. A positive result meeting the classification criteria of subparagraph 8.3.2(1)(b) (i) or (ii) of the HPR is required for only one of the test animals. This requirement remains true even if more than one animal is tested in a study. For example, where six rabbits have been tested for eye damage, a positive result in at least one animal out of six is sufficient for classification of a substance in Serious Eye Damage - Category 1.

The criteria in paragraph 8.3.2(1)(c) of the HPR consider animal data that have been assigned scoring values which assess the degree of inflammation. The scoring values are specified in OECD Test Guideline 405. Evaluation takes place separately for the cornea and iris. For each test animal, the average scores for three consecutive days (24, 48 and 72 hours) are calculated. Where three animals have been tested, if two of the animals meet or exceed the cut-off value of 3 for corneal opacity and/or exceed the cut-off value of 1.5 for iritis, the substance must be classified in Serious Eye Damage - Category 1. Where more than three animals have been tested, scores for each animal are calculated in the same manner as described above and then applied as follows according to the number of animals tested:

6 rabbits tests: mean score of ≥ 3 for corneal opacity and/or > 1.5 for iritis in at least **4** out of 6 animals

5 rabbits tests: mean score of ≥ 3 for corneal opacity and/or > 1.5 for iritis in at least **3** out of 5 animals

4 rabbits tests: mean score of ≥ 3 for corneal opacity and/or > 1.5 for iritis in at least **3** out of 4 animals (GHS, 5th revised edition, 2013, paragraphs 3.3.5.3.3-3.3.5.3.5).

As with human data, negative results from purposely generated animal studies are taken into consideration at a later step – refer to subsection 8.3.2(5) of the HPR.

Discussion of the *Hazardous Products Regulations* Subsection 8.3.2(2)

Human data – eye irritation

8.3.2(2) A substance for which human data demonstrate that it causes eye irritation is classified in the category "Eye Irritation — Category 2".

When human data is available but insufficient to meet the classification criteria for serious eye damage, the data must also be evaluated for eye irritation.

Discussion of the *Hazardous Products Regulations*
Subsection 8.3.2(3)

Animal data – eye irritation

8.3.2(3) A substance for which purposely generated animal data demonstrate that it causes eye irritation is classified in the category "Eye Irritation — Category 2" and is, if the applicable data are available, further classified in the appropriate subcategory in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Subcategory	Criteria
1	Eye Irritation — Category 2	Eye Irritation – Category 2A	A substance that is not classified in the category "Serious Eye Damage — Category 1" and in respect of which animal data acquired from tests performed in accordance with the OECD Guideline for the Testing of Chemicals, No. 405, entitled *Acute Eye Irritation/Corrosion*, as amended from time to time, demonstrate in at least two of three animals a positive response that fully reverses within an observation period of more than seven days but not more than 21 days, and the mean score calculated following gradings at 24, 48 and 72 hours after instillation of the substance, is (*a*) in the case of corneal opacity, ≥ 1; (*b*) in the case of iritis, ≥ 1; (*c*) in the case of conjunctival redness, ≥ 2; or (*d*) in the case of conjunctival edema (chemosis), ≥ 2
2	Eye Irritation — Category 2	Eye Irritation – Category 2B	A substance that is not classified in the category "Serious Eye Damage — Category 1" and in respect of which animal data acquired from tests performed in accordance with the OECD Guideline for the Testing of Chemicals, No. 405, entitled *Acute Eye Irritation/Corrosion*, as amended from time to time, demonstrate in at least two of three animals a positive response that fully reverses within an observation period of seven days, and the mean score calculated following gradings at 24, 48 and 72 hours after instillation of the substance, is (*a*) in the case of corneal opacity, ≥ 1; (*b*) in the case of iritis, ≥ 1; (*c*) in the case of conjunctival redness, ≥ 2; or (*d*) in the case of conjunctival edema (chemosis), ≥ 2

When purposely generated animal data is available but insufficient to meet classification criteria for serious eye damage, the data must also be evaluated for eye irritation.

Animal data must be derived from "purposely generated animal data", which means that the data is from an animal study designed specifically to test serious eye damage and/or irritation. Data from other studies that permit observations of eye reactions but are not specifically designed to study serious eye damage and/or eye irritation must be considered at later steps – refer to

subsection 8.3.2(4) and section 8.3.3 of the HPR. Only positive results from purposely generated animal data are considered in this step. Negative results are taken into consideration at a later step - refer to subsection 8.3.2(5) of the HPR.

Eye Irritation - Category 2 has two sub-categories: 2A, and 2B. If the data do not permit sub-categorization, the substance would simply be classified in Category 2 without further sub-categorization.

The criteria for evaluation of effects on the cornea, iris or conjunctiva, based on purposely generated animal data, are reversibility and severity of damage. Irreversible effects indicate serious eye damage and classification must be in Serious Eye Damage- Category 1. In the case of eye irritation, the effects must be reversible. The rate at which reversibility occurs is what differentiates the two sub-categories.

The criteria in subsection 8.3.2(3) of the HPR consider animal data that have been assigned scoring values that assess the degree of inflammation, according to OECD Test Guideline 405. Evaluation takes place separately for the cornea, iris, conjunctival redness (erythema) and conjunctival edema (chemosis or swelling). For each test animal, the average scores for three consecutive days (24, 48 and 72 hours) are calculated. Where three animals have been tested, if two of the animals meet or exceed the cut-off value of 1 for corneal opacity and/or 1 for iritis and/or 2 for conjunctival redness and/or 2 for conjunctival edema, the substance must be classified in Eye Irritation - Category 2.

Where more than three animals have been tested, scores for each animal are calculated in the same manner as described above, and applied according to the number of animals tested, as follows:

6 rabbits tests:	mean score of ≥ 1 for corneal opacity and/or ≥ 1 for iritis and/or ≥ 2 for conjunctival redness and/or ≥ 2 for conjunctival edema in at least **4** out of 6 animals
5 rabbits tests:	mean score of ≥ 1 for corneal opacity and/or ≥ 1 for iritis and/or ≥ 2 for conjunctival redness and/or ≥ 2 for conjunctival edema in at least **3** out of 5 animals
4 rabbits tests:	mean score of ≥ 1 for corneal opacity and/or ≥ 1 for iritis and/or ≥ 2 for conjunctival redness and/or ≥ 2 for conjunctival edema in at least **3** out of 4 animals (GHS, 5th revised edition, 2013, paragraphs 3.3.5.3.3-3.3.5.3.5)

If the effects listed above fully reverse between seven and 21 days, classification in Eye Irritation - Category 2A is appropriate. If the above effects fully reverse within seven days, then classification in Eye Irritation - Category 2B is appropriate. If the above effects fully reverse within 21 days and it is not possible to subcategorize further, Eye Irritation - Category 2 is assigned.

Discussion of the *Hazardous Products Regulations* Subsection 8.3.2(4)

Skin corrosion data

8.3.2(4) A substance that is classified in the category "Skin Corrosion — Category 1" in accordance with subsections 8.2.2(1) and (2) is also classified in the category "Serious Eye Damage — Category 1" of this hazard class.

Testing for serious eye damage is often not carried out on substances known or predicted to be corrosive to the skin. Such substances are automatically considered to be seriously damaging to the eye. Therefore, if criteria for skin corrosion are met, as per subsection 8.2.2(1) or 8.2.2(2) of the HPR, the substance is also classified in Serious Eye Damage – Category 1.

This cross-over classification is only allowed if the basis for classification for Skin Corrosion is either human data or purposely generated animal data. Other types of animal data on skin exposure are not considered here, but are considered in section 8.3.3.

Discussion of the *Hazardous Products Regulations* Subsection 8.3.2(5)

No classification

8.3.2(5) A substance that meets the following conditions need not be classified in any category of this hazard class:

(*a*) the substance is not classified further to subsections (1) to (4); and

(*b*) human data or purposely generated animal data on the substance, acquired from a scientifically validated method, with respect to serious eye damage or eye irritation, demonstrate that the substance does not cause serious eye damage or eye irritation.

In this step, negative human data or negative animal data derived from a serious eye damage and/or eye irritation study can be used to determine that the substance does not cause serious eye damage or eye irritation.

In the case of a purposely-generated animal study, at least three test animals have to be assessed and all the conditions of subsection 8.3.2(5) must be met in order to conclude that the substance does not cause serious eye damage or eye irritation.

If all the conditions of subsection 8.3.2(5) of the HPR are met, the substance can be considered as not classified under this hazard class and there is no requirement to progress further in the evaluation process. However, progression through the subsequent steps is necessary if no data or insufficient negative data are available.

Discussion of the *Hazardous Products Regulations*
Section 8.3.3

Other animal data – eye or skin exposure

8.3.3 A substance for which there are animal data on eye exposure that demonstrate, or animal data on skin exposure that support the conclusion, that the substance causes serious eye damage or eye irritation is classified in the category "Serious Eye Damage — Category 1" or the category "Eye Irritation — Category 2", and, in the latter case, if the applicable data are available, the substance is further classified in the subcategory "Eye Irritation — Category 2A" or in the subcategory "Eye Irritation — Category 2B".

Animal data from studies other than those specifically designed to test for serious eye damage and/or eye irritation must be evaluated if it has not been conclusively established that the substance does not cause serious eye damage or eye irritation according to subsection 8.3.2(5) of the HPR. These data include, for example, skin studies other than those purposely generated for skin irritation and/or skin corrosion (refer to discussion of section 8.2.3 of the HPR) and other eye exposure studies, which permit observation of eye reactions. Only positive results from such studies are considered for the classification of the substance.

Discussion of the *Hazardous Products Regulations*
Subsections 8.3.4(1) and 8.3.4(2)

***In vitro* or *ex vivo* data – serious eye damage**

8.3.4(1) A substance for which the data, *in vitro* or *ex vivo*, acquired from a scientifically validated method for the evaluation of serious eye damage demonstrate that the substance causes serious eye damage is classified in the category "Serious Eye Damage — Category 1".

***In vitro* or *ex vivo* data – eye irritation**

8.3.4(2) A substance for which the data, *in vitro* or *ex vivo*, acquired from a scientifically validated method for the evaluation of eye irritation demonstrate that the substance causes eye irritation is classified in the category "Eye Irritation —Category 2" and, if the applicable data are available, the substance is further classified in the subcategory "Eye Irritation — Category 2A" or in the subcategory "Eye Irritation — Category 2B".

Once *in vivo* human and animal data have been evaluated, *in vitro* and/or *ex vivo* data must be evaluated for serious eye damage and eye irritation. Only positive results can be considered for classification at this step.

Examples of scientifically validated test methods for **Serious Eye Damage** - **Category 1** include:

- OECD TG 437 – Bovine Corneal Opacity and Permeability (BCOP) Test: Using isolated bovine cornea, classification of the test substance in Serious Eye Damage - Category 1 is met if the IVIS (*in vitro* irritancy score) is greater than 55.
- OECD TG 438 – Isolated Chicken Eye (ICE) Test: Using enucleated chicken eyes, corneal swelling, opacity and fluorescein retention are measured and each assigned an ICE class. Classification of the test substance in Serious Eye Damage - Category 1 is met if one or more of the following requirements are satisfied:
    - All three endpoints are ICE Class IV
    - Two endpoints are ICE Class IV and the other is ICE Class III
    - Two endpoints are ICE Class IV and the other is ICE Class II
    - Two endpoints are ICE Class IV and the other is ICE Class I
    - Corneal opacity ≥3 at 30 minutes in at least 2 eyes
    - Corneal opacity = 4 at any time point in at least 2 eyes
    - Severe loosening of the epithelium in at least 1 eye

Note: At the time of writing this guidance, there are no validated and internationally accepted *in vitro* test methods available for assessing eye irritation.

(Details on test methods from website: OECD Guidelines for Testing of Chemicals, Section 4 – Health Effects)

Discussion of the *Hazardous Products Regulations* Section 8.3.5

pH

8.3.5 A substance for which the pH is less than or equal to two or equal to or greater than 11.5 is classified in the category "Serious Eye Damage — Category 1", unless an assessment of alkali or acid reserve performed in accordance with established scientific principles supports the conclusion that it need not be classified as a substance that causes serious eye damage on the basis of its pH.

A pH of ≤2.0 or ≥11.5 for a substance is sufficient to trigger its classification in Serious Eye Damage – Category 1 under section 8.3.5 of the HPR, unless data available from an assessment of alkali or acid reserve supports the conclusion that the substance need not be classified based on its pH. The alkali or acid reserve is a measure of the buffering capacity of substances. In general, the higher the buffering capacity, the higher the potential for serious eye damage.

Note: At the time of writing this guidance, there is no validated and internationally accepted method for assessing alkali or acid reserve (buffering capacity).

If the pH of a substance is ≤ 2.0 or ≥ 11.5 but an assessment of alkali or acid reserve supports the conclusion that the substance need not be classified based on its pH, it is necessary to proceed to the next step in the classification procedure (section 8.3.6 of the HPR).

Discussion of the *Hazardous Products Regulations*
Subsections 8.3.6(1) and (2)

Structure-activity relationship – serious eye damage

8.3.6(1) A substance for which a structure-activity relationship, established in accordance with established scientific principles, supports the conclusion that the substance must be classified in the category "Serious Eye Damage — Category 1" is classified in that category.

Structure-activity relationship – eye irritation

8.3.6(2) A substance for which a structure-activity relationship, established in accordance with established scientific principles, supports the conclusion that the substance must be classified in the category "Eye Irritation — Category 2" is classified in that category and, if the applicable data are available, the substance is further classified in the subcategory "Eye Irritation — Category 2A" or in the subcategory "Eye Irritation — Category 2B".

If none of the criteria in sections 8.3.2 through 8.3.5 of the HPR have been met, then a structure-activity relationship (SAR) must be considered as potential evidence in support of classification. The SAR can be used to conclude that the substance causes serious eye damage or is an eye irritant, but cannot be used to conclude that the substance does **not** cause serious damage to the eye or is **not** an eye irritant.

Discussion of the *Hazardous Products Regulations*
Section 8.3.7

Totality of available data

8.3.7 A substance for which an evaluation of the totality of available data, performed in accordance with established scientific principles, supports the conclusion that the substance causes serious eye damage or eye irritation is classified in the category "Serious Eye Damage — Category 1" or the category "Eye Irritation — Category 2"and, in the latter case, if the applicable data are available, the substance is further classified in the subcategory "Eye Irritation — Category 2A" or in the subcategory "Eye Irritation — Category 2B".

As a final step in determining classification of a substance in this hazard class, all available information must be considered. Evidence that, at some or all of the previous steps in the evaluation, were insufficient to lead to classification must be considered together. If, when

considered together, the evidence warrants the classification of the substance as causing serious eye damage or eye irritation, the substance must be classified accordingly.

If, following this evaluation, it is determined that there is insufficient data to support classification of a substance for serious eye damage or eye irritation, the substance is not classified in this hazard class.

Classification in a Category or Subcategory of the Class

Classification of mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.3.8

Order of provisions

8.3.8 The classification of a mixture as a mixture that causes serious eye damage or eye irritation in a category of this hazard class must proceed in accordance with the order of sections 8.3.9 to 8.3.11.

There is a "tiered" approach for classifying mixtures for serious eye damage or eye irritation, which means that the procedures described in sections 8.3.9 to 8.3.11 must be followed in the order in which these sections appear in the HPR. As specified in subsection 8.3.9(1), if there are test data for the mixture as a whole, these data may be used to classify the mixture, unless, according to subsection 8.3.2(5), the mixture need not be classified. As specified in subsection 8.3.9(2), if test data are available for the mixture as a whole, but the mixture cannot be classified, then the procedures described in sections 8.3.10 and 8.3.11 must be followed.

Section 8.3.10 specifies which bridging principles may be applied to this hazard class. Finally, according to section 8.3.11, if there are no test data available for the mixture as a whole and bridging principles cannot be applied, then the classification of mixtures for serious eye damage or eye irritation is based on the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 8.3.9(1)

Data available for mixture as a whole

8.3.9(1) If data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) are available for the mixture as a whole, the mixture must be classified in accordance with the order of sections 8.3.2 to 8.3.7 unless, under subsection 8.3.2(5), the mixture need not be classified.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to in subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is the same as for substances, and is carried out in accordance with sections 8.3.2 to 8.3.7 of the HPR. Therefore, the discussion corresponding to these sections and the discussion corresponding to Part 2 of the HPR are relevant to the classification of mixtures if there are data available for the mixture as a whole.

If data meet the criteria found in sections 8.3.2 through 8.3.7 of the HPR, then the mixture must be classified within the category whose criteria are met.

For example, if there are no human or animal test data (*in vivo* or *in vitro*) available for the mixture as a whole; however, the pH of the mixture can be measured and meets the criteria outlined in section 8.3.5 (pH ≤2.0 or ≥11.5), the mixture must be classified in Serious Eye Damage - Category 1. Evaluation on the mixture can stop at this point and there is no need to assess bridging principles or evaluate information available on individual ingredients of the mixture (sections 8.3.10 and section 8.3.11 of the HPR).

Likewise, if there are data on the mixture as a whole that meet the conditions of subsection 8.3.2(5) of the HPR (i.e., human or purposely generated animal data indicating that the tested substance does not cause serious eye damage or eye irritation), then there is no requirement to progress further in the evaluation process for this endpoint. The mixture is not classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Subsection 8.3.9(2)

Data available for mixture as a whole – sections 8.3.10 and 8.3.11

8.3.9(2) If data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) are available for the mixture as a whole, but the mixture cannot be classified further to subsections 8.3.2(1) to (4) or sections 8.3.3 to 8.3.7, its classification in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.3.10 and 8.3.11.

If, following the evaluation process outlined in subsection 8.3.9(1) of the HPR, the mixture as a whole cannot be classified and the mixture cannot be excluded from classification based on applicable negative data (subsection 8.3.2(5)), then the classification must proceed through, in order, sections 8.3.10 and 8.3.11 of the HPR.

Discussion of the *Hazardous Products Regulations*
Section 8.3.10

Data available for use of bridging principles

8.3.10 If data are available to enable the characterization of the mixture as a mixture that causes serious eye damage or eye irritation, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in a category or subcategory of this hazard class in accordance with those subsections.

Section 8.3.10 of the HPR describes the second step in the tiered approach for the classification of mixtures for serious eye damage/eye irritation.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

All of the bridging principles are applicable to the Serious Eye Damage/Eye Irritation hazard class, namely: dilution, production batches, increase in concentration of hazardous ingredient, interpolation, substantially similar mixtures, and aerosols.

If the bridging principles cannot be applied to classify as Serious Eye Damage – Category 1 or Eye Irritation – Category 2, then it is necessary to proceed to the third step in the tiered approach for the classification of mixtures.

Discussion of the *Hazardous Products Regulations*
Subsection 8.3.11(1)

Data available for ingredients

8.3.11(1) Subject to subsection (3), a mixture that contains one or more ingredients that are classified in the category "Serious Eye Damage — Category 1" or the category "Eye Irritation — Category 2" is classified in a category of this hazard class in accordance with subsection (2), subject to the following:

(*a*) ingredients that are classified in the category "Serious Eye Damage — Category 1" or the category "Eye Irritation — Category 2" and are present in the mixture at a concentration equal to or greater than the concentration limit of 1.0% must be included in the calculation of the sum of concentrations of ingredients; and

(*b*) ingredients that are classified in the category "Serious Eye Damage — Category 1" or the category "Eye Irritation — Category 2" and are present in the mixture at a concentration of less than the concentration limit of 1.0% must be included in the calculation of the sum of concentrations of ingredients only if there is evidence that, at the concentration at which they are present, the ingredients are substances that cause serious eye damage or eye irritation.

If a classification for the mixture has not been determined following the application of sections 8.3.9 and 8.3.10 of the HPR, then data available for the ingredients of the mixture must be considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

Application of this section considers as "relevant ingredients", ingredients that are present in concentrations at or above 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) unless there is an indication that an ingredient present at < 1% has serious eye damaging or eye irritant properties at that concentration. Paragraph 8.3.11(1)(b) builds on the concept found in subsection 2.5(1) of the HPR, where it is stated that the mixture is classified based on ingredients present below the concentration limit that still present the hazard of the hazard class. These ingredients must be considered as part of the additivity approach to determine the classification of the mixture.

The concentrations of all relevant ingredients are summed according to the rules outlined in subsection 8.3.11(2), unless the mixture contains ingredients for which the additivity approach cannot be applied. The approach for mixtures with one or more particular ingredients for which the additivity approach does not apply is discussed in subsection 8.2.11(3).

Discussion of the *Hazardous Products Regulations* Subsection 8.3.11(2)

Classification - mixture

8.3.11(2) A mixture is classified in a category of this hazard class in accordance with the following:

(*a*) if the sum of concentrations of ingredients classified in the categories "Serious Eye Damage — Category 1" and "Skin Corrosion — Category 1" is equal to or greater than 3.0%, the mixture is classified in the category "Serious Eye Damage — Category 1";

(*b*) if the sum of concentrations of ingredients classified in the categories "Serious Eye Damage — Category 1" and "Skin Corrosion — Category 1" is equal to or greater than 1.0% but less than 3.0%, the mixture is classified in the category "Eye Irritation — Category 2";

(*c*) if the sum of concentrations of ingredients classified in the category "Eye Irritation — Category 2" is equal to or greater than 10.0%, the mixture is classified in the category "Eye Irritation — Category 2"; or

(*d*) if the sum of the results of the following subparagraphs is equal to or greater than 10.0%, the mixture is classified in the category "Eye Irritation — Category 2":

(i) 10 times the total of the sum of concentrations of ingredients classified in the category "Serious Eye Damage — Category 1" and the sum of concentrations of ingredients classified in the category "Skin Corrosion — Category 1", and

(ii) the sum of concentrations of ingredients classified in the category "Eye Irritation — Category 2".

The order of precedence for applying additivity is from paragraphs 8.3.11(2)(a) through 8.3.11(2)(d) of the HPR. For this subsection, what is considered a "relevant ingredient" is identified in subsection 8.3.11(1).

If the sum of all relevant ingredients classified in Serious Eye Damage - Category 1 and Skin Corrosion – Category 1 totals 3.0% or more, the mixture is classified in Serious Eye Damage - Category 1.

If the sum of all relevant ingredients classified in Serious Eye Damage - Category 1 and Skin Corrosion – Category 1 is ≥ 1.0% but < 3.0%, the mixture is classified in Eye Irritant - Category 2.

If the mixture contains relevant Eye Irritation - Category 2 ingredients, the concentrations of those ingredients are summed, and if the sum is 10.0% or more, the mixture is classified in Eye Irritation - Category 2.

If the mixture contains relevant ingredients classified in Skin Corrosion - Category 1 and Serious Eye Damage – Category 1 and relevant ingredients classified in Eye Irritation - Category 2, a weighting factor of 10 is applied to the Category 1 ingredients. Ten times the sum of

concentrations for Category 1 ingredients added to the concentration sum of Category 2 ingredients must total 10.0% or more for the mixture to be classified in Eye Irritation - Category 2.

Table 1. Concentration of ingredients of a mixture classified in Skin Corrosion - Category 1 and/or Serious Eye Damage - Category 1 or Eye Irritation – Category 2 that triggers classification of the mixture in Serious Eye Damage - Category 1 or Eye Irritation – Category 2

Sum of ingredients classified in	Concentration triggering classification of a mixture in:	
	Serious Eye Damage	Eye Irritation
	Category 1	Category 2
Skin Corrosion - Category 1 + Serious Eye Damage - Category 1 (see Note below)	≥3%	≥ 1% but < 3%
Eye Irritation - Category 2		≥ 10%
10 x (Skin Corrosion - Category 1 + Serious Eye Damage - Category 1) (see Note below) + eye Category 2		≥ 10%

Note: If an ingredient is classified in both Skin Corrosion - Category 1 and Serious Eye Damage - Category 1, its concentration is considered only once in the calculation.

(GHS, 5th revised edition, 2013, Table 3.3.3)

Discussion of the *Hazardous Products Regulations* Subsection 8.3.11(3)

Mixtures containing particular ingredients

8.3.11(3) A mixture is classified in a category of this hazard class in accordance with the following table if the mixture contains one or more substances, such as acids, bases, inorganic salts, aldehydes, phenols or surfactants, which could cause serious eye damage or eye irritation at concentrations below the concentration limits set out in subsection (2) and at least one ingredient with a concentration that is above the concentration limits set out below:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Ingredient	Concentration Limits
1	Serious Eye Damage — Category 1	Acid with pH ≤ 2	≥ 1.0%
2	Serious Eye Damage — Category 1	Base with pH ≥ 11.5	≥ 1.0%
3	Serious Eye Damage — Category 1	Other ingredients classified in the category “Serious Eye Damage — Category 1”	≥ 1.0%
4	Eye Irritation — Category 2	Other ingredients classified in the category “Eye Irritation — Category 2”, including acids and bases	≥ 3.0%

The additivity approach explained in subsection 8.3.11(2) of the HPR might not apply for certain types of substances such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants given that many such substances could cause serious eye damage or eye irritation at concentrations less than those established for the additivity approach.

Therefore, subsection 8.3.11(3) specifies that a mixture must be classified in Serious Eye Damage – Category 1 or Eye Irritation – Category 2 based on a single ingredient of the types indicated in Column 2 of the Table to subsection 8.3.11(3) that exceeds the concentration limits listed in Column 3 of the same table.

Hazard Communication

The required symbols, signal words, hazard statement, and precautionary statements for Serious Eye Damage – Category 1 and Eye Irritation - Category 2 are specified in Section 3 of Annex 3 of the GHS (5th revised edition, 2013, pp. 350-351), subject to paragraphs 3(5)(h), (i) and (j) of the HPR. These paragraphs specify that if the hazardous product is classified in:

- Serious Eye Damage – Category 1, the information elements specified in the GHS for Eye Damage/Irritation – Category 1 apply;
- Eye Irritation – Category 2, the information elements specified in the GHS for Eye Damage/ Irritation – Category 2A apply; and
- Eye Irritation – Category 2A or 2B, the information elements specified, respectively, in the GHS for Eye Damage/Irritation – Category 2A or 2B apply.

Note: Substances classified in Skin Corrosion - Category 1 do not also have to be labelled for Serious Eye Damage – Category 1, even if they meet the criteria for classification in that category, because:

1) according to subsection 3.6(2) , if there is a requirement to provide the hazard statement “Causes severe skin burns and eye damage” any requirement to provide the hazard statement “Causes serious eye damage” does not apply;

2) the required signal word and symbol are the same for both hazard classes; and

3) the precautionary statements for Skin Corrosion —Category 1 include the precautionary statements for Serious Eye Damage — Category 1.

Classification of Serious Eye Damage/Eye Irritation for Substances

Examples

Example 1: Standard OECD TG 405 with three test animals (ECHA Guidance, 2015, p. 321)

Available data

1) Human data: not available
2) Animal data: Serious eye damage was not observed. The scoring results following application are:

Rabbit No.	Cornea:					Iris:					Conjunctiva (Erythema / Swelling):				
	1h	24h	48h	72h	21d	1h	24h	48h	72h	21d	1h	24h	48h	72h	21d
1	0	2	2	2	0	0	1	1	1	0	2/0	2/3	2/3	2/3	0/0
2	2	2	2	2	0	1	1	1	1	0	1/2	1/2	1/2	1/1	0/0
3	2	2	1	1	0	1	1	1	1	0	1/2	1/3	1/2	1/2	0/0

Classification

Eye Irritation - Category 2

Rationale

All effects were reversible within 21 days. The mean scores for cornea, iris, conjunctival erythema and conjunctival swelling for each rabbit over the time periods 24, 48 and 72 hours are, respectively:

Rabbit 1= **2, 1, 2** and **3**

Rabbit 2 = **2**, **1**, 1 and 1.7

Rabbit 3 = 1.3, **1**, 1 and **2.3**

At least two of the three rabbits meet or exceed the cut-off scores specified in the Table to subsection 8.3.2(3) of the HPR:

- 2 for cornea (2/3 rabbits)
- 1 for iris (3/3 rabbits), and
- 2 for conjunctival swelling (2/3 rabbits)

Example 2: Test with more than three test animals (ECHA Guidance, 2015, p. 323)

Available data

1) Human data: not available
2) Animal data: The scoring results following application are:

Rabbit No.	Cornea:						
	1h	24h	48h	72h	7d	14d	21d
1	1	2	3	3	1	1	0
2	1	2	2	3	1	1	0
3	1	2	3	3	2	1	0
4	1	2	4	4	2	1	0

Rabbit No.	Iris:						
	1h	24h	48h	72h	7d	14d	21d
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	1	1	1	1	0	0
4	0	0	0	0	0	0	0

Rabbit No.	Conjunctiva (Erythema/Swelling):						
	1h	24h	48h	72h	7d	14d	21d
1	2/2	2/2	2/2	1/1	1/1	1/1	0/0
2	2/2	2/2	2/1	1/1	1/1	0/0	0/0
3	2/2	2/2	2/2	1/1	1/1	1/1	1/1
4	2/2	2/2	2/2	1/1	1/1	0/1	0/1

Classification

Serious Eye Damage - Category 1

Rationale

Effects in conjunctiva are **not** reversible at 21 days. Animal #4 had maximum cornea score 4/4 at 48 and 72 hours.

Classification of Serious Eye Damage/Eye Irritation for Mixtures

Example

Classification based on the classified ingredients

Available data

Data for the mixture as a whole is not available other than the pH which was measured as 9.0-10.0. There is insufficient information available to apply the bridging principles. Therefore, classification is based on the classified ingredients.

Ingredient	Classification	Concentration (%w/w)
Substance A	Serious Eye Damage - Category 1	1.8
Substance B	Eye Irritation - Category 2	0.5
Substance C	Serious Eye Damage - Category 1	5.4
Substance D	Not classified	4
Water	Not classified	86.3

Classification

Serious Eye Damage - Category 1

Rationale

1) The pH of the mixture does not meet the criteria specified in section 8.3.5 of the HPR.
2) Substance D and water can be disregarded as they are not classified for Serious Eye Damage/Eye Irritation or for Skin Corrosion/Irritation.
3) The mixture contains 7.2% (1.8% + 5.4%) Serious Eye Damage - Category 1 ingredients. This value exceeds the 3.0% cut-off established in paragraph 8.3.11(2)(a) of the HPR.

Subpart 4
Respiratory or Skin Sensitization

Definitions

8.4 The following definitions apply in this Subpart.

"respiratory sensitization" means the production of hypersensitivity of the airways following inhalation.

"respiratory sensitizer" means a mixture or substance that is liable to lead to hypersensitivity of the airways following inhalation.

"skin sensitization" means the production of an allergic response following skin contact.

"skin sensitizer" means a mixture or substance that is liable to lead to an allergic response following skin contact.

Discussion

Sensitization is a response whereby a person or test animal is exposed to a substance that at first causes no or little immune reaction but which, upon repeated exposure, induces an immune response that is often stronger and not necessarily limited to the contact site.

Sensitization includes two phases: induction of specialized immunological memory by exposure to an allergen, followed by elicitation, i.e., the production of a cell-mediated or antibody-mediated allergic response to that allergen. Usually lower levels of the allergen are necessary for elicitation than are required for induction.

A substance or mixture can be classified as follows:

(a) Respiratory Sensitizer- Category 1;

(b) Skin Sensitizer – Category 1; or

(c) both, Respiratory Sensitizer – Category 1 and Skin Sensitizer – Category 1.

Symptoms of skin sensitization include erythema (reddening of the skin), blisters, fissures in tissue and fluid discharge. Sensitization differs from skin irritation or corrosion, which do not involve an allergic response.

Respiratory sensitization is normally seen as asthma but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction; however, immunological mechanisms do not have to be demonstrated.

Classification in a Category or Subcategory of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Subsection 8.4.1(1)

Respiratory sensitizer - category

8.4.1(1) A substance that is a respiratory sensitizer is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Respiratory Sensitizer — Category 1**	**A substance** **(a) that, according to human data, leads to specific respiratory hypersensitivity; or** **(b) in respect of which animal data acquired from scientifically validated methods for the evaluation of respiratory sensitization demonstrate positive results**

At present, classification in Respiratory Sensitizer – Category 1 is based on human data because there currently are no recognized and validated animal models available for the testing of respiratory hypersensitivity. The mouse Immunoglobulin E (IgE) test and guinea pig models are potentially useful but have not been fully standardized. The guinea pig respiratory parameter tests are reported to be poorly reproducible and are confounded by irritant effects of the test substance.

Human evidence of respiratory hypersensitivity could be (GHS 5th revised edition, 2013, paragraphs 3.4.2.1.2.3 and 3.4.2.1.2.5):

(a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) *in vivo* immunological test (e.g., skin prick test);

(ii) *in vitro* immunological test (e.g., serological analysis);

(iii) studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven (e.g., repeated low-level irritation, pharmacologically mediated effects);

(iv) a chemical structure related to substances known to cause respiratory hypersensitivity;

(b) positive data from bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction. A positive bronchial challenge test is generally considered to be the gold standard for the identification of a respiratory sensitizer and can provide sufficient evidence on its own,

but in practice many of the other examinations will already have been carried out. The test should be conducted with a sub-irritant concentration of the allergen, it should maintain blind conditions to the nature of the exposure, and account for possible confounding factors such as the use of asthma medication, smoking habits, and the existence of upper respiratory tract infections (e.g., tuberculosis). A positive response needs to be of appropriate magnitude (e.g., a decrease in the forced expiratory volume in one second of 15% or greater over and above the effect seen at the control challenge).

Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and the development of respiratory sensitization (GHS 5th revised edition, 2013, paragraph 3.4.2.1.2.4). Understanding the type and pattern of symptoms is helpful. For example, respiratory symptoms may occur during the working week and increase in severity as the week progresses, but improve during absences from work. Medical history should include a note of other allergic or airway disorders from childhood, and smoking history.

In addition to evidence such as that listed above, it is also necessary to consider the size of the population exposed and the extent of exposure.

The mechanisms by which substances induce symptoms of asthma are not yet fully known (GHS 5th revised edition, 2013, footnote 3 to paragraph 3.4.2.1.2.3). As a precaution, substances that induce symptoms of asthma are considered respiratory sensitizers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperreactivity, they should not be considered as respiratory sensitizers.

Discussion of the *Hazardous Products Regulations*
Subsection 8.4.1(2)

Respiratory sensitizer - subcategories

8.4.1(2) A substance classified in the category "Respiratory Sensitizer — Category 1" under subsection (1) is, if the applicable data are available, further classified in the subcategory "Respiratory Sensitizer — Category 1A" or in the subcategory "Respiratory Sensitizer — Category 1B" in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Subcategory	Criteria
1	Respiratory Sensitizer — Category 1	Respiratory Sensitizer — Category 1A	A substance (a) that, according to human data, leads to a high frequency of occurrence of respiratory sensitization; or (b) in respect of which animal data support the probability of a high respiratory sensitization rate in humans
2	Respiratory Sensitizer — Category 1	Respiratory Sensitizer — Category 1B	A substance (a) that, according to human data, leads to a low to moderate frequency of occurrence of respiratory sensitization; or (b) in respect of which animal data support the probability of a low to moderate respiratory sensitization rate in humans

If sufficient data are available, Category 1 respiratory sensitizers must be further divided into Respiratory Sensitizer - Category 1A or 1B. Category 1A substances demonstrate a high frequency of respiratory sensitization whereas Category 1B substances demonstrate a low to moderate frequency of respiratory sensitization. A substance must not be classified in Category 1B unless Category 1A can be excluded.

There is no quantification of "high" or "low to moderate" as these terms are used here. A scientifically defensible conclusion must be reached by conducting a thorough evaluation of all relevant data.

Discussion of the *Hazardous Products Regulations*
Subsection 8.4.1(3)

Skin sensitizer - category

8.4.1(3) A substance that is a skin sensitizer is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Skin Sensitizer — Category 1**	**A substance** **(a) that, according to human data, leads to skin sensitization; or** **(b) in respect of which animal data acquired from scientifically validated methods for the evaluation of skin sensitization demonstrate positive results**

Skin Sensitizer – Category 1 is based on human or test animal data. Human evidence can be based on positive data from:

- patch testing such as the Human Repeat Insult Patch Test (HRIPT) or Human Maximization Test (HMT),
- diagnostic patch testing from clinical data,
- epidemiological studies showing allergic contact dermatitis, and/or
- positive data from experimental studies in humans.

For Skin Sensitizer - Category 1 classification based on animal studies, examples of scientifically validated methods include:

- OECD TG 406 – This test guideline describes the Guinea Pig Maximization test and the Buehler guinea pig test.

  The Guinea Pig Maximization test (GPMT) uses an adjuvant to potentiate sensitization. Elicitation reactions are measured in previously sensitized animals. A minimum of 10 test animals and 5 control animals is needed. A response of at least 30% of the animals is considered positive.

  The Buehler guinea pig test does not use an adjuvant. Elicitation reactions are measured in previously sensitized animals. A minimum of 20 test animals and 10 control animals is needed. A response of at least 15% of the animals is considered positive.
- OECD TG 429 - Local Lymph Node Assay (LLNA): Conducted in the mouse, the LLNA measures lymphocyte proliferation in the lymph nodes draining the site of test substance application. This proliferation is proportional to the dose and to the potency of the applied allergen and provides a simple means of obtaining a quantitative measurement of sensitization. Responses provoked during the induction of sensitization are measured.

A stimulation index of three or more is considered a positive response in the LLNA. The LLNA has two additional variations:

- OECD TG 442A: LLNA: DA
- OECD TG 442B: LLNA: BrdU-ELISA

Other methods may be used provided that they are scientifically validated methods (GHS 5th revised edition, 2013, paragraph 3.4.2.2.3.1). The Mouse Ear Swelling Test (MEST) appears to be a reliable screening test to detect moderate to strong sensitizers, and can be used as a first stage in the assessment of skin sensitization potential.

Note: For both animal and human data, consideration should also be given to the impact of solvent(s). The solvent(s) should not interfere or bias the test results. OECD TG 406 and 429 provide guidance on the selection and suitability of solvent(s).

For classification of a substance in Skin Sensitizer – Category 1, based on human information, evidence could include any or all of the following:

(a) Positive data from patch testing, normally obtained from more than one dermatology clinic;

(b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) Positive data from appropriate animal studies;

(d) Positive data from experimental studies in humans;

(e) Well documented episodes of allergic contact dermatitis, normally obtained from more than one dermatology clinic; and

(f) Severity of reaction may also be considered.

Evidence from animal studies is usually much more reliable than evidence from human exposure (GHS 5th revised edition, 2013, paragraph 3.4.2.2.4.2). However, in cases where evidence is available from both animal and human sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers, but rather are usually derived from case-control or other less defined studies. Evaluation of human data must therefore be carried out with caution and consider factors such as the inherent properties of the substance, exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies.

If none of the above-mentioned conditions are met, the substance need not be classified as a skin sensitizer (GHS 5th revised edition, 2013, paragraph 3.4.2.2.4.3). However, before this decision is finalized, a combination of two or more indicators of skin sensitization as listed below must be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) Epidemiological studies of limited power, e.g., where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in paragraph 3.4.2.2.3 of the GHS , but which are sufficiently close to the limit to be considered significant;

(d) Positive data from non-standard methods;

(e) Positive results from close structural analogues.

Immunological contact urticaria

Substances which cause immunological contact urticaria with or without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers. There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, which will be similar to that for skin sensitization.

Discussion of the *Hazardous Products Regulations*
Subsection 8.4.1(4)

Skin sensitizer – subcategories

8.4.1(4) A substance classified in the category "Skin Sensitizer – Category 1" under subsection (3) is, if the applicable data are available, further classified in the subcategory "Skin Sensitizer — Category 1A" or in the subcategory "Skin Sensitizer — Category 1B" in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Subcategory	Criteria
1	Skin Sensitizer — Category 1	Skin Sensitizer — Category 1A	A substance (a) that, according to human data, leads to a high frequency of occurrence of skin sensitization; or (b) in respect of which animal data acquired from scientifically validated methods for the evaluation of skin sensitization support the probability of a high skin sensitization rate in humans
2	Skin Sensitizer — Category 1	Skin Sensitizer — Category 1B	A substance (a) that, according to human data, leads to a low to moderate frequency of occurrence of skin sensitization; or (b) in respect of which animal data acquired from scientifically validated methods for the evaluation of skin sensitization support the probability of a low to moderate skin sensitization rate in humans

If sufficient data are available, Category 1 skin sensitizers must be further classified into Skin Sensitizer - Category 1A or 1B. Category 1A substances demonstrate a high frequency of skin sensitization whereas Category 1B substances demonstrate a low to moderate frequency of skin sensitization. A substance must not be classified in Category 1B unless Category 1A can be excluded.

There is no quantification of "high" or "low to moderate" as these terms are used here. A scientifically defensible conclusion must be reached by conducting a thorough evaluation of all relevant data.

Tables 1 and 2 below can be used to differentiate between classification in Skin Sensitizer - Category 1A and 1B based on human and animal data.

Table 1. Human Evidence for Category 1A and 1B (GHS 5th revised edition, 2013, paragraph 3.4.2.2.2.1 and 3.4.2.2.2.2)

Human Data	Category 1A Criteria	Category 1B Criteria
Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT) - Induction threshold	positive responses at ≤ 500 μg/cm^2	positive responses at **>** 500 μg/cm^2
Diagnostic Patch Test Data	relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure	relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure
Other Epidemiological Evidence	relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.	relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure

Table 2. Animal Evidence for Category 1A and 1B (GHS 5th revised edition, 2013, tables 3.4.3 and 3.4.4)

Assay	Category 1A Criteria	Category 1B Criteria
Local Lymph Node Assay (LLNA)	EC3* value ≤ 2%	EC3* value **>** 2%
Guinea Pig Maximization Test (GPMT)	≥ 30% responding at ≤ 0.1% intradermal induction dose or ≥ 60% responding at > 0.1% to ≤ 1% intradermal induction dose	≥ 30% to < 60% responding at > 0.1% to ≤ 1% intradermal induction dose or ≥ 30% responding at > 1% intradermal induction dose
Buehler Assay	≥15% responding at ≤ 0.2% topical induction dose or ≥ 60% responding at > 0.2% to ≤ 20% topical induction dose	≥ 15% to < 60% responding at > 0.2% to ≤ 20% topical induction dose or ≥ 15% responding at > 20% topical induction dose

*EC3 is the estimated concentration needed to produce a stimulation index of 3

Classification in a Category or Subcategory of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.4.2

Order of provisions

8.4.2 The classification of a mixture as a respiratory sensitizer or a skin sensitizer, or both, in one or more categories of this hazard class must proceed in accordance with the order of sections 8.4.3 to 8.4.5.

There is a "tiered" approach for classifying mixtures for respiratory or skin sensitization, which means that the procedures described in sections 8.4.3 to 8.4.5 must be followed in the order in which these sections appear in the HPR.

As with a substance, the mixture may be classified as a respiratory or skin sensitizer, or both. Therefore progression through the order of provisions is required for each endpoint. For example, if, based on test data on the mixture as a whole, the supplier is able to classify the mixture for skin sensitization, there is no need to assess bridging principles or data for the ingredients for this endpoint. However, if data on the mixture as a whole is not available for respiratory sensitization, progression to bridging principles and then to ingredient data is required to classify the mixture with regard to respiratory sensitization, as applicable.

Discussion of the *Hazardous Products Regulations*
Section 8.4.3

Data available for mixture as a whole

8.4.3 If data of the types referred to in subparagraphs 2.1(a)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as a respiratory sensitizer or a skin sensitizer, or both, in accordance with section 8.4.1.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is exactly the same as for substances, and is carried out according to section 8.4.1. The discussion sections of this technical guidance corresponding to section 8.4.1, as well as the discussion section relating to the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. The data available on the mixture as a whole must be compared to the classification criteria within each category. If the data available meets the criteria in section 8.4.1, then the mixture must be classified in the category for which the criteria are met.

Care should be exercised in evaluating data on mixtures such that the dose used does not render the results inconclusive. In the case of skin sensitization, current test methods are based on application of a maximised dose, which can only be obtained using a substance by itself and not diluted in a mixture.

Discussion of the *Hazardous Products Regulations* Section 8.4.4

Data available for use of bridging principles

8.4.4 If data are available to enable the characterization of the mixture as a respiratory sensitizer or a skin sensitizer, or both, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in a category of this hazard class in accordance with those subsections.

Section 8.4.4 of the HPR describes the second step in the tiered approach for the classification of mixtures for respiratory or skin sensitization.

When there is no data or insufficient data on the mixture as a whole, bridging principles must be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

If, based on bridging principles, the mixture can be classified as a respiratory sensitizer and/or skin sensitizer, the mixture must be classified accordingly. If the mixture does not meet the criteria to be classified as a respiratory sensitizer or skin sensitizer based on bridging principles or there are insufficient data to apply bridging principles, then it is necessary to proceed to the next step in the classification process.

Discussion of the *Hazardous Products Regulations*
Section 8.4.5

Data available for ingredients

8.4.5 A mixture is classified as a respiratory sensitizer or as a skin sensitizer, or both, as the case may be, in accordance with the following:

(a) as a respiratory sensitizer,

(i) in the category "Respiratory Sensitizer — Category 1", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the category "Respiratory Sensitizer — Category 1",

(ii) in the subcategory "Respiratory Sensitizer — Category 1A", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the subcategory "Respiratory Sensitizer — Category 1A", or

(iii) in the subcategory "Respiratory Sensitizer — Category 1B", if it does not contain ingredients classified in the subcategory "Respiratory Sensitizer — Category 1A" at a concentration equal to or greater than the concentration limit of 0.1% and

(A) it contains at least one ingredient that is a solid or a liquid at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the subcategory "Respiratory Sensitizer — Category 1B", or

(B) it contains at least one ingredient that is a gas at a concentration equal to or greater than the concentration limit of 0.2% that is classified in the subcategory "Respiratory Sensitizer — Category 1B"; or

(b) as a skin sensitizer,

(i) in the category "Skin Sensitizer — Category 1", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the category "Skin Sensitizer — Category 1",

(ii) in the subcategory "Skin Sensitizer — Category 1A", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the subcategory "Skin Sensitizer — Category 1A", or

(iii) in the subcategory "Skin Sensitizer — Category 1B", if it does not contain ingredients classified in the subcategory "Skin Sensitizer — Category 1A" at a concentration equal to or greater than the concentration limit of 0.1% and it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the subcategory "Skin Sensitizer — Category 1B".

Following application of sections 8.4.3 and 8.4.4, if a classification for the mixture as a whole cannot be determined, data available for the ingredients of the mixture are considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

Respiratory and skin sensitization assessments are carried out independently since a mixture can be classified as either or both. The additivity approach is not applied to this hazard class. A single ingredient in the mixture meeting the established criteria supports classification of the mixture.

Respiratory Sensitization

For classification of mixtures using ingredient data for respiratory sensitization, a mixture is classified in Respiratory Sensitizer - Category 1 or 1A**,** if it contains at least one ingredient at ≥ 0.1% which is classified in Respiratory Sensitizer – Category 1 or 1A, respectively.

For respiratory sensitization classification based on Category 1B ingredients, the physical state and concentration of the ingredient needs to be considered, as follows:

- If the ingredient is a solid or liquid classified in Respiratory Sensitizer – Category 1B, and is present in the mixture at ≥ 1.0%, then the mixture is classified in Respiratory Sensitizer – Category 1B.
- If the ingredient is a gas classified in Respiratory Sensitizer – Category 1B, and is present in the mixture at ≥ 0.2%, then the mixture is classified in Respiratory Sensitizer – Category 1B.

Skin Sensitization

For classification of mixtures using ingredient data for skin sensitization, a mixture is classified in Skin Sensitizer - Category 1 or 1A, if it contains at least one ingredient at ≥ 0.1% which is classified in Skin Sensitizer – Category 1 or 1A, respectively.

For skin sensitization classification based on Category 1B ingredients, a mixture is classified in Skin Sensitizer - Category 1B, if it contains at least one ingredient at ≥ 1.0% which is classified in Skin Sensitizer – Category 1B.

There are exceptions to the concentration limits established in section 8.4.5 of the HPR for classifying mixtures. Although concentration limits have been established in 8.4.5, when an ingredient presents the hazard at a concentration which is below the concentration limit, and the mixture contains the ingredient at or above that concentration, the mixture must be classified in the category for which it meets the criteria. Refer to section 2.5 of the HPR and its discussion for details.

Hazard Communication

The symbols, signal words, hazard statements and precautionary statements for Respiratory or Skin Sensitization - Category 1 are specified in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013, pp. 353-354.

It should be noted that there is no differentiation in hazard communication between the two sub-categories of Category 1; Category 1A and 1B.

When a substance or mixture meets criteria as both a respiratory and a skin sensitizer, the hazard communication requirements for each class and category apply.

Classification of Respiratory or Skin Sensitization for Substances

Examples

Example 1: (ECHA Guidance, 2015, p. 355)

Available data

In a cohort of 51 workers exposed to substance X, 26 (51%) were diagnosed with occupational asthma and 12 of the 26 also experienced occupational rhinitis. The diagnosis was based on specific bronchial challenge tests with substance X.

Classification

Respiratory Sensitizer - Category 1

Rationale

There is sufficient human evidence to conclude that substance X caused the respiratory hypersensitivity, i.e., asthma and rhinitis. Sub-categorization was not considered as there is currently no clear way to establish subcategories.

Example 2: (ECHA Guidance, 2015, p. 353)

Available data

Substance Y gave a positive result in the Local Lymph Node Assay with an EC3 value of 10.4%.

Classification

Skin Sensitizer - Category 1B

Rationale

The EC3 value is above the 2% cut-off for a classification in Category 1A. Therefore, Category 1A is ruled out. An EC3 > 2% does, however, fall within the criteria for Category 1B.

Classification of Respiratory or Skin Sensitization for Mixtures

Examples

Example 1:

Available data

Data for the mixture as a whole is not available and bridging principles cannot be applied, thus classification is based on the classified ingredients.

A mixture contains substance T at 0.01%. Substance T is a very strong respiratory sensitizer as there is data available demonstrating that it causes respiratory hypersensitivity at concentrations as low as 0.001%. Substance T is a Respiratory Sensitizer – Category 1A.

There are no other ingredients in the mixture that meet the criteria for a respiratory sensitization classification.

Classification

Respiratory Sensitizer - Category 1

Rationale

As per subsection 2.5(1) of the HPR, if an ingredient is present in a mixture at a lower concentration than the concentration limit for a particular category, but still presents the hazard identified by the category, the mixture must be classified in that category or subcategory. Therefore, even though substance T is in the product below 0.1%, since there is evidence that substance T causes respiratory sensitization at concentrations which are equal to or less than the concentration of the ingredient in the mixture, the mixture must also be classified in Respiratory Sensitizer – Category 1.

Example 2:

Available data

Data for the mixture as a whole is not available and bridging principles cannot be applied, thus classification is based on the classified ingredients.

Ingredient X is in the product at 0.8% and meets the criteria to be classified in Skin Sensitizer - Category 1B. There is no data indicating that it causes sensitization at this, or lower concentrations. The other ingredients in the mixture do not meet the criteria to be classified in Skin Sensitizers.

Classification

No Classification

Rationale

The cut-off value for Category 1B in a mixture for skin sensitization is 1.0%. Since the concentration of ingredient X falls below this cut-off, the mixture is not classified.

Subpart 5
Germ Cell Mutagenicity

Definitions

8.5 The following definitions apply in this Subpart.

"genotoxicity" means the alteration of the structure, information content or segregation of DNA by an agent or process, including those agents or processes that cause DNA damage by interfering with normal replication processes or that in a non-physiological manner temporarily alter its replication.

"germ cell mutagen" means a mixture or substance that is liable to lead to an increased occurrence of mutations in the germ cells of a population.

"mutagenic" means, in relation to a mixture or substance, liable to lead to an increased occurrence of mutations in populations of cells or organisms.

"mutagenicity" means an increased occurrence of mutations in populations of cells or organisms.

"mutation" means a permanent change in the amount or structure of the genetic material in a cell and includes

(a) the heritable genetic changes that may be manifested at the phenotypic level; and

(b) the underlying DNA modifications when known, including specific base pair changes and chromosomal translocations.

Discussion – Mutagenicity and Mutation

Mutagenicity is the ability of some substances and mixtures to modify the genetic material of cells or organisms in ways that allow the changes to be transmitted during cell division. These changes are permanent and are referred to as mutations. The substance or mixture causing the change is referred to as a mutagen. Mutations can occur in the germ cells (sperm or ova) or in somatic cells (cells other than the germ cells). Germ cell mutations can be passed on to the organism's offspring. For this endpoint, there is no effect (other than the mutation) on the exposed organism; rather, the effect is passed on to future generations. Somatic cell mutations are not transmitted to the next generation. They can cause altered cell growth or cell death in the exposed organism.

There are several types of mutations:

- Gene mutation – a change in DNA sequence within a gene
- Chromosome aberration – a change in the chromosome structure
- Aneuploidy / polyploidy – an increase or decrease, respectively, in the number of chromosomes.

(OSHA Hazard Classification Guidance 2016, p. 135) (ECHA Guidance, 2015, pp. 358, 362)

Discussion – Genotoxicity

Genotoxicity is a more general term applied to substances, mixtures or processes which alter the structure, information content, or segregation of DNA. Genotoxicity test results are usually taken as indicators for mutagenic effects (GHS, 5th revised edition, 2013, paragraph 3.5.1.4).

Classification in a Category or Subcategory of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Section 8.5.1

Categories

8.5.1 A substance that is a germ cell mutagen is classified in a category or subcategory of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	**Category**	**Subcategory**	**Criteria**
1	**Germ Cell Mutagenicity — Category 1**	**Germ Cell Mutagenicity – Category 1A**	**A substance that, according to data from human epidemiological studies, induces heritable mutations in germ cells**
2	**Germ Cell Mutagenicity — Category 1**	**Germ Cell Mutagenicity – Category 1B**	**A substance in respect of which** **(a) data acquired from *in vivo* heritable germ cell mutagenicity tests in mammals demonstrate positive results;** **(b) data acquired from *in vivo* somatic cell mutagenicity tests in mammals demonstrate positive results and there is evidence that the substance has the potential to cause mutations to germ cells, such as** **(i) in germ cells, positive *in vivo* mutagenicity test results or positive *in vivo* genotoxicity test results, or** **(ii) evidence that the substance or any of its metabolites is able to interact with the genetic material of germ cells; or** **(c) data on human germ cells demonstrate mutagenic effects, with or without demonstrating transmission to offspring, including an increase in the frequency of aneuploidy in sperm of men exposed to the substance**

3	**Germ Cell Mutagenicity — Category 2**		**A substance in respect of which** **(a) data acquired from *in vivo* somatic cell mutagenicity tests in mammals demonstrate positive results;** **(b) data acquired from *in vivo* somatic cell genotoxicity tests demonstrate positive results and data acquired from *in vitro* mutagenicity tests demonstrate positive results; or** **(c) data acquired from *in vitro* mutagenicity tests in mammalian cells demonstrate positive results and the substance has a structure-activity relationship with germ cell mutagens classified in the sub category "Germ Cell Mutagenicity — Category 1A"**

This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to progeny (offspring). To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in *in vitro* tests may also be considered. (GHS, 5th revised edition, 2013, paragraph 3.5.2.2).

Classification is hazard-based, meaning that substances are classified on the basis of their intrinsic ability to induce mutations in germ cells (GHS, 5th revised edition, 2013, paragraph 3.5.2.3). Care should be taken when applying the classification criteria specified in HPR 8.5.1 with respect to the use of **mutagenicity** test results versus **genotoxicity** test results. In general, results from mutagenicity tests are more conclusive and representative for Germ Cell Mutagenicity than results from a genotoxicity test. Examples of the different types of tests are given in the discussion below (GHS, 5th revised edition, 2013, paragraph 3.5.1.4).

Classification of a substance or mixture in this hazard class offers supporting information with respect to the classification of substances and mixtures for carcinogenicity (see Subpart 6 of Part 8 - Carcinogenicity). It is increasingly accepted that the process of chemical-induced tumorigenesis in humans and animals involves genetic changes in proto-oncogenes and/or tumour suppresser genes of somatic cells. Therefore, the demonstration of mutagenic properties in somatic and/or germ cells of mammals *in vivo* may have implications for the potential classification of substances and mixtures for carcinogenicity (GHS, 5th revised edition, 2013, paragraph 3.5.5.2).

There are two categories for Germ Cell Mutagenicity classification, Category 1 and Category 2. Category 1 may be further subdivided into Category 1A and 1B. Category 1 germ cell mutagens are substances **known** to induce heritable mutations in the germ cells of humans (Category 1A) or that **should be regarded as if they induce** heritable mutations in the germ cells of humans (Category 1B). Category 2 germ cell mutagens are substances of concern due to the **possibility** that they **may** induce heritable mutations in the germ cells of humans. (GHS, 5th revised edition, 2013, Fig 3.5.1)

Category 1

Category 1 germ cell mutagens are subdivided into Category 1A, if the basis for classification is human epidemiological data, and Category 1B, if the basis for classification is other mammalian data as outlined in item 2 of section 8.5.1 of the HPR. Note that, unlike other hazard classes, substances classified for Germ Cell Mutagenicity must be classified in either Category 1A or Category 1B specifically, rather than the more generic Category 1 classification. Since the available data is either of one type (human epidemiological data) or the other (other mammalian data), the subdivision is always possible.

Health Canada is not aware, at the time of writing, of any examples of substances that are Category 1A mutagens, as epidemiological studies have yet to provide sufficient evidence. Hereditary diseases in humans typically have an unknown origin and show varying distributions in different populations. Due to the random distribution of mutations in the genome it is not expected that one particular substance would necessarily induce one particular genetic disorder (ECHA Guidance, 2015, p. 361).

Therefore, at present, substances that are Category 1 germ cell mutagens would fall into subcategory 1B. There are three possible criteria that fulfill a Category 1B classification:

a) Positive results from *in vivo* germ cell mutagenicity tests in mammals. Examples of *in vivo* heritable germ cell mutagenicity tests include:
   - OECD TG 478 – Rodent dominant lethal mutation test: Dominant lethal effects cause embryonic or fetal death indicating the substance has affected the germinal tissue. Dominant lethal effects are generally accepted to be the result of chromosomal aberrations. A positive result is indicated by a statistically significant, dose-related increase in the number of dominant lethals.
   - OECD TG 485 – Mouse heritable translocation assay: This test detects structural and numerical chromosome changes in mammalian germ cells recovered in first generation progeny. A positive result is indicated by a statistically significant increase in the number of translocations observed for at least one test point. A positive result may also be based on the detection of a statistically significant, dose-related increase in the number of translocations observed.

     (GHS, 5th revised edition, 2013, paragraph 3.5.2.5)

     (Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects)

b) Positive results from *in vivo* somatic cell mutagenicity tests and evidence for the potential to cause germ cell mutations. Examples of *in vivo* somatic cell mutagenicity tests include:
   - OECD TG 475 – Mammalian bone marrow chromosome aberration test: This test detects structural chromosome aberrations induced by test substances in bone marrow cells of animals, typically rodents. A positive result can be indicated by a dose-related increase in the relative number of cells with chromosome aberrations, or a

clear increase in the number of cells with aberrations in a single dose group at a single sampling time.

- OECD TG 484 – Mouse spot test: This test detects a mutation in, or a loss of, the dominant allele of a target gene which controls the pigmentation of the coat hairs in a melanoblast. The mutation results in the expression of the recessive phenotype in its descendant cells, and the observation of a spot of changed colour in the coat of the resulting mouse. A positive result can be indicated by a statistically significant, dose-related increase in the frequency of genetically relevant spots.
- OECD TG 474 – Mammalian erythrocyte micronucleus test: This test detects damage induced by the test substance to the chromosomes or the mitotic apparatus of erythroblasts. Damage is detected by analysis of erythrocytes as sampled in bone marrow and/or peripheral blood cells of animals, typically rodents. A positive result can be indicated by a dose-related increase in the number of micronucleated cells, or a clear increase in the number of micronucleated cells in a single dose group at a single sampling time.

  (GHS, 5th revised edition, 2013, paragraph 3.5.2.6)

  (Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects)

Evidence of the potential to cause germ cell mutations can come from test results such as:

(i) positive *in vivo* mutagenicity or positive *in vivo* genotoxicity test results in germ cells; or

(ii) evidence of interaction with the genetic material of germ cells.

Examples of *in vivo* mutagenicity tests in germ cells are:

- OECD TG 483 – Mammalian spermatogonial chromosome aberration test: This test measures chromosome events in mammalian spermatogonial germ cells and therefore is expected to be predictive of induction of inheritable mutations in germ cells. A positive result can be indicated by a dose-related increase in the relative number of cells with chromosome aberrations, or a clear increase in the number of cells with aberrations in a single dose group at a single sampling time.
- Spermatid micronucleus assay

Examples of *in vivo* genotoxicity tests in germ cells are:

- Sister chromatid exchange (SCE) analysis in spermatogonia
- Unscheduled DNA synthesis test (UDS) in testicular cells

  (GHS, 5th revised edition, 2013, paragraph 3.5.2.7)

  (Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects)

c) Data on human germ cells demonstrating mutagenic effects. The mutagenic effects are applicable with or without evidence of transmission to offspring, and may include increased frequency of aneuploidy in sperm of exposed men.

VARIANCE with HCS 2012: With or without demonstration of transmission to offspring

HPR

Note that the condition of "with or without demonstration of transmission to offspring" is specific to the HPR.

HCS 2012

Both the GHS and HCS 2012 limit the condition to "without demonstration of transmission to offspring".

It was deemed necessary to add the concept of "with" to the HPR requirements to include the requirement to classify substances when transmission of mutagenic effects to the offspring is demonstrated. For example, if there are data showing positive results of mutagenic effects in germ cells of humans (e.g., cells from umbilical cord) with transmission to offspring, then the substance must be classified in Category 1B. In the context of human data, note that classification in Category 1A requires positive mutagenic effects from human epidemiological studies (for which Health Canada is not aware of any example at the time of this writing) and classification in Category 1B require data from human germ cells.

Category 2

Category 2 germ cell mutagens do not fall into further subcategorization. There are three possible criteria that fulfill a Category 2 classification:

a) Positive results from *in vivo* somatic cell mutagenicity tests in mammals.

Examples of *in vivo* somatic cell mutagenicity tests are given above in criteria (b) for Category 1B classification. If the additional evidence for the potential to cause mutations in germ cells is not available or not sufficient to meet Category 1B classification, the substance falls into Category 2; that is, the positive *in vivo* somatic cell results on their own are sufficient for classification in Category 2.

b) Positive results from *in vivo* somatic cell genotoxicity tests and positive results from *in vitro* mutagenicity tests. Examples of *in vivo* somatic cell genotoxicity tests include:

- OECD TG 486 – Liver unscheduled DNA synthesis (UDS) *in vivo*: A test to identify substances that induce DNA repair in liver cells of treated animals. Criteria for positive responses include net nuclear grain (NNG) value(s) above a pre-set threshold, which is justified on the basis of laboratory historical data, and NNG value(s) significantly greater than the concurrent control.
- Mammalian bone marrow Sister Chromatid Exchanges (SCE)

  (GHS, 5th revised edition, 2013, paragraph 3.5.2.8)

  (Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects)

Examples of *in vitro* mutagenicity tests include:

- OECD TG 473 – *In vitro* mammalian chromosome aberration test: This test is used to identify agents that cause structural chromosome aberrations in cultured mammalian cells (e.g., Chinese hamster fibroblasts, human or other mammalian peripheral blood lymphocytes). A positive result is indicated by a concentration-related increase or a reproducible increase in the number of cells with chromosome aberrations.
- OECD TG 476 – *In vitro* mammalian cell gene mutation test: This test detects gene mutations. Suitable cell lines include L5178Y mouse lymphoma cells, the CHO, AS52 and V79 lines of Chinese hamster cells, and TK6 human lymphoblastoid cells. In these cell lines, the most commonly-used genetic endpoints measure mutation at thymidine kinase (TK) and hypoxanthine-guanine phosphoribosyl transferase (HPRT), and a transgene of xanthine-guanine phosphoribosyl transferase (XPRT). A positive result is indicated by a concentration-related or a reproducible increase in mutant frequency.
- OECD TG 471 – Bacterial reverse mutation tests: This test uses amino-acid requiring strains of *Salmonella typhimurium* and *Escherichia coli* to detect point mutations, which involve substitution, addition, or deletion of one or a few DNA base pairs. The test detects mutations which revert mutations present in the test strains, and restore the functional capability of the bacteria to synthesize an essential amino acid. The revertant bacteria are detected by their ability to grow in the absence of the amino acid required by the parent test strain. A positive result is indicated by a concentration-related increase over the range tested and/or a reproducible increase at one or more concentrations in the number of revertant colonies per plate in at least one strain with or without metabolic activation system.

  (GHS, 5th revised edition, 2013, paragraph 3.5.2.9)

  (Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects)

c) Positive results from *in vitro* mutagenicity tests in mammalian cells and a structure-activity relationship with a Category 1A germ cell mutagen. Note that only *in vitro* mutagenicity tests in mammalian cells are acceptable when applying this criteria. Therefore, OECD TG 471, which tests bacteria, is not applicable. The other *in vitro* test examples given above are applicable.

Since there are, to the best of Health Canada's knowledge at present, no defined Category 1A germ cell mutagens, this criteria cannot, at this time, be applied.

Note: As new, scientifically valid tests are developed, they may also be considered for the classification of substances and mixtures in this hazard class.

Evaluating Mutagenicity/Genotoxicity Test Results

When evaluating results from mutagenicity and/or genotoxicity tests, there are many factors to take into consideration, depending on whether the results are positive, negative or contradictory. Some considerations are outlined below:

Considerations when evaluating positive test results

- In those instances where a single well-conducted test using a scientifically valid test method is used for classification, it must provide clear and unambiguously positive results (GHS, 5th revised edition, 2013, paragraph 3.5.2.10).
- Positive results in the *in vitro* Sister Chromatid Exchange (SCE) assay should be viewed with caution, as this assay is associated with a relatively high incidence of false positive results. For example, a positive result in this assay would not be considered to be evidence of a significant clastogenic potential if negative results were available in an *in vitro* chromosome aberration assay (OSHA Hazard Classification Guidance 2016, p. 142).
- Interpretation of positive results from DNA binding assays should be viewed with caution as these assays are only considered to be indicators of DNA damage. Consequently, the observance of *in vivo* DNA adducts alone in the absence of positive findings from *in vitro* assays is generally not considered sufficient evidence of a significant genotoxic potential *in vivo* (OSHA Hazard Classification Guidance 2016, p. 142).
- The consequences of "positive" findings only at highly toxic/cytotoxic concentrations, and the presence or absence of a dose-response relationship, should be considered. The default assumption for genotoxic chemicals, in the absence of mechanistic evidence to the contrary, is that they have a linear dose response relationship. However, both direct and indirect mechanisms of genotoxicity can be non-linear or threshold, and sometimes this default assumption may be inappropriate. When interpreting positive results, considerations of the dose-response relationship and of possible mechanisms of action are important components of a hazard assessment (OSHA Hazard Classification Guidance 2016, p. 142).

Considerations when evaluating contradictory test results

- Conflicting results obtained between non-mammalian systems and mammalian cell tests may be addressed by considering possible differences in substance uptake, metabolism or in the organization of genetic material. The results of mammalian tests may be considered of higher significance (OSHA Hazard Classification Guidance 2016, p. 142).
- If contradictory findings are obtained *in vitro* and *in vivo*, in general, the results of *in vivo* tests have a higher degree of reliability. However, for evaluation of negative results *in vivo*, it should be considered whether there is adequate evidence of target tissue exposure (OSHA Hazard Classification Guidance 2016, p. 142).
- The sensitivity and specificity of different test systems varies for different classes of substances. If available test data for other related substances permits assessment of the relative performance of different assays, as applied to the substance under evaluation, the result from the test system known to produce more accurate responses should be given greater weight (OSHA Hazard Classification Guidance 2016, p. 142).

- Conflicting results may also be available from the same test, performed by different laboratories or on different occasions. In this case, an overall evaluation of the data will be required. In particular, the quality of each of the studies and of the data provided should be evaluated, with special consideration given to the study design, reproducibility of data, dose-effect relationships, and biological relevance of the findings. The purity of the test substance may also be a factor to take into account. In the case where an OECD guideline is available for a test method, a study that adheres to the requirements stated in the guideline is regarded as being of higher quality. Furthermore, studies compliant with Good Laboratory Practices may be regarded as being of a higher quality (OSHA Hazard Classification Guidance 2016, p. 143).

Considerations when evaluating negative test results

- Were the doses or concentrations of test substance used high enough?
- Was the test system used sensitive to the nature of the genotoxic changes that might have been expected?
- Were appropriate concentrations maintained in tests conducted *in vitro*? For example, was the volatility of the test substance taken into consideration?
- For *in vitro* test systems, was the metabolic activation suitable?
- For *in vivo* studies, was the test substance reaching the target organ? For example, was toxicokinetic data taken into consideration?
- Was the test substance reactive? For example, were the rate of hydrolysis, electrophilicity, presence or absence of structural alerts and other available indications taken into consideration?
- What was the response of the positive and negative controls?

(OSHA Hazard Classification Guidance 2016, p. 141)

Classification in a Category or Subcategory of the Class

Classification of mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.5.2

Order of provisions

8.5.2 The classification of a mixture as a germ cell mutagen in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.5.3 to 8.5.5.

There is a “tiered” approach for classifying mixtures for germ cell mutagenicity, meaning that the procedures described in sections 8.5.3 to 8.5.5 must be followed in the order in which these sections appear in the HPR.

As specified in sections 8.5.3 and 8.5.4, the classification of mixtures is based on evaluation of the available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified as germ cell mutagens. However, if there are test data for the mixture as a whole, these data may be used to classify the mixture, instead of data on the individual ingredients. Finally, section 8.5.5 specifies which bridging principles may be applied to the Germ Cell Mutagenicity hazard class.

Discussion of the *Hazardous Products Regulations*
Section 8.5.3

Ingredient classified in Category 1A or 1B

8.5.3 A mixture is classified in the category "Germ Cell Mutagenicity — Category 1" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the subcategory "Germ Cell Mutagenicity — Category 1A" or in the subcategory "Germ Cell Mutagenicity — Category 1B", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture is a germ cell mutagen, in which case the mixture is classified as a germ cell mutagen in accordance with section 8.5.1; or

(b) the mixture as a whole has been subjected to an *in vivo* heritable germ cell mutagenicity test that determines that the mixture is not a germ cell mutagen, and a scientifically validated method was used and the test was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

Subject to paragraphs 8.5.3(a) and (b), section 8.5.3 of the HPR specifies that, if a mixture contains at least one ingredient that is classified in Germ Cell Mutagenicity – Category 1, Category 1A or Category 1B and the ingredient is present at a concentration of ≥ 0.1%, then the mixture must be classified accordingly. Although section 8.5.3 specifies that such a mixture is classified in Germ Cell Mutagenicity – Category 1 (without sub-categorization), where there are sufficient data available to allow determination of the appropriate subcategory (1A or 1B), classification in 1A or 1B instead of in the less specific Category 1 is allowed. For example, if a mixture contains an ingredient that is classified in Germ Cell Mutagenicity – Category 1A and the ingredient is present at a concentration of 0.5%, then the mixture must be classified either in Germ Cell Mutagenicity - Category 1 or Germ Cell Mutagenicity – Category 1A. Note that, as specified in subparagraph 3(5)(m) of the HPR, the symbol, signal word, hazard statement and precautionary statements are the same for Germ Cell Mutagenicity – Category 1, 1A and 1B.

The additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Germ Cell Mutagenicity – Category 1A or 1B are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 0.1% concentration cut-off.

If there are test data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that, as the concentration of a germ cell mutagen is reduced in a mixture, the dilution effect may result in a misleading test result (i.e., a false negative) if the study was not appropriately designed to factor in the concentration of the germ cell mutagen in the mixture (OSHA Hazard Classification Guidance 2016, p. 138).

Therefore, the test results for the mixture as a whole must be shown to be conclusive, taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation and analysis of germ cell mutagenicity test systems (GHS, 5th revised edition, 2013, paragraph 3.5.3.1). If the results for the mixture as a whole are relevant and conclusive and meet the criteria for Germ Cell Mutagenicity in accordance with section 8.5.1 of the HPR, the results must be applied to classify the mixture as a germ cell mutagen.

If the results for the mixture as a whole demonstrate that the mixture is not a germ cell mutagen, based on an *in vivo* heritable germ cell mutagenicity test that was performed according to generally accepted standards of good scientific practice, and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified as a germ cell mutagen, even when Category 1A or 1B germ cell mutagen ingredients are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations*
Section 8.5.4

Ingredient classified in Category 2

8.5.4 A mixture is classified in the category "Germ Cell Mutagenicity — Category 2" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the category "Germ Cell Mutagenicity — Category 2", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture is a germ cell mutagen, in which case the mixture is classified as a germ cell mutagen in accordance with section 8.5.1; or

(b) the mixture as a whole has been subjected to an *in vivo* heritable germ cell mutagenicity test that determines that the mixture is not a germ cell mutagen, and a scientifically validated method was used and the test was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

If at least one ingredient present in the mixture at a concentration of ≥ 1.0% is classified as Germ Cell Mutagenicity - Category 2, then the mixture is classified as Germ Cell Mutagenicity – Category 2. Note that the additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Germ Cell Mutagenicity – Category 2 are

not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 1.0% concentration cut-off.

If there are test data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that, as the concentration of a germ cell mutagen is reduced in a mixture, the dilution effect may result in a misleading test result (i.e., a false negative) if the study was not appropriately designed to factor in the concentration of the germ cell mutagen in the mixture (OSHA Hazard Classification Guidance 2016, p. 138).

Therefore, the test results for the mixture as a whole must be shown to be conclusive, taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation and analysis of germ cell mutagenicity test systems (GHS, 5th revised edition, 2013, paragraph 3.5.3.1). If the results for the mixture as a whole are relevant and conclusive, and meet the criteria for Germ Cell Mutagenicity in accordance with section 8.5.1 of the HPR, the results must be applied to classify the mixture as a germ cell mutagen.

If the results for the mixture as a whole demonstrate that the mixture is not a germ cell mutagen, based on an *in vivo* heritable germ cell mutagenicity test that was performed according to generally accepted standards of good scientific practice, and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified as a germ cell mutagen, even when Category 2 germ cell mutagen ingredients are present at or above the established cut-off concentration of 1.0%.

Discussion of the *Hazardous Products Regulations*
Section 8.5.5

Data available for use of bridging principles

8.5.5 If data are available to enable the characterization of the mixture as a germ cell mutagen, in accordance with the bridging principles referred to in subsections 2.3(3), (4) and (7), the mixture must be classified in accordance with those subsections.

For this hazard class, the use of bridging principles is the final step in the tiered approach for the classification of mixtures. When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there is sufficient data available on similar tested mixtures and on the individual hazardous ingredients within the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

Note that not all of the bridging principles apply to this hazard class. Only dilution, production batches, and substantially similar mixtures are applicable. Increase in concentration of hazardous ingredient, interpolation and aerosols are not used for this hazard class.

If data on another mixture are used in the application of the bridging principles, the data on that mixture must be conclusive as discussed above under sections 8.5.3 and 8.5.4 for the mixture as a whole (OSHA Hazard Classification Guidance 2016, p. 138).

Hazard Communication

The symbol, signal words, hazard statements, and precautionary statements for Germ Cell Mutagenicity Category 1 and Category 2 are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, p. 355. Paragraph 3(5)(m) of the HPR specifies that if a hazardous product is classified in the subcategory Germ Cell Mutagenicity – Category 1A or in the subcategory Germ Cell Mutagenicity – Category 1B, the information elements specified for the category Germ Cell Mutagenicity – Category 1 apply.

Note that the symbol and precautionary statements are the same for Category 1 and Category 2; the signal word and hazard statement are different between the two categories.

As part of the hazard statement, the route of exposure must be specified if it has been conclusively proven that no other routes of exposure cause the effect. In order to be able to specify the route of exposure, test data need to be available for all three relevant routes (oral, dermal and inhalation), and the data must clearly indicate that only one route leads to positive results. It is estimated that such circumstances rarely, if ever, exist (ECHA Guidance, 2015, p. 368).

Classification of Germ Cell Mutagenicity for Substances

Examples

Example 1:

Available data

Substance X has shown positive results in the Rodent Dominant Lethal Mutation test (OECD TG 478).

Classification

Germ Cell Mutagenicity - Category 1B

Rationale

The test result fulfills Item 2 (a) of section 8.5.1 of the HPR – a positive result from an *in vivo* heritable germ cell mutagenicity test in mammals.

Example 2:

Available data

Substance Y has shown positive results in the Mammalian Bone Marrow Chromosome Aberration test (OECD TG 475).

Classification

Germ Cell Mutagenicity - Category 2

Rationale

The test result fulfills Item 3 (a) of section 8.5.1 of the HPR – a positive result from an *in vivo* somatic cell mutagenicity test in mammals.

(OSHA Hazard Classification Guidance 2016, p. 146)

Classification of Germ Cell Mutagenicity for Mixtures

Example

(OSHA Hazard Classification Guidance 2016, p. 147)

Available data

Data for the components of a mixture:

Component	Concentration (w/w)%	Classification
A	0.09	Germ Cell Mutagenicity - Category 1B
B	94.91	Not classified
C	3	Germ Cell Mutagenicity - Category 2
D	2	Germ Cell Mutagenicity - Category 1B

Data for the mixture as a whole is not available.

Classification

Germ Cell Mutagenicity - Category 1

Rationale

Component B is not classified as a germ cell mutagen; therefore, it is not considered when classifying the mixture.

Component A falls below the 0.1% cut-off value for Category 1 and has not been shown to cause mutagenic effects below this concentration. Therefore, it is not considered when classifying.

Component C is present at a concentration that is greater than 1.0%. Therefore, the mixture meets the criteria to be classified in Category 2.

Component D is present at a concentration that is greater than 0.1%. Therefore, the mixture meets the criteria to be classified Category 1.

As specified in subsection 2(2) of the HPR, where a product, mixture, material or substance meets the criteria to be classified in a category or subcategory of a hazard class that represents a more severe hazard in a classification table, it is not necessary to evaluate the product, mixture, material or substance with regard to a category or subcategory in the same classification table that represents a less severe hazard. The most severe category is used to classify the mixture.

Subpart 6
Carcinogenicity

Definitions

8.6 In this Subpart, "carcinogenic" means, in relation to a mixture or substance, liable to lead to cancer or increase the incidence of cancer.

Discussion

Other applicable definitions

In their background guidance to the Carcinogenicity hazard class, the GHS refers to the terms "sufficient evidence of carcinogenicity" and "limited evidence of carcinogenicity" as defined by the International Agency for Research on Cancer (IARC) in the context of carcinogenicity in humans and in experimental animals. Knowledge of these terms may assist suppliers in interpreting the criteria set out in the Table to section 8.6.1 of the HPR.

Carcinogenicity in humans according to IARC

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

(a) **Sufficient evidence of carcinogenicity**: a causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence;

(b) **Limited evidence of carcinogenicity**: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

Carcinogenicity in experimental animals according to IARC

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

(a) **Sufficient evidence of carcinogenicity**: a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (i) two or more species of animals or (ii) in two or more independent studies in one species carried out at different times or in different laboratories or under different protocols;

Exceptionally, a single study in one species might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset;

(b) **Limited evidence of carcinogenicity**: the data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (i) the evidence of carcinogenicity is restricted to a single experiment; or (ii) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the study; or (iii) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential, or of certain neoplasms which may occur spontaneously in high incidences in certain strains.

(IARC Preamble http://monographs.iarc.fr/)

Classification in a Category or Subcategory of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Section 8.6.1

Categories

8.6.1 A carcinogenic substance is classified in a category or subcategory of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Subcategory	Criteria
1	Carcinogenicity — Category 1	Carcinogenicity – Category 1A	A substance in respect of which human data establish a causal relationship between exposure to the substance and the development of cancer
2	Carcinogenicity — Category 1	Carcinogenicity – Category 1B	A substance in respect of which (a) human data establish a causal relationship between exposure to the substance and the development of cancer, but there are additional data that do not support, based on established scientific principles, the conclusion that the substance is the causative agent; (b) animal data establish a causal relationship between exposure to the substance and an increased incidence of malignant neoplasms or a combination of benign and malignant neoplasms in (i) two or more species of animals, as demonstrated by one or more studies, (ii) one species of animal, as demonstrated by two or more independent studies carried out at different times, in different laboratories or under different protocols, or (iii) one species of animal, as demonstrated by a single study, if the neoplasms observed in the study are, based on established scientific principles, atypical in relation to the incidence, site, type or age at onset for the species of animal under study; or (c) human data support a positive association between exposure to the substance and the development of cancer, and animal data support a positive association between exposure to the substance and an increased incidence of malignant or benign neoplasms, but the data supporting either positive association do not support a conclusion of a causal relationship, based on established scientific principles

3	**Carcinogenicity — Category 2**		**A substance in respect of which** **(a) human data support a positive association between exposure to the substance and the development of cancer, but do not support a conclusion of a causal relationship, based on established scientific principles; or** **(b) animal data support a positive association between exposure to the substance and an increased incidence of malignant or benign neoplasms, but do not support a conclusion of a causal relationship, based on established scientific principles.**

Substances and mixtures are deemed carcinogenic according to their potential to cause cancer in humans. However in most cases, epidemiological studies in humans are not available or sufficient and classification is based primarily on animal studies. Substances and mixtures which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans (GHS, 5th revised edition, 2013, paragraph 3.6.1).

There are two categories for Carcinogenicity classification according to section 8.6.1 of the HPR - Category 1 and Category 2. Category 1 may be further subdivided into Category 1A and 1B; however, sub-categorization may not always be possible. If sub-categorization is not possible, a less specific Category 1 classification is applied. Category 1A carcinogens are substances and mixtures that are **known** to be carcinogens for humans (based on human data). Category 1B carcinogens are substances and mixtures that are **presumed** to be carcinogens for humans (largely based on animal data). Category 2 carcinogens are substances and mixtures that are **suspected** to be carcinogens for humans (GHS, 5th revised edition, 2013, Figure 3.6.1).

Conclusions drawn from human and animal studies differ in the following way:

- human data demonstrate a causal relationship or a positive association between human exposure and the development of cancer, whereas
- animal data demonstrate a causal relationship or a positive association between exposure to the substance or mixture and an increased incidence of tumours.

Classification of a substance or mixture for carcinogenicity involves the enumeration of tumours in human and animal studies and determination of their level of statistical significance (GHS, 5th revised edition, 2013, paragraph 3.6.2.4), along with consideration of all other relevant information as appropriate. A number of other factors need to be considered which influence the overall likelihood that a substance or mixture poses a carcinogenic hazard in humans. Relevant information helps increase or decrease the level of concern for human carcinogenicity. The emphasis on each piece of information depends on the amount and strength of evidence it provides. In general, there is a requirement for more complete information to decrease than to increase the level of concern (GHS, 5th revised edition, 2013, paragraph 3.6.2.5.1). Information

that may be considered when assessing the overall level of concern, based on animal test results, includes:

(a) Tumour type and background incidence: By default, carcinogenic effects in experimental animals are considered relevant to humans and are considered for classification. Only when there is data showing that a certain type of tumour is not relevant to humans should this tumour type be excluded for classification. There are several reasons why a tumour observed in animals could be considered not relevant for humans or could be considered of less concern for humans:

- In most of these cases, the tumour occurs via a mode of action which does not occur in humans.
- In some cases, the tumour could occur in a tissue known to be overly susceptible to development of certain tumours in the species tested. Consequently, this observation could be considered to be less relevant for humans.
- A tumour could occur in a tissue with no equivalent in humans.
- A carcinogen that increases the incidence of a neoplastic disease that is rare in the test species or strain is of greater concern than a carcinogen that increases the incidence of a neoplasm having a high spontaneous incidence.

(b) Multisite responses: Substances and mixtures which cause tumours at multiple sites tend to be more potent carcinogens than those causing tumours at only one site in one species. This tendency is often true for substances and mixtures which are mutagenic. Thus, if a substance or mixture causes tumours at multiple sites, then it is considered to be carcinogenic. The tumour profile should be taken into account when considering the most appropriate classification.

(c) Whether responses are in a single species or several species: Positive responses in several species indicate that the substance or mixture is a carcinogen. Taking into account all of the factors, substances and mixtures with positive outcomes in two or more species should be considered to be classified in Category 1B until the human relevance of animal results are assessed in their entirety. The majority of proven human carcinogens have caused cancer in more than one species.

Positive results for one species in at least two independent studies, or a single positive study showing unusually strong evidence of malignancy should also lead to Category 1B classification. The classification criteria indicate that carcinogenicity in a single animal study should be considered sufficient to classify in Category 1B in the absence of any other data.

A single study in one species and sex should be considered sufficient for classification in Category 1B when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites.

Also, a single study in one species and sex in combination with positive *in vivo* mutagenicity data would be considered sufficient for classification in Category 1B.

(d) Progression of lesions to malignancy: If the substance or mixture has been shown to cause malignant tumours, then it must be classified in Category 1B. Generally speaking, the induction of only benign tumours is of lesser concern for carcinogenicity than the induction of malignant tumours. However, benign tumours could also be of significant concern if they are a type of tumour that has the potential to progress to malignancy. Therefore, any indication that the observed tumours have the potential to progress to malignancy will increase the level of concern. Also, for example, brain tumours are of concern in and of themselves. Benign tumours are potentially serious depending on their size, growth rate, and site of origin.

(e) Reduced tumour latency: The latency of tumour development (that is, how quickly a substance or mixture induces tumours) reflects the potency of a carcinogen. This observation is particularly true for mutagenic substances and mixtures, which often induce tumours more rapidly than non-genotoxic agents. Substances and mixtures producing tumours with reduced latency could be considered as carcinogenic, even if the tumour incidence is not statistically significant.

(f) Whether responses are in one or both sexes: Any case of gender-specific tumours must be evaluated in light of the total tumourigenic response to the substance or mixture observed at other sites (multi-site responses or incidence above background) in determining the carcinogenic potential of the substance or mixture. If tumours are seen only in one sex of an animal species, the mode of action must be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear pathophysiological difference consistent with the mode of action to explain the single sex response.

(g) Structural similarity (or not) to a substance or mixture for which there is good evidence of carcinogenicity: A substance or mixture that has not been tested for carcinogenicity could, in certain instances, be classified in Category 1 or Category 2 based on tumour data from a structural analogue when this information is considered together with substantial support from other factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.

(h) Routes of exposure: The classification should also take into consideration whether or not the substance or mixture is absorbed by a given route(s); or whether there are only local tumours at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity. Most standard carcinogenicity studies use physiological routes of exposure for humans, namely inhalation, oral or dermal exposure. The findings from such routes are usually considered directly relevant for humans. Studies using these routes will generally take precedence over similar studies using other routes of exposure (e.g. intra-muscular, sub-cutaneous, intra-peritoneal and intra-tracheal injections or instillations).

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans: when classifying, it is important to have data on the physico-chemical, toxicokinetic and toxicodynamic properties of the substance or mixture along with data on chemical analogues, such as the structure activity relationship.

(j) The possibility of a confounding effect of excessive toxicity at test doses: Tumours occurring only at excessively high doses associated with severe toxicity generally have doubtful potential for predicting carcinogenicity in humans.

(k) Tumours occurring only at sites of contact. Tumours occurring only at the site of contact must be carefully evaluated for human relevance. For example, forestomach tumours, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. Any occurrence of other tumours at distant sites must also be considered.

(l) Mode of action and its relevance for humans: Mode of action may include mutagenicity, cytotoxicity with growth stimulation, mitogenesis, or immunosuppression. Mode of action in and of itself, or consideration of comparative metabolism, should be evaluated on a case-by-case basis. One must look closely at any mode of action in animal experiments taking into consideration comparative toxicokinetics/toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. Only if a mode of action of tumour development is conclusively determined not to be operative in humans could the carcinogenic data for that tumour be discounted.

It is recognized that genetic events are central in the overall process of cancer development. Therefore, data of mutagenic activity *in vivo* may indicate that a substance or mixture has a potential for carcinogenic effects. In general, if a substance or mixture is mutagenic then it will be considered to be potentially carcinogenic in humans. However, mutagenicity data alone are insufficient information to justify a carcinogenicity classification. In some cases, where only *in vitro* and *in vivo* mutagenicity data are available without carcinogenicity data, classification in Carcinogenicity - Category 2 could be considered when all factors have been considered such as type and quality of the mutagenicity data, structure activity relationships, etc.

(ECHA Guidance, 2015, pp. 374-381) (GHS, 5th revised edition, 2013, paragraphs 3.6.5.3.2.1 to 3.6.5.3.2.5)

In extrapolation from animals to humans, it is known that the following instances of carcinogenicity may be denied as evidence of human carcinogenicity because the mechanism of tumour formation is considered not relevant for humans:

- Kidney tumours in male rats associated with substances or mixtures causing α2µ-globulin nephropathy
- Pheochromocytomas in male rats exposed to particulates through inhalation secondary to hypoxemia
- Leydig cell adenomas induced by dopamine antagonists or gonadotropin-releasing hormone (GnRH)

- Urinary bladder tumours due to crystals in the bladder
- Forestomach tumours in rodents following administration by gavage of irritating or corrosive, non-genotoxic substances or mixtures
- Certain thyroid tumours in rodents mediated by UDP glucuronyltransferase (UGT) induction
- Liver tumours in rodents conclusively linked to peroxisome proliferation

(ECHA Guidance, 2015, p. 381)

Substances evaluated by IARC, NTP or ACGIH

If a substance has been evaluated and determined to be carcinogenic by one or more of the following organizations, the substance must be considered carcinogenic under the HPR.

- IARC "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions ***at http://monographs.iarc.fr/***)
- National Toxicology Program (NTP) "Report on Carcinogens" (latest edition ***at http://ntp.niehs.nih.gov/***)

Table 1 below gives the approximate equivalencies between HPR classification and classifications by IARC and NTP.

Table 1. Correspondence between HPR, IARC, and NTP (HCS 2012, p. 826)

IARC http://monographs.iarc.fr/	**NTP**	**HPR**
Group 1 *(carcinogenic to humans)*	Known - sufficient evidence of carcinogenicity from studies in humans	**Category 1A**
Group 2A *(probably carcinogenic to humans)*	Reasonably Anticipated - Limited evidence of carcinogenicity from studies in humans OR Reasonable Anticipated - Sufficient evidence of carcinogenicity from studies in experimental animals	**Category 1B**
Group 2B *(possibly carcinogenic to humans)*	Reasonably Anticipated - Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however the substance belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either "Known" or "Reasonably Anticipated" to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.	**Category 2**

Correspondence between the HPR and a carcinogenicity designation by the American Conference of Industrial Hygienists (ACGIH) ("Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment"; latest edition at https://www.acgih.org/TLV/) is not as straightforward. If a substance is not listed by IARC or NTP, but it is listed by ACGIH as Group A1 (confirmed human carcinogen), A2 (suspected human carcinogen) or A3 (confirmed animal carcinogen with unknown relevance to humans), it should be considered a carcinogen

under the HPR. The data upon which the ACGIH designation was based and any new scientific data must be evaluated and assessed against the criteria in section 8.6.1 of the HPR to determine the most suitable category. If the substance has both an IARC or NTP classification for carcinogenicity and an ACGIH classification, the IARC or NTP classification would take precedence over the ACGIH classification.

Substances not evaluated by IARC, NTP or ACGIH

If a substance is not specifically addressed by IARC, NTP or ACGIH, this lack of determination does not relieve the supplier or importer of their obligation to consider other available data indicating that carcinogenic effects may result from exposure to the substance. The criteria described in section 8.6.1 of the HPR must be applied in the context of other available data in this regard.

Classification in a Category or Subcategory of the Class

Classification of mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.6.2

Order of provisions

8.6.2 The classification of a mixture as a carcinogenic mixture in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.6.3 to 8.6.5.

There is a "tiered" approach for classifying mixtures for carcinogenicity, meaning that the procedures described in sections 8.6.3 to 8.6.5 must be followed in the order in which these sections appear in the HPR.

As specified in sections 8.6.3 and 8.6.4, classification of mixtures for carcinogenicity is based on the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified as carcinogens. However, if there are test data for the mixture as a whole, these data may be used to classify the mixture, instead of data on the individual ingredients. Finally, section 8.6.5 specifies which bridging principles may be applied to the Carcinogenicity hazard class.

Discussion of the *Hazardous Products Regulations*
Section 8.6.3

Ingredient classified in Category 1A or 1B

8.6.3 A mixture is classified in the category "Carcinogenicity — Category 1" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the subcategory "Carcinogenicity — Category 1A" or in the subcategory "Carcinogenicity — Category 1B", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture is carcinogenic, in which case the mixture is classified as a carcinogenic mixture in accordance with section 8.6.1; or

(b) the mixture as a whole has been subjected to a carcinogenicity study that determines that the mixture is not carcinogenic, and a scientifically validated method was used and the study was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

Subject to paragraphs 8.6.3(a) and (b), section 8.6.3 of the HPR specifies that, if a mixture contains at least one ingredient that is classified in Carcinogenicity – Category 1, Category 1A or Category 1B and the ingredient is present at a concentration of ≥ 0.1%, then the mixture must be classified accordingly. Although section 8.6.3 specifies that such a mixture is classified in Carcinogenicity – Category 1 (without sub-categorization), where there are sufficient data available to allow determination of the appropriate subcategory (1A or 1B), classification in 1A or 1B instead of in the less specific Category 1 is allowed. For example, if a mixture contains an ingredient that is classified in Carcinogenicity – Category 1A and the ingredient is present at a concentration of 0.5%, then the mixture must be classified either in Carcinogenicity – Category 1 or Carcinogenicity – Category 1A. Note that, as specified in subparagraph 3(5)(n) of the HPR, the symbol, signal word, hazard statement and precautionary statements are the same for Carcinogenicity – Category 1, 1A and 1B.

The additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Carcinogenicity – Category 1A or 1B are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 0.1% concentration cut-off.

If there are data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that as the concentration of a carcinogenic ingredient is reduced in a mixture, the dilution effect may result in a misleading test result (i.e., a false negative) if the study was not appropriately designed to factor in the concentration of the carcinogenic ingredient in the mixture (OSHA Hazard Classification Guidance 2016, p. 160).

Therefore, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation, and analysis of carcinogenicity test systems (ECHA Guidance, 2015,

paragraph 3.6.3.1). If the results for the mixture as a whole are relevant and conclusive, based on established scientific principles, and meet the criteria for Carcinogenicity in accordance with section 8.6.1 of the HPR, the results must be applied to classify the mixture as a carcinogen.

If the results for the mixture as a whole demonstrate that the mixture is not carcinogenic, based on a carcinogenicity study that was performed according to generally accepted standards of good scientific practice and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified as a carcinogen even when Category 1, 1A or 1B carcinogenic ingredients are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations*
Section 8.6.4

Ingredient classified in Category 2

8.6.4 A mixture is classified in the category "Carcinogenicity — Category 2" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the category "Carcinogenicity — Category 2", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture is carcinogenic, in which case the mixture is classified as a carcinogenic mixture in accordance with section 8.6.1; or

(b) the mixture as a whole has been subjected to a carcinogenicity study that determines that the mixture is not carcinogenic, and a scientifically validated method was used and the study was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

If at least one ingredient present in the mixture at a concentration of ≥ 0.1% is classified as Carcinogenicity – Category 2, then the mixture is classified as Carcinogenicity – Category 2. Note that the additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Carcinogenicity – Category 2 are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 0.1% concentration cut-off.

However, if there are data available for the mixture as a whole, these data may be used, instead of data on the individual ingredients, to classify the mixture. The concern with using test data for the mixture as a whole is that as the concentration of a carcinogenic ingredient is reduced in a mixture, the dilution effect may result in a misleading test result (i.e., false negative) if the study was not appropriately designed to factor in the concentration of the carcinogenic ingredient in the mixture (OSHA Hazard Classification Guidance 2016, p. 160).

The test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors based on established scientific principles, such as duration, observation and analysis of carcinogenicity test systems (GHS, 5th revised edition, 2013, paragraph 3.6.3.1).

If the results for the mixture as a whole are deemed relevant and conclusive and meet the criteria for Carcinogenicity in accordance with section 8.6.1 of the HPR, the results must be applied to classify the mixture as a carcinogen.

If the results for the mixture as a whole demonstrate that the mixture is not carcinogenic based on a carcinogenicity study and a scientifically validated method was used, and the study was performed in accordance with generally accepted standards of good scientific practice, the results must be applied. The mixture cannot be classified as a carcinogen even when Category 2 carcinogenic ingredients are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations*
Section 8.6.5

Data available for use of bridging principles

8.6.5 If data are available to enable the characterization of the mixture as carcinogenic, in accordance with the bridging principles referred to in subsections 2.3(3), (4) and (7), the mixture must be classified in accordance with those subsections.

The use of bridging principles is the final step in the tiered approach for the classification of mixtures. When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there is sufficient data available on similar tested mixtures and on the individual hazardous ingredients within the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

Not all of the bridging principles apply to this hazard class. Only dilution, production batches, and substantially similar mixtures are applicable. Increase in concentration of hazardous ingredient, interpolation and aerosols are not used for this hazard class.

If data on another mixture are used in the application of the bridging principles, the data on that mixture must be conclusive as discussed above under HPR 8.6.3 and 8.6.4 for the mixture as a whole (OSHA Hazard Classification Guidance 2016, p. 161).

Hazard Communication

The symbol, signal words, hazard statements, and precautionary statements for Carcinogenicity -Category 1 and Category 2 are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, p. 356. Paragraph 3(5)(n) of the HPR specifies that if a hazardous product is classified in the subcategory Carcinogenicity – Category 1A or in the subcategory Carcinogenicity – Category 1B, the information elements specified for the category Carcinogenicity – Category 1 apply.

Note that the symbol and precautionary statements are the same for Category 1 and Category 2; the signal word and hazard statement are different between the two categories.

As part of the hazard statement, the route of exposure must be specified if it has been conclusively proven that no other routes of exposure cause the effect. In order to be able to specify the route of exposure, test data need to be available for all three relevant routes (oral, dermal and inhalation), and the data must clearly indicate that only one route leads to positive results. It is estimated that such circumstances rarely, if ever, exist (ECHA Guidance, 2015, p. 368).

Hazard Communication - Mixtures

VARIANCE with HCS 2012: Labelling of mixtures classified in Carcinogenicity - Category 2

HPR

Under the HPR, all mixtures containing a carcinogenic ingredient (whether Category 1, 1A, 1B or 2) at a concentration of 0.1% or more are required to have a label as well as an SDS.

HCS 2012

This requirement differs from the HCS 2012. As specified in the note below Table A.6.1 of the HCS 2012, "*a label warning is optional for mixtures that contain Category 2 carcinogens at concentrations between 0.1 and 1.0%, but an SDS is required*". In the HCS 2012, all mixtures containing a carcinogenic ingredient (whether Category 1, 1A, 1B or 2) at a concentration of 0.1% or more are required to have an SDS. Mixtures that contain Category 1, 1A or 1B carcinogens at a concentration of 0.1% or more and mixtures that contain Category 2 carcinogens at a concentration of 1.0% or more are required to have both a label and an SDS.

This variance has no impact on the classification of hazardous products in the Carcinogenicity hazard class. However, for mixtures that contain Category 2 carcinogens at concentrations between 0.1% and 1.0% and that are imported into Canada from the U.S., a label that meets the requirements of the HPR must be added if such a label is not already affixed to, printed on, or attached to the hazardous product or the container in which it is packaged.

Classification of Carcinogencity for Substances

Example

(OSHA Hazard Classification Guidance 2016, p. 167)

Available data

Listed by IARC as Group 2A (probably carcinogenic to humans).

Listed by NTP as Reasonably Anticipated to be human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals.

Classification

Carcinogenicity Category - 1B

Rationale

The substance has been evaluated and determined to be a carcinogen by IARC and NTP. According to the equivalencies illustrated in Table 1, the substance must be classified under the HPR in Carcinogenicity - Category 1B.

Classification of Carcinogenicity for Mixtures

Example

(OSHA Hazard Classification Guidance 2016, p. 168)

Available data

Data for the components of a mixture:

Component	Concentration (w/w)%	Classification
A	0.05	Carcinogenicity Category 1B
B	45	Not classified
C	0.5	Carcinogenicity Category 2
D	54.45	Not classified

Data for the mixture as a whole is not available.

Classification

Carcinogenicity - Category 2

Rationale

Components B and D are not classified for carcinogenicity; therefore, they are not considered when classifying the mixture.

Component A falls below the 0.1% cut-off value for Category 1 and has not been shown to cause carcinogenic effects below this concentration. Therefore, it is not considered when classifying the mixture.

Component C is present at a concentration of ≥ 0.1% and is classified in Category 2. Therefore, the mixture is classified as Carcinogenicity – Category 2.

Subpart 7
Reproductive Toxicity

Definitions

8.7 The following definitions apply in this Subpart.

"adverse effects on sexual function and fertility" means any effect of a mixture or substance that is liable to interfere with sexual function or fertility, including

(a) alterations to the female or male reproductive system;

(b) adverse effects on onset of puberty, gamete production or transport, the reproductive cycle, sexual behaviour, parturition or pregnancy outcomes;

(c) premature reproductive senescence; or

(d) any modifications to other functions that are dependent on the integrity of the reproductive system.

"adverse effects on the development of the embryo, fetus or offspring" means any adverse effects of a mixture or substance on the embryo, fetus or offspring, resulting from exposure of either parent to the mixture or substance prior to conception or exposure of the developing embryo or fetus to the mixture or substance during prenatal development, or of the offspring during postnatal development to the time of sexual maturation, that is manifested at any point in the development of the embryo or fetus, or that is manifested at any point in the lifespan of the offspring, and that includes the loss of the embryo or fetus, death of the developing offspring, structural abnormality, altered growth and functional deficiency. This definition excludes the induction of genetically based inheritable effects in the offspring.

"effects on or via lactation" means

(a) any effect of a mixture or substance that interferes with lactation; or

(b) the presence of the mixture or substance, or its metabolites, in the maternal milk in amounts for which there is evidence that supports the conclusion, based on established scientific principles, that the health of the breast-fed child or suckling animal is liable to be threatened.

"reproductive toxicity" refers to

(a) adverse effects on sexual function and fertility;

(b) adverse effects on the development of the embryo, fetus or offspring; or

(c) effects on or via lactation.

"toxic to reproduction" means, in relation to a mixture or substance, liable to lead to reproductive toxicity.

Discussion – Reproduction Toxicity

Reproductive toxicity describes the adverse effects induced by a substance or mixture on any aspect of mammalian reproduction, from sexual function and fertility to development of the embryo, fetus and offspring to lactation.

Effects on or via lactation are included in the definition of reproductive toxicity. However, these effects are assessed separately for classification since it is desirable to be able to classify specifically for this endpoint and include hazard warnings directed at lactating mothers (GHS, 5th revised edition, 2013, paragraph 3.7.1.2).

Effectively, a substance (or mixture) could be classified as follows:

(a) Reproductive Toxicity — Category 1;

(b) Reproductive Toxicity — Category 2;

(c) Reproductive Toxicity — Effects on or via Lactation;

(d) both Reproductive Toxicity — Category 1 and Reproductive Toxicity — Effects on or via Lactation; or

(e) both Reproductive Toxicity — Category 2 and Reproductive Toxicity — Effects on or via Lactation.

Classification in a Category or Subcategory of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Subsection 8.7.1(1)

Categories or subcategories – Categories 1A, 1B and 2

8.7.1(1) A substance that is toxic to reproduction is classified in a category or subcategory of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2	Column 3
Item	Category	Subcategory	Criteria
1	Reproductive Toxicity — Category 1	Reproductive Toxicity – Category 1A	A substance in respect of which human data demonstrate that exposure to the substance leads to adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring

2	**Reproductive Toxicity — Category 1**	**Reproductive Toxicity – Category 1B**	**A substance in respect of which animal data demonstrate that exposure of the animal to the substance leads to the following:** **(a) adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, in the absence of other toxic effects; or** **(b) adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, in the presence of other toxic effects, provided that such adverse effects are not considered to be a secondary non-specific consequence of the other toxic effects**
3	**Reproductive Toxicity — Category 2**		**A substance in respect of which human or animal data support a positive association between exposure to the substance and adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, but do not support a conclusion, based on established scientific principles, that exposure to the substance leads to such effects**

Reproductive Toxicity is divided into two categories; Category 1 and Category 2. Category 1 is further subdivided into Category 1A and 1B. Category 1A represents **known** human reproductive toxicants. Category 1B represents **presumed** human reproductive toxicants. Category 2 represents **suspected** human reproductive toxicants.

Category 1A

Category 1A is based on human data from epidemiological studies, clinical data and case reports. A well conducted epidemiological study should include use of appropriate controls, balanced assessment, and consideration of bias or confounding factors (GHS, 5th revised edition, 2013, paragraph 3.7.2.2.3).

Category 1B

Human data is often limited and/or does not provide conclusive support for classification. Classification in Reproductive Toxicity – Category 1B is based on data in experimental animals. Criterion (a) of Reproductive Toxicity – Category 1B includes that data must provide clear evidence of an adverse effect on sexual function and fertility or on development of the embryo, fetus or offspring, in the absence of other toxic effects, including maternal toxicity. Criterion (b) of Reproductive Toxicity – Category 1B includes that adverse effects occurring together with other toxic effects, such as maternal toxicity, can also be considered. However, the adverse effects on reproduction must not be a secondary non-specific consequence of the other toxic effects. Guidance on the interpretation of maternal toxicity and other toxic effects is provided below.

Category 2

Category 2 includes situations when there is evidence from humans or experimental animals of an adverse effect on reproduction, possibly supplemented with other information, but the

evidence is not sufficiently convincing for a Category 1A or 1B classification. For instance, deficiencies in the study may make the quality of evidence less convincing and a Category 2 classification could be more appropriate.

As with Category 1B, adverse reproductive effects observed in animals must be in the absence of other toxic effects or, if occurring together with other toxic effects, must not be a secondary non-specific consequence of the other toxic effects. However, unless it can be clearly demonstrated that the adverse effects are secondary to the maternal toxicity, classification in Category 2 must be considered.

Classification is intended to be used for substances or mixtures which have an intrinsic, specific property to produce an adverse effect on reproduction. If such an effect is produced solely as a non-specific secondary consequence of other toxic effects, the substance or mixture should not be classified in Reproductive Toxicity hazard class (GHS, 5th revised edition, 2013, paragraph 3.7.2.2.1). It is important to consider the possible influence of maternal toxicity when assessing reproductive toxicity.

Experimental Data (GHS, 5th revised edition, 2013, paragraph 3.7.2.5)

- There is a hierarchy with respect to the quality and reliability of evidence to justify classification. Different types of scientifically validated studies that may be used to support classification are listed below, in order from highest to lowest in terms of quality and reliability.
    - A number of internationally accepted test methods are available, which include methods for developmental toxicity, peri- and post-natal toxicity or one / two generation reproduction toxicity. For example,
        - OECD TG 414 – Prenatal Developmental Toxicity Study: This study is designed to provide general information concerning the effects of prenatal exposure on the pregnant test animal and on the developing organism; this may include assessment of maternal effects as well as death, structural abnormalities, or altered growth in the fetus. The dams are exposed to the substance and effects from preimplantation through the entire period of gestation to the day before caesarean section are examined (Details on test method from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects).
        - International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline S5A, 1993: Detection of Toxicity to Reproduction for Medicinal Products
        - ICH S5B, 1995: Addendum to Detection of Toxicity to Reproduction for Medicinal Products: Toxicity to Male Fertility
        - OECD TG 415 – One Generation Reproduction Toxicity Study: This study is designed to provide general information concerning the effects of a test substance on male and female reproductive performance, such as gonadal function, oestrous cycle, mating behaviour, conception, parturition, lactation, and weaning. The study may also provide preliminary information about developmental toxic effects of the test substance, such as neonatal morbidity, mortality, behaviour, and teratogenesis, and to serve as a guide for subsequent

tests. The test substance is administered to both males and females for a period prior to mating and during the mating period. Thereafter, only the females are dosed throughout pregnancy and nursing. The evaluation will include the relationship between the dose of the test substance and the presence or absence, the incidence and severity, of abnormalities, including fertility, clinical abnormalities, body weight changes, effects on mortality and any other toxic effects.

- OECD TG 416 – Two Generation Reproductive Toxicity Study: In addition to studying growth and development of the F1 generation, as described for OECD TG 415, this study is also intended to assess the integrity and performance of the male and female reproductive systems as well as growth and development of the F2 generation.

(Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects).

- Screening tests: In the absence of a full study, screening tests can be used to justify classification. For example,
  - OECD TG 421 – Reproduction / Developmental Toxicity Screening Test: This test provides initial information on possible effects on reproduction and/or development. It does not provide complete information on all aspects of reproduction and development, offering only limited means of detecting post-natal manifestations of pre-natal exposure, or effects that may be induced during post-natal exposure. Due to the relatively small numbers of animals in the dose groups, the selectivity of the endpoints, and the short duration of the study, this method will not provide evidence for definite claims of no effects. Dosing is similar to that described above for OECD TG 415; however the pre-mating and post-delivery periods are shortened.
  - OECD TG 422 – Combined Repeated Dose Toxicity Study with Reproduction / Developmental Toxicity Screening Test: This test provides information on the possible health hazards likely to arise from repeated exposure over a relatively limited period of time (at least 28 days), combined with the reproduction / developmental toxicity screening test as described above for OECD TG 421.

(Details on test methods from website: OECD Guidelines for the Testing of Chemicals, Section 4 – Health Effects).

- Short or long term repeated dose toxicity studies that demonstrate reproductive toxicity in the absence of significant generalized toxicity (e.g., histopathological changes in the gonads) can be used as a basis for classification. Toxicological effects observed in a standard repeat dose study could be considered valid for the pre-mating phase for adult females and the pre- and post-mating phases for adult males. A detailed assessment of toxicity in pregnant animals cannot be extrapolated from studies with non-pregnant animals. However, information from general toxicity studies might give an indication of the maternal toxicity that could be anticipated in a subsequent developmental toxicity study.

  - *In vitro* assays, non-mammalian tests or structure-activity relationships can contribute to the classification.
- Route of administration: Dermal, inhalation or oral routes of exposure in animal studies could relate to the potential route of exposure in humans for characterizing the hazardous properties of a substance with respect to reproductive toxicity in humans.
- Limit dose: In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (e.g., doses that induce prostration, severe loss of appetite, excessive mortality) would not normally support classification. Specification of the limit dose will depend upon the test method.

General Considerations (GHS, 5th revised edition, 2013, paragraph 3.7.2.3)

There are factors, other than maternal toxicity, to consider when evaluating data for reproductive toxicity. Some of which are discussed below:

- Toxicokinetic studies: If it can be conclusively demonstrated that the mechanism or mode of action causing the reproductive toxicity has no relevance for humans, or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans, then the substance should not be classified based on those factors (refer to the discussion of subsection 2(9) in Part 2 of this technical guidance).
- Effects of low or minimal toxicological significance: These effects could include small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments. Such effects may not be sufficient for classification.

Maternal Toxicity (GHS, 5th revised edition, 2013, paragraph 3.7.2.4)

Maternal toxicity may influence the development of the embryo, fetus or offspring via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations. When evaluating observations of developmental toxicity in the presence of maternal toxicity, the preferred approach is to consider adverse effects in the embryo or fetus first and then maternal toxicity.

The presence of maternal toxicity cannot be used to negate adverse effects on development of the embryo, fetus or offspring unless it can be clearly demonstrated that the effects are secondary to maternal toxicity, especially when the effects in the offspring are significant (e.g., irreversible effects such as structural malformations, embryo/fetal lethality and significant postnatal functional deficiencies). In other words, when maternal toxicity is not severe and it cannot be shown to have a causal relationship to the adverse developmental effects on the offspring, classification in Reproductive Toxicity - Category 1 must be considered. When there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Reproductive Toxicity - Category 2 must be considered instead.

Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, need to be evaluated in light of their statistical or biological significance and dose response relationship.

(a) Maternal mortality: an increased incidence of mortality among the treated dams over the controls should be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level should not normally be considered for further evaluation.

(b) Mating index (N° animals with seminal plugs or sperm/N° mated × 100)

(c) Fertility index (N° animals with implants/N° of matings × 100)

(d) Gestation length (if allowed to deliver)

(e) Body weight and body weight change: consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight should be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. For example, a significant reduction in maternal body weight gain throughout gestation, without a concomitant change in corrected maternal weight gain, would indicate an intrauterine effect in the absence of maternal toxicity. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

(f) Food and water consumption (if relevant): the observation of a significant decrease in the average food or water consumption in treated dams compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption should be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

(g) Clinical evaluations (including clinical signs, markers, haematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams relative to the control group may be useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs should be reported in the study. Examples of clinical signs of maternal intoxication include coma, prostration, hyperactivity, loss of righting reflex, ataxia, or laboured breathing.

(h) Post-mortem data: increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, e.g., absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio. When supported by findings of adverse histopathological effects in the affected

organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams, compared to those in the control group, may be considered evidence of maternal toxicity.

Note that for classification purposes, the known induction of genetically based inheritable effects in the offspring is more appropriately addressed in Germ Cell Mutagenicity. (GHS, 5th revised edition, 2013, paragraph 3.7.1.1)

Discussion of the *Hazardous Products Regulations* Subsection 8.7.1(2)

Category – effects on or via lactation

8.7.1(2) A substance that is toxic to reproduction is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Reproductive Toxicity — Effects on or via Lactation**	**A substance that, according to human or animal data, has effects on or via lactation**

Effects on or via lactation are allocated to a separate single category and must be evaluated independently of the adverse effects covered in subsection 8.7.1(1) of the HPR.

As defined in section 8.7 of the HPR, effects on or via lactation means:

(a) any effect that interferes with lactation; or

(b) the substance (including metabolites) is present in breast milk in amounts sufficient to cause concern for the health of a breastfed child or suckling animal.

If a substance causes marked, overt, systemic maternal toxicity at the same dose level as it interferes with lactation, then it is possible that the maternal toxicity may indirectly impair milk production or impair maternal care as a non-specific secondary effect. If there is evidence to indicate that the effects on lactation are not caused directly by the substance then it must not be classified as such. A substance which does not cause overt toxicity in the mother but which interferes with milk production or quality will normally be classified for effects on or via lactation because, in this case, the effect on lactation is most likely a direct substance-related effect.

When the effect on the offspring is caused by the substance (or metabolite) after transport through the milk, then maternal toxicity has no relevance for classification.

In exceptional circumstances, if there are substantiated grounds for **concern** that the substance may have an adverse effect via lactation then it may be classified as such in the absence of direct evidence. This determination should be based on a quantitative comparison of the estimated

transfer of the substance via the milk and the threshold for toxicity in the offspring. This situation might apply in cases:

- where the substance has the capacity to bioaccumulate, which would lead to a potentially higher burden in the offspring, or
- where there is evidence that the offspring may be more sensitive to the substance's toxicity than adult.

The mere presence of the substance in the milk alone, without a justification for a concern to offspring, would normally not support classification for effects on or via lactation (ECHA Guidance, 2015, p. 398).

Classification in Reproductive Toxicity - Effects on or via Lactation can be assigned on the basis of human or animal data meeting one or more of the following conditions:

(a) absorption, metabolism, distribution, and excretion studies which indicate the likelihood that the substance would be present in potentially toxic levels in breast milk: The implicit assumption behind this condition is that the offspring may receive a body burden of the substance (or metabolite) through suckling that is sufficient to cause toxicity.

The toxicokinetics of a substance and the likelihood that it will enter the breast milk may be predicted on the basis of the physico-chemical properties of the substance (e.g., using characteristics such as pKa, logP, water solubility, and molecular weight) and this information could be used as part of the argument outlined above.

The potential of a substance to bioaccumulate following repeated exposure may also contribute to the body burden in the offspring. Studies where the offspring/neonates have extended exposure, such as multi-generation studies, implicitly allow for bioaccumulation.

There may be toxicokinetic and toxicodynamic reasons why neonates may potentially be more or less vulnerable to a particular adverse effect than adults. In the absence of any reliable information, it should be assumed that neonates and adults are equivalent in terms of sensitivity to the substance.

Overall, classification for effects on or via lactation can be assigned on the basis of toxicokinetic data or a well substantiated estimate of the exposure through the milk alone, provided that it is supported by an argument clearly justifying that the level present in the breast milk would be likely to harm developing offspring.

(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk: These studies directly observe the offspring during lactation and any adverse effects that can be directly observed and quantified, such as deaths, decreased viability, or clinical signs such as reduced body weight gain etc. However, it must be considered whether these effects in the offspring are due to a direct adverse effect on lactation, or are due to impaired nursing behaviour which is a non-specific secondary consequence of maternal toxicity. If the impaired nursing behaviour is proven to be a substance-related specific effect on behaviour, then classification may be appropriate. It is also important to note that some developmental effects resulting from exposure in utero would only manifest post-natally, and these effects should not be used for classification. Cross-

fostering studies, where available, may help establish whether effects are due to *in utero* or lactational exposure. If there is sufficient data indicating that animal results are not relevant to humans, they should not be taken into account (refer to the discussion of subsection 2(9) in Part 2 of this technical guidance).

(c) human evidence indicating a hazard to babies during the lactation period: Human observations of adverse effects in breastfed babies of mothers exposed to a substance provide clear evidence supporting classification. However, in practice, useful human data are rare due to the nature of the endpoint. More likely available are survey type studies which measure the levels of the substance in breast milk. Such studies may provide useful information on the potential for maternal exposure and the presence of the substance in the breast milk. Therefore, these studies may be of use in assessing the need for classification (ECHA Guidance, 2015, pp. 399-400) (GHS, 5th revised edition, 2013, paragraph 3.7.2.1)

Classification in a Category or Subcategory of the Class

Classification of mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.7.2

Order of provisions

8.7.2 Subject to subsection 8.7.5(2), the classification of a mixture as a mixture that is toxic to reproduction in a category or subcategory of this hazard class must proceed in accordance with the order of sections 8.7.3 to 8.7.6.

There is a "tiered" approach for classifying mixtures for reproductive toxicity, which means that the procedures described in sections 8.7.3 to 8.7.6 must be followed in the order in which these sections appear in the HPR.

As specified in sections 8.7.3, 8.7.4, and 8.7.5 classification of mixtures is based on evaluation of the individual ingredients of the mixture using concentration cut-off values for the ingredients classified in Reproductive Toxicity. However, if there are test data for the mixture as a whole, these data may be used to classify the mixture, instead of data on the individual ingredients. Finally, section 8.7.6 specifies which bridging principles may be applied to the Reproductive Toxicity hazard class.

Two evaluations for classification of the mixture must be done. The mixture must be assessed for adverse effects on sexual function and fertility or adverse effects on development. The mixture must also be assessed for effects on or via lactation.

Therefore, a substance or mixture could be classified in Reproductive Toxicity - Category 1A, 1B, or 2 **and** in Reproductive Toxicity – Effects on or via Lactation.

Discussion of the *Hazardous Products Regulations*
Section 8.7.3

Ingredient classified in Reproductive Toxicity - Category 1A or 1B

8.7.3 A mixture is classified in the category "Reproductive Toxicity — Category 1" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the subcategory "Reproductive Toxicity — Category 1A" or in the subcategory "Reproductive Toxicity — Category 1B", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture has adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, in which case the mixture is classified as a mixture that is toxic to reproduction in accordance with subsection 8.7.1(1); or

(b) the mixture as a whole has been subjected to a reproductive toxicity study that determines that the mixture does not have adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, and a scientifically validated method was used and the study was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

Subject to paragraphs 8.7.3(a) and (b), section 8.7.3 of the HPR specifies that, if a mixture contains at least one ingredient that is classified in Reproductive Toxicity – Category 1, Category 1A or Category 1B and the ingredient is present at a concentration of ≥ 0.1%, then the mixture must be classified accordingly. Although section 8.7.3 specifies that such a mixture is classified in Reproductive Toxicity – Category 1 (without sub-categorization), where there are sufficient data available to allow determination of the appropriate subcategory (1A or 1B), classification in 1A or 1B instead of in the less specific Category 1 is allowed. For example, if a mixture contains an ingredient that is classified in Reproductive Toxicity – Category 1A and the ingredient is present at a concentration of 0.5%, then the mixture must be classified either in Reproductive Toxicity – Category 1 or Reproductive Toxicity – Category 1A. Note that, as specified in subparagraph 3(5)(o) of the HPR, the symbol, signal word, hazard statement and precautionary statements are the same for Reproductive Toxicity – Category 1, 1A and 1B.

The additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Reproductive Toxicity – Category 1A or 1B are not to be added together, and the sum of the concentration of those ingredients is not to be compared to the 0.1% concentration cut-off.

If there are data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that, as the concentration of a reproductive toxicant is reduced in a mixture the dilution effect may result in a misleading test result (i.e. false negative) if the study was not appropriately designed to factor in the concentration of the reproductive toxicant in the mixture (OSHA Hazard Classification Guidance 2016, p. 179).

Therefore, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation and analysis of reproduction test systems (GHS, 5th revised edition, 2013, paragraph 3.7.3.1). If the results for the mixture as a whole are deemed relevant and conclusive, and meet the criteria for Reproductive Toxicity in accordance with subsection 8.7.1(1) of the HPR, the results must be applied to classify the mixture as a reproductive toxicant.

If the results for the mixture as a whole demonstrate that the mixture is not a reproductive toxicant, based on a reproductive toxicity study that was performed according to generally accepted standards of good scientific practice, and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified in Reproductive Toxicity – Category 1, even when Category 1A or 1B reproductive toxicant ingredients are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations* Section 8.7.4

Ingredient classified in Reproductive Toxicity - Category 2

8.7.4 A mixture is classified in the category "Reproductive Toxicity — Category 2" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the category "Reproductive Toxicity— Category 2", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture has adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, in which case the mixture is classified as a mixture that is toxic to reproduction in accordance with subsection 8.7.1(1); or

(b) the mixture as a whole has been subjected to a reproductive toxicity study that determines that the mixture does not have adverse effects on sexual function and fertility or adverse effects on the development of the embryo, fetus or offspring, and a scientifically validated method was used and the study was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

If at least one ingredient present in the mixture at a concentration of ≥ 0.1% is classified in Reproductive Toxicity - Category 2, then the mixture is classified in Reproductive Toxicity – Category 2. Note that the additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Reproductive Toxicity – Category 2 are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 0.1% concentration cut-off.

If there are test data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that as the concentration of a reproductive toxicant is reduced in a mixture

the dilution effect may result in a misleading test result (i.e. false negative) if the study was not appropriately designed to factor in the concentration of the reproductive toxicant in the mixture (OSHA Hazard Classification Guidance 2016, p. 179).

Therefore, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation and analysis of reproduction test systems (GHS, 5th revised edition, 2013, paragraph 3.7.3.1). If the results for the mixture as a whole are relevant and conclusive, and meet the criteria for Reproductive Toxicity in accordance with subsection 8.7.1(1) of the HPR, the results must be applied to classify the mixture as a reproductive toxicant.

If the results for the mixture as a whole demonstrate that the mixture is not a reproductive toxicant, based on a reproductive toxicity study that was performed according to generally accepted standards of good scientific practice, and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified in Reproductive Toxicity – Category 2, even when Category 2 reproductive toxicant ingredients are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations*
Subsection 8.7.5(1)

Ingredient classified in Reproductive Toxicity – Effects on or via Lactation

8.7.5(1) A mixture is classified in the category "Reproductive Toxicity — Effects on or via Lactation" if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 0.1% that is classified in the category "Reproductive Toxicity — Effects on or via Lactation", unless

(a) there are data for the mixture as a whole that demonstrate conclusively, based on established scientific principles, that the mixture has effects on or via lactation, in which case the mixture is classified as a mixture that is toxic to reproduction in accordance with subsection 8.7.1(2); or

(b) the mixture as a whole has been subjected to a reproductive toxicity study that determines that the mixture does not have effects on or via lactation, and a scientifically validated method was used and the study was performed in accordance with generally accepted standards of good scientific practice at the time it was carried out.

If at least one ingredient present in the mixture at a concentration of ≥ 0.1% is classified in Reproductive Toxicity – Effects on or via Lactation, then the mixture is classified in Reproductive Toxicity – Effects on or via Lactation. Note that the additive approach is not applied to this hazard class. That is, the concentrations of individual ingredients that fall into Reproductive Toxicity – Effects on or via Lactation are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 0.1% concentration cut-off.

If there are test data available for the mixture as a whole, these data may be used instead of data on the individual ingredients to classify the mixture. The concern with using test data for the mixture as a whole is that as the concentration of a reproductive toxicant is reduced in a mixture the dilution effect may result in a misleading test result (i.e. false negative) if the study was not appropriately designed to factor in the concentration of the reproductive toxicant in the mixture (OSHA Hazard Classification Guidance 2016, p. 179).

Therefore, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors based on established scientific principles, such as duration of exposure, observation and analysis of effects on or via lactation (GHS, 5th revised edition, 2013, paragraph 3.7.3.1). If the results for the mixture as a whole are relevant and conclusive, and meet the criteria for Reproductive Toxicity in accordance with subsection 8.7.1(2) of the HPR, the results must be applied to classify the mixture in Reproductive Toxicity - Effects on or via Lactation.

If the results for the mixture as a whole demonstrate that the mixture does not present effects on or via lactation based on a study that was performed according to generally accepted standards of good scientific practice, and a scientifically validated method was used, the results must be applied. That is, the mixture must not be classified in Reproductive Toxicity — Effects on or via Lactation, even when ingredients classified in Reproductive Toxicity — Effects on or via Lactation are present at or above the established cut-off concentration of 0.1%.

Discussion of the *Hazardous Products Regulations* Subsection 8.7.5(2)

Classification in Category 1A, 1B or 2, and in Reproductive Toxicity – Effects on or via Lactation

8.7.5(2) Despite subsection 2.2(3), a mixture that has been classified in accordance with section 8.7.3 or 8.7.4 and meets the criteria of subsection (1) is also classified in the category "Reproductive Toxicity — Effects on or via Lactation".

This provision allows for dual classification within the same hazard class. A mixture may be classified as both Reproductive Toxicity – Category 1 or 2 **and** Reproductive Toxicity – Effects on or via Lactation. The mixture must be additionally and independently assessed for effects on or via lactation, regardless of whether the mixture has been classified in Category 1 or 2.

Discussion of the *Hazardous Products Regulations*
Section 8.7.6

Data available for use of bridging principles

8.7.6 If data are available to enable the characterization of the mixture as toxic to reproduction in accordance with the bridging principles referred to in subsections 2.3(3), (4) and (7), the mixture must be classified in accordance with those subsections, in the following categories:

(a) "Reproductive Toxicity — Category 1";

(b) "Reproductive Toxicity — Category 2";

(c) "Reproductive Toxicity — Effects on or via Lactation";

(d) both "Reproductive Toxicity — Category 1" and "Reproductive Toxicity — Effects on or via Lactation"; or

(e) both "Reproductive Toxicity — Category 2" and "Reproductive Toxicity — Effects on or via Lactation".

For this hazard class, the use of bridging principles is the final step in the tiered approach for the classification of mixtures. When there is no or insufficient data on the ingredients or the mixture as a whole, bridging principles can be applied if there is sufficient data available on similar tested mixtures and on the individual hazardous ingredients within the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

Note that not all of the bridging principles apply to this hazard class. Only dilution, production batches, and substantially similar mixtures are applicable. Increase in concentration of hazardous ingredient, interpolation, and aerosols are **not** used for this hazard class.

If data on another mixture are used in the application of the bridging principles, the data on that mixture must be conclusive as discussed above under sections 8.7.3, 8.7.4 and 8.7.5 of the HPR for the mixture as a whole.

Based on bridging principles, a mixture can be classified in either Category 1 and Effects on or via Lactation or Category 2 **and** Effects on or via Lactation.

Hazard Communication

The symbol, signal words, hazard statements, and precautionary statements for Reproductive Toxicity Category 1 and Category 2 are specified in Section 3 of Annex 3 of the GHS, 5th revised edition, p. 357. Paragraph 3(5)(o) of the HPR specifies that if the hazardous product is classified in the subcategory Reproductive Toxicity – Category 1A or in the subcategory Reproductive Toxicity – Category 1B, the information elements specified for the category Reproductive Toxicity – Category 1 apply.

Note that the symbol and precautionary statements are the same for Category 1 and Category 2; the signal word and hazard statement are different between the two categories.

As part of the hazard statement, the specific effect must be specified, if known (i.e. impairment of sexual function and fertility **or** developmental toxicity). However, it may be difficult to differentiate adverse effects on sexual function and fertility compared to developmental toxicity. Where the effect cannot be clearly differentiated, the general hazard statement for Category 1 or 2, as applicable, must be applied (ECHA Guidance, 2015, p. 417).

Also as part of the hazard statement, the route of exposure must be specified if it has been conclusively proven that no other routes of exposure cause the effect. In order to be able to specify the route of exposure, test data need to be available for all three relevant routes (oral, dermal and inhalation), and the data must clearly indicate that only one route leads to positive results. It is estimated that such circumstances rarely, if ever, exist (ECHA Guidance, 2015, p. 417)

The hazard and precautionary statements for Reproductive Toxicity - Effects on or via Lactation are specified in Section 3 of Annex 3 of the GHS, p. 358. There is no symbol or signal word associated with this classification.

Classification of Reproductive Toxicity for Substances

Examples

(OSHA Hazard Classification Guidance 2016, p. 186)

Example 1:

Available data

Substance X was tested for reproductive toxicity using OECD TG 415. There was a statistically significant decrease in the number of fetuses per litter, a significant decline in the ability of males to impregnate females, and a significant increased incidence of preimplantation embryo deaths. Effects were dose-dependent and without observations of general toxicity.

Classification

Reproductive Toxicity - Category 1B

Rationale

The test result fulfills Item 2 (a) of subsection 8.7.1(1) of the HPR – clear evidence of an adverse effect in experimental animals.

Example 2:

Available data

Human epidemiological studies describe increased incidence of natural abortion after exposure, abnormal development and malformation of newborns caused by prenatal abuse, and decreased plasma concentrations of luteinizing hormone and testosterone after exposure.

Increased risk of late spontaneous abortions associated with exposure at levels around 88 ppm (range 50-150 ppm).

Evidence of increased incidences of fetal death and delayed ossification, a decrease and unossification of sternebrae, a shift in rib profile, excess ribs, retarded skeletal development, delayed reflex response, learning disability, and early vaginal opening and testes descent at dose levels not toxic to dams from rat and mouse teratogenicity tests.

Classification

Reproductive Toxicity - Category 1A

Rationale

The test result fulfills Item 1 of subsection 8.7.1(1) of the HPR – clear evidence of an adverse effect in humans (supported by adverse effects in experimental animals). Note that the evidence regarding adverse effects in experimental animals is useful, but not necessary, to support classification in Category 1A.

Classification of Reproductive Toxicity for Mixtures

Example

(OSHA Hazard Classification Guidance 2016, p. 187)

Available data

Data for the components of a mixture:

Component	Concentration (w/w)%	Classification
A	0.05	Reproductive Toxicity - Category 1B
B	97.75	Not Classified
C	2	Reproductive Toxicity - Category 2
D	0.2	Reproductive Toxicity - Effects on or via Lactation

Data for the mixture as a whole is not available.

Classification

Reproductive Toxicity - Category 2 and Reproductive Toxicity - Effects on or via Lactation

Rationale

Component B is not classified for Reproductive Toxicity therefore is not considered when classifying the mixture.

Component A falls below the 0.1% cut-off value for Category 1 and has not been shown to cause reproductive effects below this concentration, therefore it is not considered when classifying.

Component C is ≥ 0.1%, and therefore meets Category 2 criteria for the mixture.

Component D is ≥ 0.1%, and therefore meets Effects on or via Lactation criteria for the mixture.

Subpart 8
Specific Target Organ Toxicity – Single Exposure

Discussion – Specific Target Organ Toxicity Arising From a Single Exposure (STOT-SE)

The Specific Target Organ Toxicity (STOT) classification addresses substances or mixtures that affect target organ systems of the body after either single or repeated exposure by any route (oral, dermal or inhalation) that is relevant for human exposure. The HPR addresses two different types of STOT hazards: toxicity that occurs after a **single exposure** (STOT–SE), and toxicity that occurs after **repeated exposures** (STOT-RE). STOT-RE is discussed in Subpart 9.

For STOT-SE, substances and mixtures can be classified in more than one hazard category. Subsection 2(2) of the HPR specifies that, if a product, mixture, material or substance meets the criteria for a more severe hazard category of a hazard class (e.g., Category 1 for most hazard classes), it must be classified in that category and does not need to be further evaluated against the criteria for another less severe hazard category within the same classification table of the same hazard class.

The STOT-SE hazard class does not follow this rule. As specified in subsections 8.8.1(1) and (2), there are three hazard categories and, for the purposes of classification, a substance or mixture must be evaluated against the criteria for all three categories. It is, therefore, possible to have a substance or mixture that is classified in the following category(ies) of this hazard class (see discussion of subsections 8.8.1(1) and (2) below):

- STOT-SE – Category 1, Category 2, or Category 3,
- STOT-SE – Category 1 and Category 3, or
- STOT-SE – Category 2 and Category 3.

Subsection 2.2(3) of the HPR specifies that, except in the case of Subparts 1, 4, 7 and 8 of Part 8 (Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity and STOT-SE, respectively), the first provision that results in a mixture being classified in a category or subcategory of a health hazard class concludes the process of classification with regard to that particular health hazard class. No further evaluation of the mixture in relation to the remaining provisions for the classification of mixtures in that health hazard class is necessary.

For STOT-SE, a supplier must evaluate the data for a mixture against the criteria for all three hazard categories and then follow the criteria in the table to subsection 8.8.1(2) to determine the resulting classification (see discussion of subsection 8.8.1(2) below).

Definitions

8.8 The following definitions apply in this Subpart.

"narcotic effects" means central nervous system depression that

(a) in humans, may present as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, vertigo, severe headache or nausea and may lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception or coordination, prolonged reaction time or sleepiness; and

(b) in animals, may be observed as lethargy, lack of coordination righting reflex, narcosis or ataxia.

"organ" includes any biological system.

"respiratory tract irritation" means localized redness, edema, pruritis or irritant effects in the respiratory tract that impair its function, whether or not accompanied by cough, pain, choking, breathing difficulties or other respiratory symptoms.

"specific target organ toxicity arising from a single exposure" means specific, non-lethal toxic effects on target organs that arise from a single exposure to a mixture or substance, including all health effects liable to impair function of the body or any of its parts, whether reversible or irreversible, immediate or delayed, but excludes effects resulting from health hazards addressed by Subparts 1 to 7 and 10 of this Part.

Narcotic Effects

Narcotic effects may range from slight dizziness to deep unconsciousness and may be caused by, for example, organic industrial chemicals (such as solvent vapours) which may have unspecific effects on central nervous system (CNS)-membranes, organic chemicals with similarities to and interference with CNS-transmitters (e.g., solvents such as butandiol, butyrolactone, methoxyethanol), or chemicals with high specific CNS toxicity or narcotic effects close to near-lethal doses (e.g., hydrogen sulphide).

Narcotic effects are typically reversible upon cessation of exposure causing no permanent changes or damages (ECHA Guidance, 2015, paragraph 3.8.2.4.1).

Organ

An organ is a part of the body that carries out one or more special functions. Examples of organs include lungs, liver, eyes, blood and the central nervous system.

Respiratory Tract Irritation

The respiratory tract consists of the air passages from the nose to the air sacs of the lungs, including the pharynx, larynx, trachea, and bronchi.

The generic term "respiratory tract irritation" covers two different effects: sensory irritation and local cytotoxic effects. Sensory irritation refers to the local and central reflex interaction of a substance with the autonomic nerve receptors, which are widely distributed in the mucosal tissues of the eyes and upper respiratory tract. Sensory irritation-related effects are fully reversible given that the biological function of the autonomic nerve receptors is to serve as a warning against substances that could damage the airways. Local cytotoxic effects induce tissue changes at the site of contact. Such effects may induce long lasting functional impairment of the respiratory system (ECHA Guidance, 2015, paragraph 3.8.2.3). For the purposes of the HPR, "respiratory tract irritation" is limited to local cytotoxic effects, since "respiratory tract irritation" refers to "localized redness, edema, pruritis or irritant effects in the respiratory tract that impair its function, whether or not accompanied by cough, pain, choking, breathing difficulties or other respiratory symptoms".

Specific target organ toxicity arising from a single exposure versus other health hazard classes

Classification in STOT-SE is assigned only when specific, non-lethal toxic effects on target organs that arise from a single exposure are observed and another health hazard class in the HPR does not address the observed toxicity. For example, substances and mixtures that cause skin corrosion from a single exposure must be classified in Skin Corrosion – Category 1, not in STOT-SE.

STOT-RE is not included in the list of other health hazard classes that must be considered before a classification in STOT-SE is assigned because this hazard class applies to target organ toxicity that arises from a **repeated** exposure, not a **single** exposure. Therefore, a substance can be classified in both STOT-SE **and** STOT-RE, if the respective criteria are met.

Acute Toxicity addresses **lethal** toxic effects and STOT-SE addresses **non-lethal** specific target organ toxic effects. Therefore, a substance could be classified in both the Acute Toxicity **and** STOT-SE hazard classes, if the respective criteria are met. However, the substance must not be assigned to both hazard classes (Acute Toxicity and STOT-SE) for the same effect. In such a case, the most severe hazard class (Acute Toxicity) must be assigned. Classification in STOT-SE is only warranted where there is data available for specific organ toxicity, and the effects are **non-lethal**.

Classification in a Category of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Subsection 8.8.1(1)

Two evaluations

8.8.1(1) In order to establish the classification of a substance that causes specific target organ toxicity arising from a single exposure in one or more categories of this hazard class, the substance must be evaluated in accordance with all the criteria set out in column 2 of the following table, in relation to toxic effects on

(*a*) the central nervous system and respiratory tract; and

(*b*) other specific target organs.

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Specific Target Organ Toxicity — Single Exposure — Category 1	A substance that (a) according to human data, causes specific target organ toxicity arising from a single exposure; or (b) according to animal data, causes specific target organ toxicity arising from a single exposure at low exposure concentrations, within the concentration value ranges set out for Category 1 in Table 3.8.1 of the GHS
2	Specific Target Organ Toxicity — Single Exposure — Category 2	A substance that, according to animal data, causes specific target organ toxicity arising from a single exposure at moderate exposure concentrations, within the concentration value ranges set out for Category 2 in Table 3.8.1 of the GHS
3	Specific Target Organ Toxicity — Single Exposure — Category 3	A substance in respect of which data demonstrate that a single exposure to the substance generates transient narcotic effects or transient respiratory tract irritation

The hazard class STOT-SE has three categories. Categories 1 and 2 are very distinct from Category 3.

The data required to evaluate STOT-SE for Category 1 and 2 is based on specific target organ toxicity arising from single exposure in humans or from studies conducted in experimental animals. The data from standard animal (i.e., rats or mice) studies, such as acute toxicity studies which include details on clinical observations and/or macroscopic and microscopic examination, are acceptable for classification in STOT-SE. Data from acute toxicity studies conducted in other species are also acceptable provided that these data provide relevant information on toxic effects on target organs/tissues (GHS, 5th revised edition, 2013, paragraph 3.8.2.1.5).

Category 3 covers “transient effects” occurring after a single exposure, specifically respiratory tract irritation and narcotic effects. These are target organ effects for which the available data for

a substance does not meet the criteria for Category 1 or 2. They are effects which alter function for a short duration after exposure but are essentially reversible upon cessation of exposure with no permanent damage or changes to the respiratory tract or central nervous system.

STOT-SE - Category 1 or Category 2

The dose or concentration at which effects are produced in animal studies needs to be considered to determine relevance for humans. Therefore, concentration value ranges have been established for Category 1 and Category 2. These concentration value ranges are only applied when classifying based on animal data. The comparison to the specified concentration value ranges provides the necessary information to assign classification in the appropriate category.

The concentration value ranges from Table 3.8.1 of the GHS are reproduced in the Table below.

There are no corresponding concentration value ranges for human data. Positive human data, regardless of probable dose, predominates over animal data (GHS, 5th revised edition, 2013, paragraph 3.8.2.1.10.2). A substance with well-substantiated human data showing a specific target organ toxic effect after a single exposure at very high doses must be classified in Category 1 even if there are animal data available which do not show toxicity at or below the established concentration value ranges. Similarly, there are no concentration value ranges for STOT-SE -Category 3 since classification in this category is typically based on human data.

Table 1. Concentration value ranges for single-dose exposures (GHS, 5th revised edition, 2013, Table 3.8.1)

		Concentration value ranges for:	
Route of exposure	**Units**	**Category 1**	**Category 2**
Oral (rat)	mg/kg body weight	C ≤ 300	2000 ≥ C > 300
Dermal (rat or rabbit)	mg/kg body weight	C ≤ 1000	2000 ≥ C > 1000
Inhalation (rat) gas	ppm V/4h	C ≤ 2500	20000 ≥ C > 2500
Inhalation (rat) vapour	mg/litre/4h	C ≤ 10	20 ≥ C > 10
Inhalation (rat) dust/mist/fume	mg/litre/4h	C ≤ 1.0	5.0 ≥ C > 1.0

Note: In the case of inhalation studies with exposure times other than 4 hours, an extrapolation to 4 hours can be performed.

If a substance meets the classification criteria for Category 1 for one route of exposure and Category 2 for another, the substance is only classified in Category 1, as required by subsection 2(2). The relevant route(s) of exposure (oral, dermal and/or inhalation) by which the substance causes specific target organ effects must be disclosed in section 11 of the safety data sheet (SDS). In addition, if there is only one relevant route of exposure and it is conclusively proven that no other routes cause the hazard, then the relevant route of exposure (oral, dermal or inhalation) must be specified in the hazard statement provided on the label and in section 2 of the SDS.

Evaluating target organ toxicity

As described in the GHS (5th revised edition, 2013, paragraphs 3.8.2.1.7.3 and 3.8.2.1.8), the following are examples of relevant toxic effects in humans and/or animals considered to support classification in Category 1 or 2:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system and in the central or peripheral nervous systems or other organs or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver). Adaptive changes or changes in organ weights with no evidence of organ dysfunction do not support classification; and

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

Effects may be seen in humans and/or animals that would not support classification in Category 1 or 2. Such effects include:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate “significant” toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant; and,

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health (subsection 2(9) of the HPR).

It is important to note that the primary target organ(s) must be identified for the evaluation of toxicity; organs in which secondary effects were observed should not be included. For example, in the case of a hepatotoxicant, data on the secondary effects that it produces in the nervous or gastro-intestinal systems should not be included in the evaluation of classification.

STOT-SE - Category 3

Classification in STOT- SE- Category 3 (respiratory tract irritation or narcotic effects) is primarily based on human data, such as occupational case reports. However, animal data can also be included in the assessment.

There must be a clear relationship between exposure and the development of signs of respiratory irritation, with respiratory irritation appearing relatively soon after the start of exposure. Symptoms of function impairment in humans could include cough, pain, choking, and breathing difficulties.

Symptoms observed in humans must be representative of those seen in the general population, rather than only in individuals with hypersensitive airways (e.g., asthma patients).

Ambiguous reports of "irritation" must be excluded as the term is commonly used to describe a wide range of sensations. Subjective human observations must be supported by objective measurements of clear respiratory tract irritation (e.g., electrophysiological responses or biomarkers of inflammation) (GHS, 5th revised edition, 2013, paragraph 3.8.2.2.1).

Clinical signs of respiratory tract irritation in animals could include dyspnea and rhinitis. Histopathology indicative of respiratory tract irritation in animals could include hyperemia, edema, minimal inflammation and thickened mucous layer (GHS, 5th revised edition, 2013, paragraph 3.8.2.2.1).

Generally, animal data for respiratory tract irritation and/or narcotic effects would be observed from acute inhalation studies where reversible clinical signs of toxicity and histopathology could be used to support classification. However, narcosis could be observed in studies with other routes of exposure (dermal and/or oral) and these observations must also be considered for classification of a substance in STOT-SE-Category 3 (narcotic effects).

Note: A solid substance which causes respiratory tract irritation due to physical or mechanical irritation when inhaled as a dust must not be considered for classification in Category 3 (respiratory irritation) (ECHA Guidance, 2015, paragraph 3.8.2.4.1).

Structure-Activity Relationships

A substance that has not been tested for specific target organ toxicity may, in certain instances, be classified in STOT-SE - Category 1, 2, or 3 on the basis of data from a validated structure activity relationship or extrapolation results from a structural analogue that has previously been classified in STOT-SE. This information, together with substantial support from other important factors such as formation of common significant metabolites could result in classification (GHS, 5th revised edition, 2013, paragraph 3.8.2.1.10.3). The potential use of (Q)SAR models for predicting effects relevant to STOT-SE - Category 1 and 2 is currently quite limited and may only be applicable in specific cases. However, they may be useful for STOT-SE - Category 3 where there are some well established relationships between physicochemical properties or chemical structure and narcosis and respiratory tract irritation. For instance, substances such as

aldehydes, unsaturated carbonic esters and reactive inorganic compounds are generally found to be respiratory tract irritants (ECHA Guidance, 2015, paragraph 3.8.2.1.2).

Discussion of the *Hazardous Products Regulations* Subsection 8.8.1(2)

Classification

8.8.1(2) Following the evaluations referred to in subsection (1), the substance is classified in one or more categories of this hazard class, based on the results of the evaluations of its toxic effects as set out in columns 1 and 2 of the following table, in accordance with the corresponding category set out in column 3:

TABLE

	Column 1	Column 2	Column 3
	Item Number of the Table to Subsection (1) that is Associated with the Criteria in Column 2 of that Table that are Determined to Have Been Met as a Result of the Evaluation of the Following:		Classification
Item	Toxic Effects on the Central Nervous System and Respiratory Tract	Toxic Effects on Other Specific Target Organs	Category of the "Specific Target Organ Toxicity – Single Exposure" Hazard Class
1	None	Item 1	Category 1
2	Item 1	None	Category 1
3	Item 1	Item 1	Category 1
4	None	Item 2	Category 2
5	Item 2	None	Category 2
6	Item 1	Item 2	Category 1
7	Item 2	Item 1	Category 1
8	Item 2	Item 2	Category 2
9	Item 3	None	Category 3
10	Item 3	Item 1	Category 1 and Category 3
11	Item 3	Item 2	Category 1 and Category 3

Since a substance is assessed for effects on other specific target organs (Category 1 or 2) **and** specific effects on the central nervous system and respiratory tract (Category 3) separately, two classifications may result. Table 2 - *Decision on classification of substances* provides the appropriate classification of a substance using the results from the initial evaluations for the CNS and respiratory tract and, toxic effects on other specific target organs. If effects are observed in the CNS and/or respiratory tract which meet classification criteria in Category 1 or 2, further classification of any transient effects in these same organ systems meeting Category 3 criteria for the same endpoint is not necessary. If classification in Category 1 or 2 is based on effects observed in a target organ(s) other than the CNS or respiratory tract, any transient effects in the CNS or respiratory tract must also be considered for a possible Category 3 classification in addition to the established Category 1 or 2.

Examination of Table 2 - *Decision on classification of substances* shows that if a substance meets the criteria:

- for Category 1 only, it must be classified as Category 1;
- for Category 2 only, it must be classified as Category 2;
- for both Category 1 and Category 2, it must be classified as Category 1; or
- for Category 3, it can be classified either as:
    - Category 3 alone, or
    - as part of classification with either Category 1 or Category 2 (e.g., final classification would be Category 1 and Category 3, or Category 2 and Category 3, depending on the other classification that applies to the substance).

Table 2. Decision on classification of substances

Toxic Effects on the Central Nervous System and Respiratory Tract	Toxic Effects on Other Specific Target Organs	Overall STOT-SE Classification
None	Category 1	Category 1
Category 1	None	Category 1
Category 1	Category 1	Category 1
None	Category 2	Category 2
Category 2	None	Category 2
Category 1	Category 2	Category 1
Category 2	Category 1	Category 1
Category 2	Category 2	Category 2
Category 3 (transient respiratory tract irritation or narcotic effects)	None	Category 3
Category 3 (transient respiratory tract irritation or narcotic effects)	Category 1	Category 1 and Category 3
Category 3 (transient respiratory tract irritation or narcotic effects)	Category 2	Category 2 and Category 3

Classification in a Category of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.8.2

Order of provisions

8.8.2 The classification of a mixture as a mixture that causes specific target organ toxicity arising from a single exposure in a category of this hazard class must proceed in accordance with the order of sections 8.8.3 to 8.8.5.

There is a "tiered" approach for classifying mixtures for STOT-SE, which means that the procedures described in sections 8.8.3 to 8.8.5 must be followed in the order in which these sections appear in the HPR. As specified in section 8.8.3, if there are test data for the mixture as a whole, these data may be used to classify the mixture. Section 8.8.4 specifies which bridging principles may be applied to the STOT-SE hazard class. Finally, section 8.8.5 specifies that classification of mixtures for STOT-SE is based on the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Section 8.8.3

Data available for mixture as a whole

8.8.3 If data of the types referred to in subparagraphs 2.1(a)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as a mixture that causes specific target organ toxicity arising from a single exposure in accordance with section 8.8.1.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is the same as for substances, and is carried out according to section 8.8.1. The discussion sections of this technical guidance corresponding to section 8.8.1, as well as the discussion section relating to the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. The data available on the mixture as a whole must be compared to the classification criteria within each category. If the data available meets the criteria in section 8.8.1, then the mixture must be classified in the category for which the criteria are met.

Discussion of the *Hazardous Products Regulations*
Section 8.8.4

Data available for use of bridging principles

8.8.4 If data are available to enable the characterization of the mixture as a mixture that causes specific target organ toxicity arising from a single exposure, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in one or more categories of this hazard class, based on the table to subsection 8.8.1(2), in accordance with those subsections.

For this hazard class, the use of bridging principles is the second step in the tiered approach for the classification of mixtures.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging

principles are discussed in more detail in subsections 2.3(1) to 2.3(8) of the HPR.

All of the bridging principles are applicable to the STOT-SE hazard class, namely: dilution, production batches, increase in concentration of hazardous ingredient, interpolation, substantially similar mixtures, and aerosols.

Discussion of the *Hazardous Products Regulations* Subsection 8.8.5(1)

Data available for ingredients – Category 1, 2 or 3

8.8.5(1) A mixture that contains one or more ingredients that are classified as a substance that causes specific target organ toxicity arising from a single exposure is classified as follows:

(*a*) in the category "Specific Target Organ Toxicity — Single Exposure — Category 1", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 1";

(*b*) in the category "Specific Target Organ Toxicity — Single Exposure —Category 2", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 2"; or

(*c*) in the category "Specific Target Organ Toxicity — Single Exposure —Category 3", if it contains at least one ingredient that is classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 3" that is

(i) at a concentration equal to or greater than the concentration at which the effect is elicited, if known,

(ii) at a concentration equal to or greater than the concentration limit of 20.0%, or

(iii) at a concentration of 1.0% or more that which, when added to the concentration of all other ingredients present individually at a concentration of 1.0% or more and classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 3", is equal to or greater than the concentration limit of 20.0%.

Following application of 8.8.3 and 8.8.4, if a classification for the mixture as a whole cannot be determined, data available for the ingredients of the mixture are considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

Since Category 1 and 2 address different hazards than Category 3, the hazard assessment for these categories must be done independently.

For mixtures, a concentration limit of ≥1% has been established when determining Category 1 or Category 2 classification. If at least one ingredient present in the mixture at a concentration of ≥ 1% is classified as STOT-SE-Category 1 or 2, then the mixture is classified as STOT-SE-Category 1 or 2, as applicable.

As outlined below, for classification in Category 1 or 2 of STOT-SE, the additive approach is not applied. That is, the concentrations of individual ingredients that fall into STOT- SE - Category 1 or 2 are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 1% concentration cut-off. However, for classification in Category 3, the additive approach is employed (see below).

When classifying mixtures based on ingredient information, ingredients which demonstrate potentiation or synergistic interactions when combined must be considered (subsection 2.4(1) of the HPR). Ingredients that are present in the mixture at < 1% concentration and cause specific target organ toxicity when combined with potentiating ingredients must also be considered for classification.

A concentration limit of ≥20% has been established for determining classification in STOT-SE-Category 3. If the mixture contains an ingredient which meets classification criteria for STOT-SE - Category 3 at a concentration ≥20%, then the mixture must be classified as STOT-SE - Category 3.

For Category 3 only, the additive approach must be applied. Concentrations of the ingredients meeting the criteria for STOT-SE - Category 3 for the same hazard (respiratory tract irritation or narcotic effects) are summed up separately, i.e., concentrations of ingredients that cause narcotic effects should not be added to the concentrations of ingredients that cause respiratory tract irritation effects. If either sum is ≥20%, then the mixture must be classified as Category 3 for that hazard.

Note: A mixture could be classified as Category 3 (respiratory tract irritation) or Category 3 (narcotic effects) or both.

Note: There are exceptions to the concentration limits established in 8.8.5(1) for classifying mixtures. Although concentration limits have been established in 8.8.5(1), when an ingredient presents the hazard at a concentration which is below the concentration limit, and the mixture contains the ingredient at or above that concentration, the mixture must be classified in the category for which it meets the criteria. Refer to section 2.5 of this technical guidance and its discussion for details.

Discussion of the *Hazardous Products Regulations*
Subsection 8.8.5(2)

Data available for ingredients – Categories 1 and 3 or 2 and 3

8.8.5(2) Despite subsection 2.2(3), a mixture that has been classified in accordance with paragraph (1)(*a*) or (*b*) and meets the criteria of paragraph (1)(*c*) is also classified in the category "Specific Target Organ Toxicity — Single Exposure — Category 3".

Subsection 2.2(3) specifies that, once the mixture is classified, the provisions that follow do not apply. Classification of mixtures for STOT-SE, in accordance with subsection 8.8.5(2), is one of the exceptions to this provision. If criteria are met for classification in Category 1 or 2

and classification in Category 3, under subsection 8.8.5(1), the mixture must be classified in Category 1 and 3 or Category 2 and 3, as appropriate. The principles described in the discussion to subsection 8.8.1(2) above, for classifying substances in both Category 1 or 2 and Category 3, would apply.

Hazard Communication

The symbols, signal words, hazard statements, and precautionary statements for STOT-SE Categories 1, 2 and 3 are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013, pp. 359-361.

Note: As part of the hazard statement, the route(s) of exposure must be specified if it has been conclusively proven that no other routes of exposure cause the effect. In order to be able to specify the route of exposure, test data need to be available for all three relevant routes (oral, dermal and inhalation) and the data must clearly indicate that only one route leads to positive results. It is estimated that such circumstances rarely, if ever, exist (ECHA Guidance, 2015, p. 368).

For both substances and mixtures, the hazard statement must include all organs affected, if known. Therefore, if the mixture is classified on the basis of information available for its ingredients, the target organs affected by the ingredients must be identified. This information must be provided on the SDS and label.

Classification of STOT-SE for Substances

Examples

Example 1: Use of valid human evidence supported by animal data (ECHA Guidance, 2015, paragraph 3.8.6.1.2)

Available data

1) Human data: There are well documented case reports of severe neurotoxic effects
2) Animal data: Severe neurotoxic effects (paralysis) were observed after single exposure to doses < 200 mg/kg bw. Rat oral LD_{50} = 3000 – 3900 mg/kg bw

Classification

STOT-SE Category 1

Rationale

The classification criteria are fulfilled based on human evidence as well as on results of animal studies at non-lethal doses.

Example 2: Use of valid animal data (ECHA Guidance, 2015, paragraph 3.8.6.1.4)

Available data

1) Human data: not available
2) Animal data: In valid animal experiments, narcotic effects (transient effect on nervous system) at ≥ 8 mg/l were observed.

Classification

STOT-SE Category 3 (Narcotic effects).

Rationale

The classification criteria for Category 3 (Narcotic Effects) are fulfilled based on well documented results in animal experiments.

Example 3: Use of valid animal data where same effect after single exposure leads to Acute Toxicity classification (ECHA Guidance, 2015, paragraph 3.8.6.2.1)

Available data

1) Human data: not available
2) Animal data: In a study in rats, severe damage in liver (macroscopic examination) and mortality in 6/10 animals were observed after a single exposure to 2,000 mg/kg bw.

Classification

No classification in STOT-SE.

Rationale

Though a specific organ is damaged, the substance must be classified in Acute Toxicity (Category 4), since lethality due to the liver impairment was observed. It is assumed that the LD_{50} is ≤ 2,000 mg/kg bw. There must not be a "double" classification for the same effect/mechanism causing lethality by impairment of a specific organ.

Classification of STOT-SE for Mixtures

Example

Application of additivity approach

Available data

No test data with respect to STOT-SE are available for the mixture as a whole.

Bridging principles cannot be applied, since no respective test data on a similar mixture are available.

The classification of the mixture is based on the classified ingredients:

Ingredient	Concentration (%w/w)	Classification
1	0.5	Not Classified
2	3.5	STOT-SE- Category 3 (Respiratory tract irritation)
3	15	STOT-SE- Category 3 (Narcotic effects)
4	15	STOT-SE- Category 3 (Narcotic effects)
5	66	Not Classified

Classification

STOT-SE- Category 3 (Narcotic effects)

Rationale

The sum of ingredients (weight/weight %) classified as Category 3 (Narcotic effects) is 15% + 15% = 30%, which is > 20%. Therefore, the mixture is classified as Category 3 (Narcotic effects).

The sum of ingredients (weight/weight %) classified as Category 3 (Respiratory tract irritation) is 3.5%, which is < 20%. Therefore, the mixture is not classified in Category 3 (Respiratory tract irritation).

Subpart 9
Specific Target Organ Toxicity – Repeated Exposure

Discussion – Specific Target Organ Toxicity Arising From Repeated Exposure (STOT-RE)

The Specific Target Organ Toxicity (STOT) classification addresses substances and mixtures that affect target organ systems of the body after either single or repeated exposure by any route (oral, dermal or inhalation) that is relevant for human exposure. The HPR addresses two different types of STOT hazards: toxicity that occurs after a **single exposure** (STOT–SE), and toxicity that occurs after **repeated exposures** (STOT-RE) to a substance or mixture. STOT-SE is discussed in Subpart 8.

Definitions

8.9 The following definitions apply in this Subpart.

"organ" includes any biological system.

"specific target organ toxicity arising from repeated exposure" means specific toxic effects on target organs that arise from repeated exposure to a mixture or substance, including all health effects liable to impair function of the body or any of its parts, whether reversible or irreversible, immediate or delayed, but excludes effects resulting from health hazards addressed by Subparts 1 to 7 and 10 of this Part.

Organ

An organ is a part of the body that carries out one or more special functions. Examples of organs include lungs, liver, eyes, blood and the central nervous system.

Specific target organ toxicity arising from repeated exposure

STOT-RE includes specific toxic effects on target organs that arise from repeated exposure to a substance or mixture, including those that can impair function of the body or any of its parts, both reversible or irreversible, immediate or delayed. Classification in STOT-RE is assigned only when specific toxic effects on target organs that arise from repeated exposure are observed and another health hazard class in the HPR does not address the observed toxicity. For example, a substance or mixture that causes skin sensitization following repeated exposure must be classified as a Skin – Sensitizer - Category 1, 1A or 1B, as appropriate, rather than in STOT-RE. However, studies that support the classification of a substance or mixture in another health hazard class must be considered in the assessment of classification for STOT-RE if they also provide evidence of specific target organ toxicity following repeated exposure.

STOT-SE is not included in the list of other health hazard classes that must be considered before a classification in STOT-RE is assigned because this hazard class applies to target organ toxicity

that arises from a **single** exposure, not a **repeated** exposure. Therefore, a substance can be classified in both STOT-RE **and** STOT-SE, if the respective criteria are met.

Classification in a Category of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Section 8.9.1

Categories

8.9.1 A substance that causes specific target organ toxicity arising from repeated exposure is classified in a category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Specific Target Organ Toxicity — Repeated Exposure — Category 1**	**A substance that** **(*a*) according to human data, causes specific target organ toxicity arising from repeated exposure; or** **(*b*) according to animal data, causes specific target organ toxicity arising from repeated exposure at low exposure concentration, within the concentration value ranges set out in Table 3.9.1 of the GHS**
2	**Specific Target Organ Toxicity — Repeated Exposure — Category 2**	**A substance that, according to animal data, causes specific target organ toxicity arising from repeated exposure at moderate exposure concentrations, within the concentration value ranges set out in Table 3.9.2 of the GHS**

The hazard class STOT-RE has two categories. The data required to evaluate STOT-RE for Category 1 and 2 comes either from repeated exposure in humans or from studies conducted in experimental animals. Toxicity can occur by any route that is relevant for humans (oral, dermal or inhalation). If a substance meets the classification criteria for Category 1 for one route of exposure and Category 2 for another, the substance must only be classified in Category 1, as required by subsection 2(2) of the HPR. The relevant route(s) of exposure by which the substance causes specific target organ effects must be disclosed in section 11 of the safety data sheet (SDS). In addition, if there is only one relevant route of exposure and it is conclusively proven that no other routes cause the hazard, then the relevant route of exposure (oral, dermal or inhalation) must be specified in the hazard statement provided on the label and in section 2 of the SDS.

For the classification of substances and mixtures in STOT-RE - Category 1 and 2, data from standard animal (i.e., rats or mice) studies, including 28-day, 90-day or lifetime (up to 2 years) studies that include hematological, clinico-chemical, and detailed macroscopic and microscopic examination, are considered. Data from repeat dose studies conducted in other animal species are also acceptable provided that these data provide relevant information on toxic effects on target organs/tissues.

Concentration value ranges

The dose or concentration at which effects are produced in animal studies needs to be considered to determine relevance for humans. Therefore, concentration value ranges have been established. These concentration value ranges are only applied when classifying based on animal data. The comparison to the specified concentration value ranges provides the necessary information to assign classification in the appropriate category.

The concentration value ranges from Table 3.9.1 and 3.9.2 of the GHS, which are based on a standard 90-day study conducted in rats, are reproduced in Table 1 below. Extrapolation, similar to Haber's rule for inhalation, can be done for studies of longer or shorter duration. This extrapolation for a 28-day study is also shown in Table 1. Haber's rule for inhalation states that the effective dose is directly proportional to the exposure concentration and the duration of exposure.

The assessment must be done on a case-by-case basis; for example, for a 28-day study, the concentration value ranges must be increased by a factor of three (GHS, 5th revised edition, 2013, paragraph 3.9.2.9.5). Note that adjusting the concentration value ranges for very short study durations can lead to very high concentration value ranges which are not appropriate. For example, for a four-day exposure, a guidance value of 2250 mg/kg bw/day for classification in STOT-RE - Category 2 could potentially be produced. This is above the upper LD_{50} value for Acute Toxicity – Oral – Category 4 of 2000 mg/kg bw. It does not make sense to have a guidance value for repeated dose toxicity that is above the guidance value for mortality after acute exposure.

To address this problem, a pragmatic approach is proposed. For studies with exposure durations shorter than nine days (i.e., 10% of the 90 days to which the default general guidance value applies), the guidance value used should be no greater than 10 times the default guidance value. For example, the effects in an oral range-finding study of nine days or less should be compared with a guidance value of 1000 mg/kg bw/day for STOT-RE Category 2 (ECHA Guidance, 2015, pp. 459-460).

There are no corresponding concentration value ranges for human data. Positive human data, regardless of probable dose, predominates over animal data. A substance with well-substantiated human data showing a specific target organ toxic effect after repeated exposure at very high doses must be classified in Category 1 even if there are animal data available which do not show toxicity at or below the established concentration value ranges.

Table 1. Concentration value ranges for repeat-dose exposures (adapted from: GHS, 5th revised edition, 2013, Tables 3.9.1 and 3.9.2)

		Concentration value ranges for:			
		Category 1		Category 2	
Route of exposure	**Units**	**90 day study**	**28 day study**	**90 day study**	**28 day study**
Oral (rat)	mg/kg bw/d	≤ 10	≤ 30	10 < C ≤ 100	30 < C ≤ 300
Dermal (rat or rabbit)	mg/kg bw/d	≤ 20	≤ 60	20 < C ≤ 200	60 < C ≤ 600
Inhalation (rat) gas	ppm V/6h/d	≤ 50	≤ 150	50 < C ≤ 250	150 < C ≤ 750
Inhalation (rat) vapour	mg/litre/6h/d	≤ 0.2	≤ 0.6	0.2 < C ≤ 1.0	0.6 < C ≤ 3.0
Inhalation (rat) dust/mist/fume	mg/litre/6h/d	≤ 0.02	≤ 0.06	0.02 < C ≤ 0.2	0.06 < C ≤ 0.6

bw = body weight; h = hour; d = day; C= dose/concentration

Test substances in repeat-dose animal studies are often administered in the feed or water, and the dosages are typically expressed in ppm or mg test substance/kg (feed) or mg (test substance)/litre (drinking water). Since the guidance values are expressed in mg/kg bw, a conversion from the reported value to mg/kg bw is necessary to determine whether classification criteria have been met. Occasionally, enough information is provided in the study to perform the conversion. Where the study provides insufficient detail to perform the conversion, Table 2 can be used to approximate the dose in mg/kg bw.

Table 2**.** Conversion to mg/kg bw (Table V of Registry of Toxic Effects of Chemical Substances, U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, July 1997)

Animal	Weight (g)	Food consumed (g/day)	Water consumed (ml/day)	Conversion- 1ppm in food in mg/kg bw/d	Conversion- 1ppm (mg/l) in water in mg/kg bw/d
Mouse	25	3	5	0.12	0.20
Rat (male)	250	15	25	0.06	0.10
Rat (female)	200	10	20	0.05	0.10
Rat (unspecified)	200	15	25	0.08	0.12
Rabbit	2000	60	330	0.03	0.16

Evaluating target organ toxicity

As described in GHS (GHS, 5th revised edition, 2013, paragraphs 3.9.2.7.3 and 3.9.2.8), the following are examples of relevant toxic effects in humans and/or animals considered to support classification:

(a) Morbidity or death resulting from repeated or long-term exposure;

(b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver). Adaptive changes or changes in organ weights with no evidence of organ dysfunction do not support classification; and

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

Effects may be seen in humans and/or animals that would **not** support classification. Such effects include:

a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate “significant” toxicity;

b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

c) Changes in organ weights with no evidence of organ dysfunction;

d) Adaptive responses that are not considered toxicologically relevant; and,

e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health (subsection 2(9) of the HPR).

A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified in STOT–RE Category 1 or 2 on the basis of data from a validated structure activity relationship or extrapolation results from a structural analogue that has previously been classified, together with substantial support from consideration of other important factors such as formation of common significant metabolites (GHS, 5th revised edition, 2013, paragraph 3.9.2.10.3).

It is important to note that the primary target organ(s) must be identified for the evaluation of toxicity; organs in which secondary effects were observed should not be included. For example, in the case of a hepatotoxicant, data on the secondary effects that it produces in the nervous or gastro-intestinal systems should not be included in the evaluation of classification.

Classification in a Category of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.9.2

Order of provisions

8.9.2 The classification of a mixture as a mixture that causes specific target organ toxicity arising from repeated exposure in a category of this hazard class must proceed in accordance with the order of sections 8.9.3 to 8.9.5.

There is a "tiered" approach for classifying mixtures for STOT-RE, which means that the procedures described in sections 8.9.3 to 8.9.5 of the HPR must be followed in the order in which these sections appear in the HPR. As specified in section 8.9.3, if there are test data for the mixture as a whole, these data may be used to classify the mixture. Section 8.9.4 specifies which bridging principles may be applied to the STOT-RE hazard class. Finally, according to section 8.9.5, if there are no test data available for the mixture as a whole and bridging principles cannot be applied, then the classification of mixtures for STOT-RE is based on the evaluation of available test data for the individual ingredients of the mixture using concentration cut-off values for the ingredients classified in this hazard class.

Discussion of the *Hazardous Products Regulations*
Section 8.9.3

Data available for mixture as a whole

8.9.3 If data of the types referred to in subparagraphs 2.1(*a*)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as a mixture that causes specific target organ toxicity arising from repeated exposure in accordance with section 8.9.1.

The first step in the tiered approach for the classification of mixtures uses data of the types referred to subparagraphs 2.1(a)(i) to (iv) of the HPR when available for the mixture as a whole. In this case, the classification procedure is the same as for substances, and is carried out according to section 8.9.1 of the HPR. The discussion sections of the technical guidance corresponding to section 8.9.1, as well as the discussion section relating to the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. The data available on the mixture as a whole must be compared to the classification criteria within each category. If the data available meets the criteria in section 8.9.1, then the mixture must be classified in the category for which the criteria are met.

Discussion of the *Hazardous Products Regulations* Section 8.9.4

Data available for use of bridging principles

8.9.4 If data are available to enable the characterization of the mixture as a mixture that causes specific target organ toxicity arising from repeated exposure, in accordance with the bridging principles referred to in subsections 2.3(3) to (8), the mixture must be classified in a category of this hazard class in accordance with those subsections.

For this hazard class, the use of bridging principles is the second step in the tiered approach for the classification of mixtures.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there are sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

All of the bridging principles are applicable to the STOT-RE hazard class, namely: dilution, production batches, increase in concentration of hazardous ingredient, interpolation, substantially similar mixtures, and aerosols.

Discussion of the *Hazardous Products Regulations* Section 8.9.5

Data available for ingredients

8.9.5 A mixture that contains one or more ingredients that are classified as a substance that causes specific target organ toxicity arising from repeated exposure is classified as follows:

(*a*) in the category "Specific Target Organ Toxicity — Repeated Exposure — Category 1", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the category "Specific Target Organ Toxicity — Repeated Exposure — Category 1"; or

(*b*) in the category "Specific Target Organ Toxicity — Repeated Exposure — Category 2", if it contains at least one ingredient at a concentration equal to or greater than the concentration limit of 1.0% that is classified in the category "Specific Target Organ Toxicity — Repeated Exposure — Category 2".

Following application of sections 8.9.3 and 8.9.4 of the HPR, if a classification for the mixture as a whole cannot be determined, data available for the ingredients of the mixture are considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

For mixtures, a concentration limit of ≥1% has been established when determining Category 1 or Category 2 classification for STOT-RE. If the mixture contains at least one ingredient which meets classification criteria for STOT-RE (Category 1 or 2) and is present in the mixture at a concentration ≥1%, then the mixture must be classified as STOT-RE - Category 1 or 2, as applicable.

As outlined below, for classification in Category 1 or 2 of STOT-RE, the additive approach is not applied. That is, the concentrations of individual ingredients that fall into STOT- RE - Category 1 or 2 are not to be added together, and the sum of the concentrations of those ingredients is not to be compared to the 1% concentration cut-off.

When classifying mixtures based on ingredient information, ingredients which demonstrate potentiation or synergistic interactions when combined need to be considered (subsection 2.4(1) of the HPR). Therefore, ingredients that are present in the mixture at < 1% and cause specific target organ toxicity when combined with potentiating ingredients must also be considered for classification.

Note: There are exceptions to the concentration limits established in section 8.9.5 for classifying mixtures. Although concentration limits have been established in section 8.9.5, when an ingredient presents the hazard at a concentration which is below the concentration limit, and the mixture contains the ingredient at or above that concentration, the mixture must be classified in the category for which it meets the criteria. Refer to section 2.5 of the HPR and its discussion for details.

Hazard Communication

The symbol, signal words, hazard statements, and precautionary statements for STOT-RE - Categories 1 and 2 are provided in Section 3 of Annex 3 of the GHS, 5th revised edition, 2013, pp. 362-363.

Note: As part of the hazard statement, the route(s) of exposure must be specified if it has been conclusively proven that no other routes of exposure cause the effect. In order to be able to specify the route of exposure, test data need to be available for all three relevant routes (oral, dermal and inhalation) and the data must clearly indicate that only one route leads to positive results. It is estimated that such circumstances rarely, if ever, exist (ECHA Guidance, 2015, p. 368).

For both substances and mixtures, the hazard statement must include all organs affected, if known. For example, if the mixture is classified on the basis of information available for its ingredients, the target organs affected by the ingredients must be identified. This information must be provided on the SDS and label.

Classification of STOT-RE for Substances

Examples

Example 1: Evaluation/classification and allocation of hazard statements with respect to specific target organs and route of exposure (ECHA Guidance, 2015, paragraph 3.9.6.1.2)**:**

Available data

1) Human data: no information available
2) Animal data:
   - LD_{50} oral, rat 132 (males) and 176 (females) mg/kg -> Acute Toxicity (Oral) - Category 3
   - LD_{50} dermal 424 (males) and 983 (females) mg/kg -> Acute Toxicity (Dermal) - Category 3
   - 4 hour LC_{50} rat 0.69 mg/l -> Acute Toxicity (Inhalation) - Category 2
   - Corrosive in animal experiments -> Skin Corrosion - Category 1

STOT-RE oral**:** 28 day rat oral (gavage) study: doses 0; 1; 10; 50 mg/kg bw/d

- 1 mg/kg: No Observable Effect Level
- 10 mg/kg: Lowest Observable Effect Level
  - Increased liver weight but not statistically significant
  - Hepatic and splenic changes
  - Diminished red blood cell counts in females, no other changes in blood chemistry
  - Histopathology: in 2/10 males and 3/10 females swelling of parenchymal cells and increased polymorphism of the hepatocyte nuclei and the nuclear cells
- 50 mg/kg:
  - Mortality (3/8 males; 3/8 females); hepato-and nephrotoxicity responsible for mortality; no distinct hepato-and nephrotoxicity described for survivors
  - Hematology: decrease in red blood cell count ca. 20% and 21% in hemoglobin both in males and females; decrease in hematocrit 11%.

STOT-RE inhalation**:** 4 week inhalation study (vapour) rats: doses 0.5; 5; and 25 mg/m^3/6h/d

- 0.5 mg/m^3: No Observed Adverse Effect Concentration (NOAEC) for local effects in the respiratory tract
- 5 mg/m^3 and 25 mg/m^3: minimal – slight focal squamous metaplasia and inflammation in the larynx
- 25 mg/m^3: NOAEC for systemic effects including hematology, clinical chemistry, histopathology and neuropathology examinations

Assessment

STOT-RE Oral: The substance has a high acute toxicity and a low cumulative potential. The cumulative potential is only a factor of 2-3 times, as calculated by comparing the oral LD_{50} dose

(132/176 mg/kg) and the 28 day lethal dose (50 mg/kg). On the other hand, there is a steep dose response in the 28-day oral study. Therefore, it can be concluded by interpolation that at 30 mg/kg (30 mg/kg = 10 mg/kg x 3, according to Haber's rule) moderate but no "significant/ severe" toxicity could be expected. By the same logic, severe effects are expected at 150 mg/kg (50 mg/kg x 3).

STOT-RE Inhalation: There were no systemic effects observed up to the highest concentration tested. Since the substance is classified as corrosive to the skin, irritation of the respiratory tract by the vapour (a local effect) is expected and was observed at a minimal to slight degree at 5 and 25 mg/m^3. It is assumed that the irritation would increase with higher concentrations. The corrosive/irritation potential is covered by the classification as Skin Corrosion - Category 1. Thus, no classification as STOT-RE with respect to the inhalation route would result.

Classification

STOT-RE – Category 2

Rationale

For a 28-day study, the GHS concentration value range for Category 2, adjusted according to Haber's rule, is 30-300 mg/kg/day. Significant effects were observed in the oral 28-day study for this substance at 50 mg/kg. These significant effects are not expected below 30 mg/kg/day, the adjusted concentration value limit for Category 1. Therefore, the substance must be classified in STOT-RE - Category 2 for the oral route, with the liver and kidneys as the target organs.

Classification for the inhalation route is not warranted, since at the highest concentration tested (25 mg/m^3), only local effects were observed. The local effects (corrosivity/irritation) would be covered by the Skin Corrosion – Category 1 classification.

Labelling

The substance is classified as STOT-RE via the oral route, but not the inhalation route. In addition, specific toxicity has not been conclusively excluded for the dermal route (it can be expected due to high dermal absorption and classification as Acute Toxicity - Dermal - Category 3). Therefore, the hazard statement for STOT-RE must be applied without specifying a route. The hazard statement would be the following: "May cause damage to liver and kidneys through prolonged or repeated exposure".

Example 2: Evaluation/classification for mechanisms not relevant to humans (ECHA Guidance, 2015, paragraph 3.9.6.2.1)

Available data

1) Human data: no information available
2) Animal data: The only available data relate to a number of oral dose studies (up to 90 days duration) in rodents. In rats, the liver, thyroid and kidneys are the target organs for repeated dose toxicity. For the liver, increases in weight and changes in enzyme activity are seen in rats at exposure levels of 36 mg/kg/day or more. These effects are considered part of an

adaptive response to an increase in metabolic demand. At higher exposure levels (around 360 mg/kg/day), single cell necrosis was observed in rats.

Increased thyroid weight was observed in a 90-day study only at the highest exposure level tested, 625 mg/kg/day. Histopathologically, lesions such as hyperplasia have been observed down to the lowest exposure levels tested (e.g., 0.4 mg/kg/day) with an exposure related increase in severity. However, the severity only ranged from "mild" to "moderate" even with an increase in exposure of three orders of magnitude. The thyroid changes (increased weight, and follicular hypertrophy and hyperplasia) are considered to occur as a result of repeated stimulation of this organ caused by the well-characterized negative feedback control effect arising from plasma T4 depletion. This repeated stimulation is related to an increase in the activity of hepatic UDPG-transferase. Humans, unlike rodents, possess a T4 binding protein that greatly reduces susceptibility to plasma T4 depletion and thyroid stimulation.

No adverse renal effects were seen in male and female rats at 0.4 mg/kg/day in a 90-day study. Inner medullary tubular dilatation in the kidneys was seen at 4 mg/kg/day in females only. These lesions were slight, with changes increasing only marginally in severity and incidence at higher dose levels (up to 420 mg/kg/day for females). An exposure-related increase in the incidence and severity of a mixed population of interstitial inflammatory cells, tubular regeneration and minimal degenerative changes in the tubular epithelium was seen in treated males and females at 10 mg/kg/day or more. At 10 mg/kg/day, the severity of these changes was graded as 'trace', and even at the highest exposure level (625 mg/kg/day) the severity was only 'mild'. Mechanistic studies indicate deposition of β2μ globulin in proximal convoluted tubules, and this may be the primary mechanism for renal toxicity in male rats.

Classification

No classification for STOT-RE

Rationale

Effects on the liver justifying the classification (necrosis) are observed at a dose (360 mg/kg/day) that is above the concentration value ranges (10-100 mg/kg/day). Effects observed on the thyroid are specific for the rat and do not justify classification. Data regarding effects on the kidneys at doses around the concentration value ranges are not detailed enough to justify classification in any category.

Classification of STOT-RE for Mixtures

Examples

Example 1: Data are available for the complete mixture (ECHA Guidance, 2015, paragraph 3.9.6.3.1)

Available data

A mixture has been tested in a valid 90-day oral study. At 90 mg/kg/day, severe liver damage (necrosis) was observed, and at 30 mg/kg/day, slight to moderate liver impairment was seen. The No Observed Adverse Effect Level was 9 mg/kg/day.

Classification

STOT-RE-Category 2

Rationale

Data is available from a valid, appropriate animal study for the complete mixture. Therefore, the criteria for substances are applied. Severe effects observed at 90 mg/kg/day in a 90-day study falls within the concentration value ranges for STOT-RE - Category 2 (10-100 mg/kg/day).

Example 2: Data are available for the ingredients of a mixture

Available data

No test data with respect to STOT-RE are available for the mixture as a whole. Bridging principles cannot be applied since no respective test data on a similar mixture are available. The classification of the mixture must then be based on the ingredients:

Ingredient	Concentration (%w/w)	Classification
1	39	Not Classified
2	0.5	STOT-RE- Category 2
3	49.5	Not Classified
4	0.6	STOT-RE-Category 2

Classification

No classification for STOT-RE

Rationale

No ingredient is classified in Category 1. Therefore, the mixture cannot be classified in Category 1.

For STOT-RE, the additivity approach does not apply. No individual ingredient with a STOT-RE classification is present in the mixture at ≥ 1.0%.

Notes:

If ingredient 2 and/or 4 is potentiated or demonstrates synergistic properties when combined with another ingredient in the mixture, a STOT-RE - Category 2 may result, in accordance with subsection 2.4(1) of the HPR.

Also according to subsection 2.5(1) of the HPR, if ingredient 2 and/or 4 has demonstrated target organ effects after repeat exposure at concentrations less than 1%, the mixture must be classified as STOT-RE - Category 2.

Subpart 10
Aspiration Hazard

Definitions

8.10 The following definitions apply in this Subpart.

"aspiration toxicant" means a mixture or substance that is liable to cause aspiration toxicity.

"aspiration toxicity" includes severe acute effects, such as chemical pneumonia, varying degrees of pulmonary injury or death, following the entry of a liquid or solid directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

Discussion

Aspiration is the entry of liquid or solid materials through the mouth or nose into the trachea and lower respiratory system. Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative substance or mixture lodges in the throat (GHS, 5th revised edition, 2013, paragraph 3.10.1.4). Aspiration can also occur as the substance or mixture is vomited following ingestion. The substance or mixture is swallowed, the swallowing leads to vomiting, and the resulting mixture of gastric juices and the substance or mixture enters the lungs (DGUV- Information, Fachbereich Holz und Metall, FB HM-049, Issue 11/2013).

Classification in the Category of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Section 8.10.1

Category

8.10.1 A substance that is an aspiration toxicant is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Aspiration Hazard — Category 1	A substance that (a) according to human data, produces aspiration toxicity if aspirated; or (b) in the case of a liquid hydrocarbon, has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40°C

Classification is based on human evidence of aspiration toxicity or on the viscosity of a **liquid** substance (the viscosity of solids and substances suspended in the gas phase are not considered). Although the definition of aspiration toxicity includes the entry of solids into the lower respiratory system, classification according to item 1(b) of the criteria is intended to apply to liquid substances and mixtures only (GHS, 5th revised edition, 2013, paragraph 3.10.1.6.4).

Classification based on viscosity refers to kinematic viscosity. The conversion between dynamic and kinematic viscosity is:

$$\text{Kinematic Viscosity } (mm^2/s) = \text{Dynamic viscosity (mPa.s)} / \text{Density } (g/cm^3)$$

Viscosity depends on temperature. In the case of a liquid, viscosity generally becomes lower as the temperature increases. Therefore, if the kinematic viscosity for a liquid is 20.5 mm^2/s at room temperature, the liquid must be classified in Aspiration Hazard - Category 1 based on the assumption that at 40°C (a higher temperature), the viscosity would be even lower. However, the temperature dependency of viscosity of liquids is generally not linear. Therefore, it is preferable to confirm the viscosity of the substance at 40°C (http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25jgov_en.pdf).

Classification of Aerosol/Mist Products

Aerosol and mist products need to be considered for classification unless it can be shown that the performance of the container would not allow the product to pool in the mouth. Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, and trigger and pump sprayers. The key to classifying these products is determining whether a pool of product may be formed in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is in a finely divided form, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed. Additionally, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed. Classification must also be considered when the pump mechanism can be removed and contents would be available to swallow (GHS, 5th revised edition, 2013, paragraph 3.10.1.6.5).

Animal Evidence

While a methodology for determining an aspiration hazard in animals has been developed, it has not been standardized (GHS, 5th revised edition, 2013, paragraph 3.10.1.6.2). Aspiration Hazard - Category 2, which exists under the GHS, has not been adopted in the HPR. Therefore, animal data are not considered for classification. If positive experimental evidence with animals is the only aspiration data available, then the substance is not classified.

Classification in the Category of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.10.2

Order of provisions

8.10.2 The classification of a mixture as an aspiration toxicant in the category of this hazard class must proceed in accordance with the order of sections 8.10.3 to 8.10.5.

There is a "tiered" approach for classifying mixtures for aspiration hazard, which means that the procedures described in sections 8.10.3 to 8.10.5 must be followed in the order in which these sections appear in the HPR.

Discussion of the *Hazardous Products Regulations*
Section 8.10.3

Data available for mixture as a whole

8.10.3 If data of the types referred to in subparagraphs 2.1(a)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as an aspiration toxicant in accordance with section 8.10.1.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is the same as for substances, and is carried out according to section 8.10.1 of the HPR. The discussion sections of this technical guidance corresponding to section 8.10.1, as well as the discussion section relating to the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. If the available data meets the criteria in section 8.10.1, then the mixture must be classified in Aspiration Hazard - Category 1.

Discussion of the *Hazardous Products Regulations*
Section 8.10.4

Data available for use of bridging principles

8.10.4 If data are available to enable the characterization of the mixture as an aspiration toxicant, in accordance with the bridging principles referred to in subsections 2.3(3) to (7), the mixture must be classified in accordance with those subsections. However, subsection 2.3(3) does not apply if the concentration of aspiration toxicant in the mixture is less than the concentration limit of 10.0%.

For this hazard class, the use of bridging principles is the second step in the tiered approach for the classification of mixtures.

When there is no or insufficient data on the mixture as a whole, bridging principles can be applied if there is sufficient data available on similar tested mixtures and on the individual hazardous ingredients in the mixture to adequately assess the hazards of the mixture. The bridging principles are discussed in more detail in section 2.3 of Part 2 of this technical guidance.

All of the bridging principles, except for aerosols (subsection 2.3(8) of the HPR), are applicable to the Aspiration Hazard class, namely: dilution (note that the dilution principle does not apply if the concentration of aspiration toxicant(s) in the mixture is less than 10%), production batches, increase in concentration of hazardous ingredient, interpolation, and substantially similar mixtures.

Discussion of the *Hazardous Products Regulations* Section 8.10.5

Data available for ingredients

8.10.5 A mixture that contains one or more ingredients that are classified as an aspiration toxicant is classified in the category "Aspiration Hazard — Category 1" if

(a) the sum of the concentrations of the ingredients that are present individually at a concentration of 1.0% or more and that are classified in the category "Aspiration Hazard — Category 1" is equal to or greater than the concentration limit of 10.0% and the mixture has a kinematic viscosity less than or equal to 20.5 mm^2/s, measured at 40°C; or

(b) it separates into two or more distinct layers, in one of which the sum of the concentrations of the ingredients that are present individually at a concentration of 1.0% or more and that are classified in the category "Aspiration Hazard — Category 1" is equal to or greater than the concentration limit of 10.0% and the kinematic viscosity of this layer, measured at 40°C, is less than or equal to 20.5 mm^2/s.

Following the application of sections 8.10.3 and 8.10.4 of the HPR, if a classification for the mixture as a whole cannot be determined, data available for the ingredients are considered as the final step in the tiered approach for the classification of mixtures in this hazard class.

This section considers "relevant ingredients" as ingredients that are present in concentrations of ≥ 1% unless, pursuant to subsection 2.5(1) of the HPR, there are data available that show that an ingredient present at < 1% poses an aspiration hazard at that concentration. The concentrations of all the relevant ingredients in Category 1 are added together (additivity approach) (see examples 1 and 2 of "Classification of Aspiration Hazard for Mixtures"). The sum of all the Aspiration Hazard - Category 1 ingredients must be ≥ 10.0% and the mixture must have a kinematic viscosity ≤ 20.5 mm^2/s at 40°C for the mixture to be classified in this hazard class.

Special consideration has been given to mixtures which separate into two or more distinct layers. In these cases, the entire mixture is classified in Aspiration Hazard - Category 1 if in any distinct layer the sum of the concentration of ingredients in Category 1 is ≥ 10.0% and that layer has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40°C.

Hazard Communication

The symbol, signal word, hazard statement, and precautionary statements for Aspiration Hazard - Category 1 are specified in Section 3 of Annex 3 of the GHS, 5th revised edition, p. 364. The GHS Aspiration Hazard – Category 2 has not been adopted in the HPR.

Classification of Aspiration Hazard for Substances

Example

A review of the medical literature on chemical aspiration revealed that some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans (GHS, 5th revised edition, 2013, paragraph 3.10.1.6.1).

Examples of substances included in Aspiration Hazard - Category 1 are certain aliphatic, acyclic and aromatic hydrocarbons, turpentine and pine oil.

Available data

Substance X is a hydrocarbon with a kinematic viscosity of 0.76 mm^2/s at 25°C.

Human case reports indicate “may cause chemical pneumonia if swallowed”.

Classification

Aspiration Hazard - Category 1

Rationale

The kinematic viscosity test result meets the criterion in Item 1(b) of the table to section 8.10.1– as it can be assumed that at a higher temperature of 40°C, the viscosity would only be lower. Available human data provides supporting evidence for classification.

Classification of Aspiration Hazard for Mixtures

Examples

Example 1:

Available data

Human data for a mixture as a whole is not available and bridging principles cannot be applied. Therefore, classification is based on the ingredients in the mixture. The mixture is not a liquid hydrocarbon. The mixture has a kinematic viscosity of 17 mm^2/s at 40°C.

Data for the components of the mixture:

Component	Concentration (w/w)%	Classification
A	1.5	Aspiration Hazard - Category 1
B	9.5	Aspiration Hazard - Category 1
C	8	Not Classified
D	15	Not Classified
E	66	Not Classified

Classification

Aspiration Hazard - Category 1

Rationale

Components C, D and E are not classified as aspiration hazards and therefore are not considered.

Components A and B are present at 1.5% and 9.5%, respectively, which are greater than the 1% cut-off concentration for a relevant ingredient.

Applying the additivity approach, the sum of Category 1 ingredients (Components A and B) is 11%. This value exceeds the concentration cut-off of 10%, as set out in paragraph 8.10.5 (a) of the HPR, and the kinematic viscosity of the mixture is ≤ 20.5 mm^2/s at 40°C.

Example 2:

Available data

Human data for a mixture as a whole is not available and bridging principles cannot be applied. Therefore classification is based on the ingredients in the mixture. The mixture is not a liquid hydrocarbon.

Data for the components of the mixture:

Component	Concentration (w/w)%	Classification
A	0.9	Aspiration Hazard - Category 1
B	9.2	Aspiration Hazard - Category 1
C	8.9	Not Classified
D	15	Not Classified
E	66	Not Classified

Classification

Not classified

Rationale

Components C, D and E are not classified as aspiration hazards and therefore are not considered.

The concentration of Component A is less than 1%, and there is no evidence that it poses an aspiration hazard at or below its concentration in the mixture, therefore it is not considered in the summation.

Component B is present at 9.2%, which is greater than the 1% cut-off concentration for a relevant ingredient, but is not ≥ 10% as set out in paragraph 8.10.5 (a) of the HPR.

Subpart 11
Biohazardous Infectious Materials

Biohazardous Infectious Materials is not a health hazard class in the GHS, but it has been retained in the HPR to maintain the previous level of worker protection. There is no hazard class for biohazardous infectious materials in the HCS 2012 since these materials in the work place are not regulated by that standard.

Discussion of the *Hazardous Products Regulations*
Section 8.11

Definition of "biohazardous infectious material"

8.11 In this Subpart, "biohazardous infectious material" means any microorganism, nucleic acid or protein that causes or is a probable cause of infection, with or without toxicity, in humans or animals.

Biohazardous infectious materials are materials that contain one or more of the following and that cause or are likely to cause infection in humans or animals:

- Microorganisms (e.g., bacteria, fungi, protozoa);
- Nucleic acid (e.g., viruses, retroviruses); and
- Protein (e.g., prions).

To classify a material as a biohazardous infectious material, the supplier must have information that the material contains a microorganism, nucleic acid, or protein that causes or is a probable cause of infection in humans or animals. If the supplier does not know or is uncertain as to whether a material contains such a microorganism, nucleic acid or protein, the material should not be classified in the Biohazardous Infectious Materials hazard class.

Distribution of diagnostic samples (such as blood, feces, sputum, urine, organs, or body tissue) for which the infectious status is unknown need not be classified in the Biohazardous Infections Materials hazard class. However, if the infectious status is known, such as blood containing HIV, then the product is classified. Note, however that a number of exceptions apply specifically to products classified in this hazard class.

Classification in the Category of the Class

Classification of substances

Discussion of the *Hazardous Products Regulations*
Subsection 8.11.1

Category

8.11.1 A substance that is a biohazardous infectious material is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	**Category**	**Criteria**
1	**Biohazardous Infectious Materials — Category 1**	**A biohazardous infectious material that** **(a) falls into "Risk Group 2", "Risk Group 3" or "Risk Group 4", as defined in subsection 3(1) of the *Human Pathogens and Toxins Act*; or** **(b) has been shown to be a cause or probable cause of infection or infection and toxicity in animals**

Other Applicable Definitions

The following definition of "Risk Group Classification" appears in subsection 1(1) of the HPR and is also discussed in Part 1 of this technical guidance.

"Risk group classification" means, in relation to the "Biohazardous Infectious Materials" health hazard class, classification in Risk Group 2, Risk Group 3 or Risk Group 4 as defined in subsection 3(1) of the *Human Pathogens and Toxins Act*.

Discussion – Risk Group Classification

Under the *Human Pathogens and Toxins Act* (HPTA), human pathogens are divided into four risk groups. Only three of these risk groups are relevant to classification under the HPR. Criteria for determining the risk group of a pathogen is based upon characteristics, such as:

- Pathogenicity – capacity to cause disease in humans/animals (hosts)
- Virulence – severity of disease in an infected host
- Infectious dose – amount of pathogen or number of organisms required to cause an infection in the host
- Mode of transmission – path travelled to infect person/animals (e.g., direct contact, aerosolized droplets)
- Route of infection – route of entry into the host (e.g., ingestion, inhalation)
- Host range – number of species that pathogen can infect
- Availability of effective preventive measures (e.g., vaccines)

- Availability of effective treatment (e.g., antibiotics, antivirals)
- Survival in the environment – stability of the pathogen outside the host.

The following terms are used in this Part, but their formal definitions appear in subsection 3(1) of the HPTA:

- Risk Group 2
- Risk Group 3
- Risk Group 4

"Risk Group 2" means a category of human pathogens that pose a moderate risk to the health of individuals and a low risk to public health and includes the human pathogens listed in Schedule 2. They are able to cause serious disease in a human but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of disease caused by those pathogens is low.

Discussion – Risk Group 2

Risk Group 2 pathogens represent a moderate individual risk and a low community risk. They are listed in Schedule 2 of the HPTA and include:

- bacteria such as *Bordetella pertussis* (causes whooping cough) and *Salmonella spp;*
- viruses such as those that cause Hepatitis A, B, C, D and E;
- fungi such as *Aspergillis niger* (causes fungal ear infections);
- protozoa such as *Plasmodium falciparum* (causes malaria); and
- prions such as those that cause chronic wasting disease.

"Risk Group 3" means a category of human pathogens that pose a high risk to the health of individuals and a low risk to public health and includes the human pathogens listed in Schedule 3. They are likely to cause serious disease in a human. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by those pathogens is low.

Discussion – Risk Group 3

Risk Group 3 pathogens represent a high individual risk and a low community risk. They are listed in Schedule 3 of the HPTA and include:

- bacteria such as *Mycobacterium tuberculosis* (causes tuberculosis);
- viruses such as Human Immunodeficiency Disease (causes HIV/AIDS);
- fungi such as Blastomyces dermatitidis (causes blastomycosis – a lung infection); and
- prions such as Bovine Spongiform (causes mad cow disease).

Note: No protozoa are listed in Schedule 3.

"Risk Group 4" means a category of human pathogens that pose a high risk to the health of individuals and a high risk to public health and includes the human pathogens listed in Schedule 4. They are likely to cause serious disease in a human. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high.

Discussion – Risk Group 4

Risk Group 4 pathogens represent a high individual risk and a high community risk, and include:

- viruses such as Ebola virus, Marburg virus.

Note: Only viruses are listed in Schedule 4 of the HPTA.

A substance is classified in Biohazardous Infectious Material – Category 1 if it meets Risk Group 2, 3, or 4, as defined in subsection 3(1) of the HPTA. In practice, this means that a substance could meet the definition of Risk Group 2, 3 or 4 but may not be listed on either Schedule 2, 3 or 4 of the HPTA. If the material is not listed on any of these Schedules in the HPTA, it must be classified based on available data that shows that the material causes or has the probability of causing infection or toxicity and infection in humans or animals.

Classification in the Category of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Subsection 8.11.2

Mixture containing more than one biohazardous infectious material

8.11.2 A mixture that contains one or more ingredients that are classified as a biohazardous infectious material must be classified in accordance with section 8.11.1.

Subsection 8.11.2 indicates that there are no special rules, such as bridging principles, for classifying a mixture containing biohazardous infectious material as one of its ingredients. If a mixture contains at least one ingredient that meets the Biohazardous Infectious Material – Category 1 classification criteria, then the mixture must also be classified in Biohazardous Infectious Material – Category 1.

A concentration cut-off for Biohazardous Infectious Materials has not been established in the HPR, as these materials present a hazard even in miniscule amounts for which a definite number cannot be assigned.

Hazard Communication

The symbol and signal word required on the label for the Biohazardous Infectious Materials hazard class are found in Part 5 of Schedule 5 of the HPR. A hazard statement is also required,

as indicated in Part 5 of Schedule 5 of the HPR; however, the specific wording of the hazard statement has not been prescribed. The supplier must provide a hazard statement that uses wording that describes the nature of the hazard. Specific precautionary statements have not been specified either, but appropriate precautionary statements relating to general, prevention, response, storage and disposal are required under subparagraph 3(1)(d)(ii) of the HPR.

For biohazardous infectious materials, a nine-heading safety data sheet (SDS) appendix, which follows the format set out in Schedule 2 of the HPR – *Information elements on safety data sheet – Biohazardous Infectious Materials*, is required **in addition** to the 16-heading SDS detailed in Schedule 1 of the HPR – *Information elements on a safety data sheet*. This appendix must be provided immediately after the 16-heading SDS. Further information on this can be found in Part 4 of this technical guidance.

VARIANCE with HCS 2012: SDS requirements for Biohazardous Infectious Materials

HPR

An SDS is required to be provided for Biohazardous Infectious Materials (BIM).

For hazardous products classified in the Biohazardous Infectious Materials hazard class, the SDS must include not only the item numbers, headings and the content of the specific information elements listed in Schedule 1 of the HPR, but also a nine-heading SDS appendix and the content of the specific information elements listed in Schedule 2 of the HPR (for each Biohazardous Infectious Material), which provide information that specifically pertains to the material. The Schedule 1 SDS and the Schedule 2 nine-heading appendix/appendices are not two distinct SDSs; together, they constitute one SDS for this material. Subsection 4(2) of the HPR allows the omission of the specific information elements under items 12 through 15 of Schedule 1 as long as the item numbers and headings appear.

HCS 2012

There is no requirement for an SDS for biohazardous infectious materials, since HCS 2012 does not regulate these materials in the work place.

Exemptions

There are three exemptions, in subsections 5(2), 5(3) and 5(5) of the HPR, that pertain to labelling and SDS requirements for laboratory samples of hazardous products that are classified only in the Biohazardous Infectious Materials hazard class. These exemptions are discussed in Part 5 of this technical guidance.

Subpart 12
Health Hazards Not Otherwise Classified

Health Hazards Not Otherwise Classified is not a GHS health hazard class. The HCS 2012 defines "hazards not otherwise classified" (HNOC) but does not contain a hazard class for such hazards. In the HPR, unlike HCS 2012, HNOCs are classified in Health Hazards Not Otherwise Classified (Subpart 8.12 of the HPR) or Physical Hazards Not Otherwise Classified (Subpart 7.20 of the HPR), depending on the hazard presented.

Discussion of the Hazardous Products Regulations
Section 8.12

Definition of "health hazard not otherwise classified"

8.12 In this Subpart, "health hazard not otherwise classified" means a health hazard presented by a mixture or substance that is different from any other health hazard addressed by any other Subpart in this Part and that has the characteristic of occurring via acute or repeated exposure and having an adverse effect on the health of a person exposed to it, including an injury, or resulting in the death of that person.

The Health Hazards Not Otherwise Classified (HHNOC) hazard class is intended to capture health hazards which are not already covered by any of the other health hazard classes discussed in Part 8 of the HPR.

This hazard class includes adverse health effects that

- could occur through acute or repeated exposure to the substance or mixture, and
- may or may not be lethal.

However, it does not include health hazards which fall into a GHS hazard category that has not been adopted in the HPR. For example, a substance or mixture that would fall under GHS Acute Toxicity - Category 5 or GHS Skin Irritation – Category 3 should not be classified in HHNOC.

Classification in the Category of the Class

Classification of Substances

Discussion of the *Hazardous Products Regulations*
Section 8.12.1

Category
8.12.1 A substance that presents a health hazard not otherwise classified is classified in the category of this hazard class in accordance with the following table:

TABLE

	Column 1	Column 2
Item	Category	Criteria
1	Health Hazards Not Otherwise Classified — Category 1	A substance that presents a health hazard not otherwise classified

A substance is classified in HHNOC – Category 1 based on available human or animal data. If the substance meets the definition for a health hazard not otherwise classified, it must be classified in this hazard class.

Classification in the Category of the Class

Classification of Mixtures

Discussion of the *Hazardous Products Regulations*
Section 8.12.2

Order of provisions

8.12.2 The classification of a mixture as a health hazard not otherwise classified in the category of this hazard class must proceed in accordance with the order of sections 8.12.3 and 8.12.4.

There is a “tiered” approach for classifying mixtures for health hazards not otherwise classified, which means that the procedures described in sections 8.12.3 and 8.12.4 must be followed in the order in which these sections appear in the HPR.

It is important to note that the bridging principles do not apply for this hazard class.

Discussion of the *Hazardous Products Regulations* Section 8.12.3

Data available for mixture as a whole

8.12.3 If data of the types referred to in subparagraphs 2.1(a)(i) to (iv) are available for the mixture as a whole, the mixture must be classified as a health hazard not otherwise classified in accordance with section 8.12.1.

As the first step in the tiered approach for the classification of mixtures, if data of the types referred to in subparagraphs 2.1(a)(i) to (iv) of the HPR are available for the mixture as a whole, the classification procedure is the same as for substances, and is carried out according to section 8.12.1. The discussion section of this technical guidance corresponding to section 8.12.1, as well as the discussion section relating to the classification of substances in general (Part 2), are relevant to the classification of mixtures if there is data available for the mixture as a whole. If the data available meets the criteria in section 8.12.3, then the mixture must be classified in Health Hazards Not Otherwise Classified – Category 1.

Discussion of the *Hazardous Products Regulations* Section 8.12.4

Data available for ingredients

8.12.4 A mixture that contains one or more ingredients that are classified as a health hazard not otherwise classified at a concentration equal to or greater than the concentration limit of 1.0% is classified in the category "Health Hazards Not Otherwise Classified — Category 1".

As a final step, when there is no data for the mixture as a whole, then classification of the mixture must be based on available information for the ingredients in the mixture.

For classification of mixtures using data on ingredient(s), a mixture is classified in Health Hazards Not Otherwise Classified - Category 1, if it contains at least one ingredient at a concentration of greater than or equal to 1.0% that is classified in Health Hazards Not Otherwise Classified – Category 1.

Note: There are exceptions to the concentration limits established in 8.12.4 for classifying mixtures. Although concentration limits have been established in 8.12.4, when an ingredient presents the hazard at a concentration which is below the concentration limit, and the mixture contains the ingredient at or above that concentration, the mixture must be classified in the category for which it meets the criteria. Refer to section 2.5 of the HPR and its discussion for details.

Hazard Communication

For substances and mixtures that meet the criteria to be classified in HHNOC – Category 1, the following information elements are required to be provided on the label, as specified in paragraph 3(1)(d) of the HPR:

- an appropriate hazard pictogram (i.e., a hazard pictogram from Schedule 3 of the HPR that is applicable to the hazard);
- the signal word “Danger”;
- hazard statement(s) that are appropriate to the hazard (i.e., statements that describes the nature of the hazard); and
- appropriate precautionary statements.

As specified in item 2(b) of Schedule 1 of the HPR, these information elements must also be provided on the SDS.

Under item 2(a) of the SDS, the hazard classification (for example, HHNOC-Category 1) or a description of the hazard identified is required.

Classification of a Health Hazard Not Otherwise Classified for Mixtures

Example

Available data

Data for the mixture as a whole is not available. Therefore, classification is based on data for the ingredients of the mixture, as follows:

Ingredient	Concentration (w/w)%	Classification
A	0.6	Health Hazards Not Otherwise Classified - Category 1
B	96.9	Not Classified
C	2	Not Classified
D	0.5	Health Hazards Not Otherwise Classified - Category 1

Classification

Not Classified

Rationale

Ingredients B and C are not classified as HHNOC therefore are not considered when classifying the mixture.

Ingredients A and D are both classified in Health Hazards Not Otherwise Classified - Category 1. Their combined concentration is 1.1% (> 1.0%). However, the additive approach does not apply to this hazard class. Neither ingredient A nor D is in the mixture above the established concentration cut-off of 1.0%. There are no data indicating that either ingredient A or D presents a health hazard not otherwise classified at the concentration at which they are present in the mixture. Therefore, subsection 2.5(1) of the HPR does not apply. Thus, the mixture is not classified in Health Hazards Not Otherwise Classified – Category 1.

APPENDIX A

Confidential Business Information

The Workplace Hazardous Materials Information System (WHMIS) requires that suppliers provide employers with the necessary information for the safe use of hazardous products in Canadian workplaces. This goal is accomplished through product labels and Safety Data Sheets (SDS), as legislated under the *Hazardous Products Act* (HPA) and its associated regulation, the *Hazardous Products Regulations* (HPR). If a product is classified as a hazardous product but certain information required to be disclosed on the SDS or label is considered confidential business information (CBI) or a trade secret by a supplier or employer, a claim may be filed with Health Canada to protect this information from disclosure under the *Hazardous Materials Information Review Act* (HMIRA). Both suppliers and employers may apply for an exemption from disclosure. **Health Canada conducts a post-market review of each application to ensure that while the CBI is protected, the hazard and safe use information required by the HPR is still provided to workplaces through the end-resulting compliant label and SDS.** As a result, this mechanism balances workers' right-to-know with industry's need to protect trade secrets. CBI protection remains largely the same under WHMIS 2015 as it was under WHMIS 1988.

VARIANCE with HCS 2012: Confidential Business Information

HPR

In Canada, the HMIRA sets out a process by which requests to protect CBI are filed with Health Canada for approval. These requests must be filed before market access, and involve a post-market review of the compliance status of the product's SDS and label, as well as a decision on the validity of the claim.

HCS 2012

The US OSHA HCS generally allows the same pieces of information to be protected as CBI as is allowed by the HPA and its associated regulations. However, the mechanism by which CBI can be protected is very different. Under the US OSHA HCS, there is no requirement to make a submission to OSHA for permission to protect a particular piece of CBI.

The CBI Legislation

The circumstances in which exemptions from disclosing CBI are permitted along with the mechanism to file are outlined in various Acts and Regulations, namely:

- **The *Hazardous Products Act* (HPA) requires certain information to be disclosed on an SDS and/or label subject to exemptions for CBI that may be claimed under the HMIRA.**

• The ***Hazardous Materials Information Review Act*** **(HMIRA)** prescribes the types of information that may be eligible for a trade secret claim, and defines the structure and function of the claims process. The HMIRA also requires Health Canada to rule on the validity of claims for exemption, to assess the compliance of the SDS or label to which a claim relates, and to administer an appeal process related to these rulings.

• The ***Hazardous Materials Information Review Regulations*** **(HMIRR)** include the criteria that must be considered when the validity of a claim of confidential business information is assessed by Health Canada, and establish the fees that apply to the filing, refiling or the appeal of a claim.

• Sections 5.7 and 5.8 of the ***Hazardous Products Regulations*** **(HPR)** prescribe for the supplier the information that must be disclosed on the supplier SDS and label which are the subject of a claim for exemption (a) upon the filing of the claim and (b) subsequent to the Health Canada ruling on the claim.

• The ***Hazardous Materials Information Review Act Appeal Board Procedures Regulations*** establishes the procedure for dealing with appeals of decisions, orders or undertakings made under the HMIRA, and conducting appeal hearings.

In their WHMIS legislation(s), the federal, provincial and territorial (FPT) occupational health and safety (OHS) agencies all designate Health Canada to oversee, review and issue decisions on claims for CBI disclosure exemption. Employers seeking trade secret protection therefore file their submission with Health Canada in accordance with their jurisdiction's regulations' reference to the HMIRA and there is no requirement to notify any FPT OHS agencies. Disclosure requirements of the HPR are also mirrored by each of the FPT OHS legislations.

- The ***Canada Labour Code*** prescribes safety requirements for federally regulated workplaces, and it is directly referred to in the HMIRA. However, the rules are generally the same as those set out by all of the other FPT OHS agencies; and
- The ***Accord Act*** prescribes safety requirements for specific offshore regulated workplaces, and it is directly referred to in the HMIRA. However, the rules are generally the same as those set out by all of the other FPT OHS agencies.

Hazardous Materials Information Review Act – Key Clauses

The HMIRA is divided into 4 key parts each pertaining to specific aspects of the CBI claim for exemption process.

A: Filing a Claim for Exemption,

B: The Claim for Exemption Review and Decision Process,

C: The Appeal Process and;

D: Confidentiality

A: Filing a Claim for Exemption

If information required to be disclosed on the SDS or label is considered by a claimant to be CBI, a claim may be filed with Health Canada to protect that information from the disclosure requirements of the HPA and HPR. The information that may be protected differs based on whether the claim is made by a supplier or an employer.

Claim for exemption by supplier

HMIRA 11(1) Any supplier who is required, either directly or indirectly, because of the provisions of the *Hazardous Products Act*, to disclose any of the following information may, if the supplier considers it to be confidential business information, claim an exemption from the requirement to disclose that information by filing with the Chief Screening Officer a claim for exemption in accordance with this section:

(a) in the case of a material or substance that is a hazardous product,

(i) the chemical name of the material or substance,

(ii) the CAS registry number, or any other unique identifier, of the material or substance, and

(iii) the chemical name of any impurity, stabilizing solvent or stabilizing additive that is present in the material or substance, that is classified in a category or subcategory of a health hazard class under the *Hazardous Products Act* and that contributes to the classification of the material or substance in the health hazard class under that Act;

(b) in the case of an ingredient that is in a mixture that is a hazardous product,

(i) the chemical name of the ingredient,

(ii) the CAS registry number, or any other unique identifier, of the ingredient, and

(iii) the concentration or concentration range of the ingredient; and

(c) in the case of a material, substance or mixture that is a hazardous product, the name of any toxicological study that identifies the material or substance or any ingredient in the mixture.

Subsection 11(1) of the HMIRA specifies the information that can be exempted from disclosure for suppliers. The information eligible for exemption is called the “subject” of the claim. The subjects are separated into two broad categories; those to protect information linked to sole ingredient products (substances), and those to protect elements of multi-ingredient products (mixtures).

A supplier may seek an exemption from disclosing information that has economic value because it is confidential. The intent of the Act is to allow suppliers to protect the exact formulation or other information that, if disclosed, would disadvantage the supplier. Note that only information required to be disclosed by the HPA and HPR is eligible for an exemption from disclosure.

For sole ingredient products (i.e., a material or substance that is a hazardous product), a supplier may seek an exemption from disclosing the identity of the ingredient (chemical name, CAS registry number, and the name of any impurities, stabilizing additives or solvents that would identify an ingredient). In this example, a supplier would, instead of disclosing the chemical name and CAS registry number of the ingredient, disclose a generic chemical name (GCN) (see subsection 5.7(5) of the HPR) on the SDS. Similarly, if there are impurities, stabilizing additives, or solvents that would otherwise be required to be disclosed but that require protection from disclosure, a supplier may file a claim to disclose a GCN in lieu of the chemical name and CAS Registry Number (if available) of the impurities, stabilizing additives, or solvents. The GCN chosen must convey as much of the chemical characteristics of the ingredient, impurity, stabilizing solvent or additive as possible, without disclosing its identity. Additional guidance on the creation of a suitable GCN can be found in Appendix A-1.

For products with multiple ingredients (i.e., a mixture that is a hazardous product), the ingredients and/or the concentrations of one or more ingredients may be considered confidential business information. Once a temporary claim exemption is granted by Health Canada, the supplier is required to reference the claim for exemption in lieu of disclosing the true concentration or true concentration range of the ingredient (see item 3(2)(d) of Schedule 1 and section 4.5 of the HPR). Note that the information provided on an SDS must not be false, misleading or likely to create an erroneous impression (see section 14.2 of the HPA). Where the ingredient concentration is the subject (or part of the subject) of the claim for exemption, a replacement range should be provided, as a best practice, in lieu of the true concentration or the true concentration range, subject to the following conditions:

- When a replacement concentration range is used on the SDS, the hazard classification must be accurate for the true concentration or the true concentration range **and** the replacement concentration range; and
- All other information provided on the SDS must be equally reflective of the true concentration or true concentration range and the replacement concentration range (e.g., the true concentration and true concentration range must be contained within the replacement concentration range).

A supplier may also claim for an exemption from disclosing the name of a toxicological study that would identify the trade-secret hazardous ingredient. Recall that in accordance with section 6.1 of the HPR, a supplier “must disclose, as soon as feasible, the source of information for any toxicological data used in the preparation of a safety data sheet on the request of an inspector, any person or government to which the hazardous product is sold or any user of a hazardous product”. However, section 6.1 of the HPR specifies that it is subject to the application of the HMIRA, such that the requested information could be withheld if a claim had been made under the HMIRA to exempt that information from disclosure.

Example:

Product Composition:

Substance	CAS Number	% (w/w)
Methanol	67-56-1	20%
Trichloroisocyanuric Acid	87-90-1	0.1%
Water	7732-18-5	79.9%

SDS Section 3: Composition/Information on ingredients

Substance	CAS Number	% (w/w)
Alcohol*	Proprietary*	Proprietary (15-30%)*
Trichloroisocyanuric Acid	87-90-1	0.1%

* HMIRA Registry Number: 3333 – Filing Date January 1, 2021

Note that the water does not require disclosure on the SDS as it does not meet any health hazard classification criteria.

Claim for exemption by employer

HMIRA 11(2) Any employer who is required, either directly or indirectly, because of the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, to disclose any of the following information may, if the employer considers it to be confidential business information, claim an exemption from the requirement to disclose it by filing with the Chief Screening Officer a claim for exemption in accordance with this section:

(a) in the case of a material or substance that is a hazardous product,

(i) the chemical name of the material or substance,

(ii) the CAS registry number, or any other unique identifier, of the material or substance, and

(iii) the chemical name of any impurity, stabilizing solvent or stabilizing additive that is present in the material or substance, that is classified in a category or subcategory of a health hazard class under the *Hazardous Products Act* and that contributes to the classification of the material or substance in the health hazard class under that Act;

(b) in the case of an ingredient that is in a mixture that is a hazardous product,

(i) the chemical name of the ingredient,

(ii) the CAS registry number, or any other unique identifier, of the ingredient, and

(iii) the concentration or concentration range of the ingredient;

(c) in the case of a material, substance or mixture that is a hazardous product, the name of any toxicological study that identifies the material or substance or any ingredient in the mixture;

(d) the product identifier of a hazardous product, being its chemical name, common name, generic name, trade-name or brand name;

(e) information about a hazardous product, other than the product identifier, that constitutes a means of identification; and

(f) information that could be used to identify a supplier of a hazardous product.

Employer claims are very similar to supplier claims. The main difference is that the intent of the submission is to allow employers to keep confidential information that must appear on an SDS where that SDS is intended to be used in their workplace. If the employer were to sell the same product to another person, rather than just using it in their workplace, they would become a "supplier" and a separate supplier claim would need to be filed with Health Canada under the HMIRA. In the case of an employer claim, the claimant seeks to protect specific information on the product that, if disclosed, would disadvantage the employer. With that intent, the HMIRA allows employers to claim for the same exemptions as suppliers, plus these additional exemptions:

- Information that would reveal the supplier of the product. This exemption includes not disclosing the actual product identifier (whether it be the chemical name, common name, generic name, trade-name or brand name). In this case, an employer must "re-brand" the product for use within its workplace(s).
- Other information that would reveal the actual product identifier or supplier. In this case, the employer must replace the information with its own coding.

Example:

Original Product

SDS Section 1: Identification

Super Sanitizer
Use: Sanitization Supplier: Brand Name Company 100 James Bay Street, Mytown Ont 123-456-7890 Emergency phone number: 1-800-XXX-XXXX

SDS Section 3: Composition/Information on ingredients

Substance	CAS Number	% (w/w)
Methanol	67-56-1	20%
Trichloroisocyanuric Acid	87-90-1	0.1%

Employer Redacted Product

SDS Section 1: Identification

Employer Sanitizing product*
Use: Sanitization Supplier: Employer's name* 13 Fedstreet, Yourtown Ont 123-000-1234 Emergency phone number: 1-800-YYY-YYYY

SDS Section 3: Composition/Information on ingredients

Substance	CAS Number	% (w/w)
Methanol	67-56-1	20%
Trichloroisocyanuric Acid	87-90-1	0.1%

*HMIRA RN: 4444 – Filing Date January 1, 2022

Manner of filing claim and fee payable

HMIRA 11(3) A claim for exemption shall be in such form and be filed in such manner as is prescribed and shall be accompanied by the prescribed fee or a fee calculated in the manner prescribed.

Contents of claim

(4) A claim for exemption shall be accompanied by the safety data sheet or label to which the claim relates and shall contain

(a) the information in respect of which the exemption is claimed;

(b) a declaration stating that the claimant believes that the information in respect of which the exemption is claimed is confidential business information that meets the criteria prescribed under paragraph 48(1)(*a*) and that information substantiating the claim — as specified in the regulations — is in the possession of, or is available to, the claimant and will be provided on request;

(c) a summary of the information substantiating the claim; and

(d) any other prescribed information.

Restriction

(5) Where a supplier or an employer files a claim for exemption in accordance with this section and the final disposition of the proceedings in relation to the claim is that the claim or a portion of the claim is not valid, the supplier or employer, as the case may be, is not entitled to file any other claim for exemption in relation to the information in respect of which the claim or portion of the claim was determined to be invalid.

Claims for exemptions must be made in writing, and can be submitted either in hard copy by mail or in electronic form through the Secure Document Exchange (SDX) system. Health Canada does not consider applications sent by email to be confidential because email is not a secure method of transmission. Electronic signatures are acceptable under the SDX.

The information required for a claim for exemption includes:

- Claimant information, including contact details for the claimant and Canadian importer, if applicable;
- Subject matter of the claim for exemption and supporting information, as applicable;
- Product information, including a description of the full composition;
- Hazard communication information, (i.e., SDS and/or label); and
- Payment information

Health Canada has developed a form that captures all information required by the HMIRA and HMIRR to file a claim. The form can be found on the Health Canada website or by e-mailing WHMIS-SIMDUT.Conf@hc-sc.gc.ca. For further guidance on a “complete application package”,

see Appendix A-2 to this section: Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form.

Claimant information

The name, address, telephone number and, if applicable, the facsimile number and electronic mail (e-mail) address of the claimant must be provided as part of the claim for exemption. If the claimant is using a third party for the purposes of managing the claim process, the name, address, telephone number and, if applicable, the facsimile number and electronic mail address of that third party, must also be included. Furthermore, in the event that the claimant is located outside of Canada, the contact information of a Canadian regulated party should also be provided. If this information is requested under subsection 14(1) of the HMIRA, the information must be provided.

Subject matter of the claim

The subject matter must be clearly indicated (i.e., chemical identity and/or concentration and/or name of a toxicological study and/or product identifier and/or supplier identifier). Where the chemical identity of an ingredient (the chemical name, the CAS number or any other unique identifier etc.) is the subject of the claim for exemption, a GCN which must be used in lieu of the actual chemical identity must also be provided. Additional guidance on the creation of a suitable GCN can be found in Appendix A-1 to this section. In addition to indicating the subject of the claim for exemption, the claimant must also indicate whether the claim is new or is being refiled for renewal. A refiled claim is defined in subsection 2(1) of the HMIRR and refers to a claim for which an exemption is sought before or after the original filing has expired (i.e., a second, third etc. filing for the same product). To be considered a refiled claim, the claim must repeat what was claimed in the previous filing. More information on refile requirements can be found in Appendix A-2 to this section.

Product information

Complete product information is required at the time of filing a claim for exemption. The composition sheet must list each ingredient, impurity, stabilizing additive and stabilizing solvent with their respective concentration in the product**.** This list includes the full chemical name and, if any, the CAS registry number and any other unique identifier of all hazardous and non-hazardous ingredients, impurity, stabilizing additive and stabilizing solvent. Health Canada's review of a claim for exemption includes a determination of all ingredient disclosure requirements. To conduct this review, Health Canada requires the full product composition (i.e., 100%). Where an ingredient may be present in a range of concentrations in the product, the actual range must be provided. The application form has been developed to enable a direct input of the full product composition. However, it is also acceptable to identify only the CBI components on the application form and submit a full product composition separately.

Hazard communication information

Because the wording of the provision is that the "claim for exemption shall be accompanied by the safety data sheet or label to which the claim relates" and a supplier can only file a CBI claim

for information required to appear on the SDS, a supplier claim must be accompanied by the SDS. In contrast, an employer can file a CBI claim for information required to appear on the label and the SDS, so both documents must be submitted with the claim if the claim relates to the label and SDS. The SDS (and label) must not be missing any information. The product identifier, composition information, and any GCNs that must appear on the SDS must also match the information submitted in the application.

In addition, claimants should also specify the basis for the development of the SDS and label by including comments such as "based on publicly available ingredient toxicological data", or "based on the classification of a similar mixture ABC using the bridging principles" and provide any and all relevant toxicological studies that were used to support the development of the SDS and label content. Where no studies were used, the claimant should detail the sources of information used to develop the SDS and label, as appropriate.

All proprietary (i.e., not publicly available) data that the claimant wishes to have Health Canada consider must be submitted at the time of filing the application.

Payment information

The claim must be presented with the prescribed fee (refer to sections 4, 5 and 7 of the HMIRR):

Claim type	**Per claim (claims 1-15)**	**Volume discount**		**Small Business (claims 1-15)**	**Small Business Volume discount**	
		claims 16-25	**>claims 25**		**claims 16-25**	**>claims 25**
Original	$1,800 each	$400 each	$200 each	$900 each	$200 each	$100 each
Refile	$1,440 each	$320 each	$160 each	$720 each	$160 each	$80 each

To be eligible for the small business fee, the claimant must have had a gross annual revenue of not more than three million dollars in the year prior to filing, and employ not more than 100 employees.

The complete application should be sent to Health Canada by courier or registered mail at:

Claims Registration
Health Canada, Healthy Environments and Consumer Safety Branch
Workplace Hazardous Materials Bureau
269 Laurier Avenue West, 8th Floor (4908B)
Ottawa, Ontario
K1A 0K9
Canada

Or by using the Secure Document Exchange (SDX) system:
https://sdx-edp.hc-sc.gc.ca/english/Account/LogOn

Additional guidance, including the requirements of a 'complete application package' and guidance on filling out the Claim for Exemption under the HMIRA Application form is available in Appendix A-2.

Once a complete application package is received by Health Canada, the claim will be assigned an HMIRA Registry Number (service standard is 7 calendar days). If an application does not have all the necessary information, the missing information may result in delays. Once the HMIRA Registry Number is issued, the claimant is granted a temporary exemption from disclosing the CBI until a final decision is made on both the claim validity and the compliance status of the SDS, and, if applicable, label. **After an HMIRA Registry Number has been issued, the product can be sold or imported into Canada** (or used in the workplace for employer claims). Note: the HMIRA Registry Number and filing date must be disclosed on the SDS and/or label (if applicable) in order for the product to be legally sold or imported into Canada (or used in a workplace in Canada for employer claims) without disclosing the confidential information (e.g., "HMIRA claim for exemption (RN XXXX) filed on dd/mm/yyyy). This HMIRA filing date allows all affected parties, inspectors, and health professionals to know that the claim is currently under review by Health Canada.

Note: when submitting a claim electronically via the SDX system, uploading/downloading may take upwards of 4 hours, and applications may not be received by Health Canada the same day uploading has begun. The service standard of 7 calendar days does not begin until Health Canada has received a complete application package.

Duties of Chief Screening Officer

HMIRA 12(1) The Chief Screening Officer shall, on receipt of a claim for exemption and the safety data sheet or label to which it relates and of payment of the required fee,

(a) cause a notice of the filing of the claim to be published in the *Canada Gazette*; and

(b) assign a screening officer to review the claim and the safety data sheet or label to which it relates.

Notice

(2) The notice referred to in paragraph (1)(a) shall contain a statement offering every affected party the opportunity to make, within the period specified in the notice, written representations to the screening officer with respect to the claim for exemption and the safety data sheet or label to which it relates.

Restriction

(3) The notice referred to in paragraph (1)(a) shall not disclose any information in respect of which the claim for exemption is made.

Once a HMIRA Registry Number is assigned to the claim, a Notice of Filing will be published by Health Canada in Part I of the *Canada Gazette.* The Notice of Filing includes only the name of the claimant, the product identifier, the subject(s) of the claim, the date of filing (the date on which the HMIRA Registry Number was assigned) and the associated HMIRA Registry Number. The

purpose of the notice is to allow any affected party - that is, a person who is not a competitor of the claimant but who uses, supplies or is otherwise involved in the use or supply of the hazardous product at a work place - the opportunity to voice a concern over the filing of the claim. No CBI is disclosed as part of the Notice of Filing.

The Chief Screening Officer subsequently assigns the claim to the screening officer who is responsible for the review of the claim and the SDS or label, as applicable.

A summary of active claims for exemption that have been filed under the HMIRA is listed on the Health Canada website. http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/hmira-lcrmd/exemption-derogation/active_claims-actives_avis/list-liste-eng.php

This list provides information about the date a claim was published in the *Canada Gazette*, as well as the date the decisions made on a claim for exemption were published in the *Canada Gazette* and the expiry date of the claim.

Duties of screening officer

HMIRA 13(1) A screening officer shall review a claim for exemption and the safety data sheet or label to which it relates in accordance with the prescribed procedures and shall

(a) decide whether, having regard to the criteria prescribed pursuant to paragraph 48(1)(a), the claim or any portion of the claim is valid; and

(b) decide whether the safety data sheet or label to which the claim relates, except to the extent that it does not disclose the information in respect of which the claim is made, complies with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be.

Substantiating information

(1.1) The screening officer may, for the purpose of determining the matter referred to in paragraph (1)(a), ask the claimant to provide the information substantiating the claim for exemption in the following circumstances:

(a) an affected party has made written representations with respect to the claim;

(b) the information contained in the summary referred to in paragraph 11(4)(c) is to be verified; or

(c) any other prescribed circumstances.

Health Canada will review each submitted claim and render a decision on its validity and on the compliance of the SDS and label, if applicable. The screening officer may be assisted by any analysis or recommendations made by regulatory and scientific personnel.

Claim Validity:

To be granted a final exemption from the full disclosure requirements of the HPA, a decision must be reached that the claim is valid. The requirements to determine claim validity are set out in section 3 of the HMIRR. Health Canada must follow the regulations to make a determination of whether:

- the information is confidential to the claimant and known only to certain people, such as:
    - designated persons employed by or in a business relationship with the claimant,
    - government officials, in compliance with regulatory reporting requirements,
    - health professionals, in situations of emergency for medical diagnosis or treatment;
- the claimant has taken measures that are reasonable under the circumstances to maintain the confidentiality of the information. For example,
    - the claimant must have alerted employees and business associates who are aware of the information that the information must be kept confidential, such as through confidentiality agreements;
    - the claimant must have physical and electronic security measures in place to safeguard the confidential business information.
- the information has actual or potential economic value to the claimant or to the claimant's competitors and disclosure of the information would result in a material financial loss to the claimant or a material financial gain to the claimant's competitors.
    - if the information represents significant developmental costs to the claimant, the money and business resources expended to develop the information (e.g., the ingredient identity or concentration in the product) may be used to further support an exemption request. Although this information can be taken into account, an exemption would not be denied on the grounds that insufficient expenses were incurred to develop the information.
- the information must be disclosed on an SDS and/or label as prescribed by the HPA. Products which are not subject to the HPA, or ingredients which are not hazardous, cannot be part of a claim for exemption under the HMIRA.

The outcome of this portion of the claim review is either a finding that the claim is valid, partially valid, invalid, or that additional information is required. The claimant may be asked to provide information to substantiate any or all of the above information. Such requests would primarily be made to verify that security measures are in place to maintain the confidentiality of the information, when inconsistencies exist with the information submitted as part of the claim, or in response to the receipt of a written representation from an affected party in respect to a claim.

SDS and Label Compliance:

The review of the SDS and label, as applicable, is based on the scientific review of physical and toxicological data and is done in accordance with the requirements of the HPA, HPR, HMIRA and HMIRR. Refer to Sections B and C of this document for more information on the requirements of the HPA and HPR.

If the claimant has proprietary data (i.e., not publicly available) they want Health Canada to consider, Health Canada will take it into consideration during the assessment of the compliance of the SDS and, if applicable, the label. As such, it is imperative that claimants submit these studies at the time of filing (i.e., with the application package).

The outcome of this portion of the claim review is either a finding that the SDS and/or label (where applicable) are compliant; or that they are non-compliant and corrective measures are required to bring the SDS and/or label (where applicable) into compliance.

Screening officer may request additional information

HMIRA 14(1) A screening officer may, for the purposes of determining any matter referred to in paragraph 13(1)(*a*) or (*b*), by registered mail, send a written notice to a claimant requesting the claimant to submit such additional information as the screening officer may require.

Claimant shall comply with request

(2) Every claimant to whom a notice referred to in subsection (1) is sent shall disclose to the screening officer, in the manner and within the period specified in the notice, any information that is requested in the notice and is in the possession of, or is available to, the claimant.

If additional information is required to make a decision on claim validity, and/or SDS or label compliance, Health Canada is authorized, pursuant to subsection 14(1) of the HMIRA, to request additional information from the claimant. In most cases, claimants will be given seven to fourteen days to produce the requested information. Although the nature of the requests varies, the following paragraphs outline the most common requests.

Typical requests related to the evaluation of claim validity:

In some instances, in accordance with section 8.1 of the HMIRR, additional information may be requested to substantiate a claim. Typically, details on the following are requested:

- Additional information to assess the confidentiality of the information that is the subject of the claim
    - Number of people with knowledge of, or who have access to, the information (the number of employees, officers or directors of the claimant who have knowledge of or access to the information; the number of persons other than the ones employed by the claimants who have knowledge of or access to the information)
    - Details of the measures implemented by the claimant to restrict knowledge of or access to the information
        - Physical security measures in place (site security)
        - Computer security measures in place (IT security)
    - Whether persons who have knowledge of the information have signed a confidentiality agreement in respect of that information

- Additional information to assess the value of the confidential business information
    - The method of calculation used to determine the values reported
    - Details on the amount of money or resources spent to develop the information.

Typical requests related to the evaluation of SDS and label compliance:

Information may be requested to assist Health Canada in the evaluation of the SDS and/or label. Typically, information is requested to clarify the composition of the product, for example:

- Generic CAS numbers:

    A generic CAS number refers to a group of related but different chemicals with different toxicological profiles. The hazard properties may vary with the form of the chemical, the molecular weight, or the number of repeating units.

    For example, silica has a generic CAS number (7631-86-9) that refers to all types of silica found. There are also eleven specific CAS numbers for silica, which may be mineral, biogenic or synthetic in origin. Silica can also be crystalline or amorphous in form.

  When a generic CAS is provided in the product composition, Health Canada may contact the claimant to identify if there is a more specific identity for that ingredient than what is represented by the generic CAS number.

- Complex mixtures:

    A “complex mixture” is defined in section 5.6 of the HPR as a mixture that has a commonly known generic name and that is:

    (*a*) naturally occurring;

    (*b*) a fraction of a naturally occurring mixture that results from a separation process; or

    (*c*) a modification of a naturally occurring mixture or a modification of a fraction of a naturally occurring mixture that results from a chemical modification process.

    For example, commercial xylene is a mixture of three isomers, the ratio depending on the source, with m-xylene predominating. It also contains ethylbenzene (6-20%), and smaller amounts of toluene, trimethylbenzene, phenol, thiophene, pyridine and non-aromatic hydrocarbons.

  When a complex mixture appears to be part of the product based on the composition information provided by the claimant, Health Canada may contact the claimant to establish if the components of the mixture were added separately or as a complex mixture. If the components were not added separately, Health Canada will only assess the complex mixture, as opposed to individual components.

Claimants are required to comply with any request for additional information made in the context of subsection 14(1) of the HMIRA. If the additional information requested is not available, Health Canada may proceed with its evaluation, but would do so by assuming the worst case scenario.

Decision in writing

HMIRA 15(1) A screening officer shall, as soon as is practicable, render a decision in writing on a claim for exemption and the safety data sheet or label to which it relates, including reasons for the decision, and shall

(a) cause a copy of the decision to be given to the claimant; and

(b) cause a notice of the decision to be given to each affected party who made written representations to the screening officer with respect to the claim for exemption or the safety data sheet or label to which it relates.

Notice of decision

(2) The notice referred to in paragraph (1)(*b*) shall contain sufficient information to indicate the purport of a decision of a screening officer and the reasons therefor but shall not disclose any information in respect of which a claim for exemption is made.

Once Health Canada has reached a decision on the validity of the claim, the compliance of the SDS and, if applicable, the label, an administrative consultation may be initiated with the claimant by sharing a "Consultation Document". A Consultation Document communicates identified issues of non-compliance to the claimant, and generally permits 30 calendar days for review and feedback. Should the findings require the claimant to disclose potentially confidential information (e.g., chemical identity and/or concentration of an ingredient), the claimant is provided the opportunity to amend the subject of the claim for exemption to add that information. The due date for feedback communicated in the Consultation Document must be adhered to by the claimant for any additional information to be taken into consideration before a final decision is issued. Where required, an extension may be granted by Health Canada if requested prior to the communicated deadline and if appropriate justification is provided.

A final decision on the validity of the claim, and the compliance of the SDS and, if applicable, the label is communicated either through:

- a Compliance letter (for a valid claim, and compliant SDS and label if applicable); or
- through a Statement of Decision and Compliance Undertaking, a document which outlines the decisions on the validity of the claim and the compliance of the SDS and, if applicable, the label. The Statement of Decisions details the rationale behind the validity and compliance decisions, as well as the corrective measures required to reach compliance, if applicable. The Compliance Undertaking is discussed further below.

Order of screening officer

HMIRA 16(1) If, under paragraph 13(1)(a), a screening officer determines that a claim or portion of a claim for exemption is not valid, the screening officer shall order the claimant to comply, in the manner and within the period specified in the order, with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act in respect of which the claim or portion of the claim for exemption was determined not to be valid.

No retrospective effect

(2) No order made under subsection (1) shall have retrospective effect.

Compliance with order

(3) Every claimant to whom an order made under subsection (1) is directed shall comply with the order in the manner and within the period specified in the order.

Deemed compliance

(4) Every claimant who complies with an order under subsection (1) in the manner and within the period specified in the order shall, for the purposes of the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, be deemed to have complied with those provisions.

If a claim does not meet the criteria laid out in section 3 of the HMIRR, it will be declared invalid by the screening officer. In cases where the exemption is sought for more than one ingredient or subject, such as identity and concentration, the claim must be declared partially valid if some of the ingredients or subjects do not meet the said criteria.

Typical examples of invalid claims include:

1. Evidence of disclosure of the proprietary ingredient in a public domain. In this case, Health Canada will order the disclosure of the information for which an exemption from disclosure is declared invalid and/or the removal of the HMIRA Registry Number, as applicable. Health Canada will request evidence that demonstrates that the order has been satisfied, and upon its receipt, will confirm that the claimant has been deemed compliant.
2. Seeking an exemption from disclosure of an ingredient that is not hazardous under the HPR. In this case, Health Canada will require the removal of the HMIRA Registry Number. Health Canada will request evidence that demonstrates that the order has been satisfied, and upon its receipt, will confirm that the claimant has been deemed compliant.

As SDS and label compliance are not related to the decision on validity, Health Canada will also assess and ensure the compliance of any SDS or label submitted with the claim.

For valid and partially valid claims, once the decision on validity and on the compliance of the SDS and label (where applicable) has been issued, the decision granted date must be disclosed on the SDS and label, where applicable, to replace the date of filing.

Example:

SDS Section 3: Composition/Information on ingredients

Substance	CAS Number	% (w/w)
Alcohol*	Proprietary*	Proprietary (15-30%)*
Trichloroisocyanuric Acid	87-90-1	0.1%

* HMIRA RN: 3333 – Decision Granted Date April 1, 2021

Undertaking

HMIRA 16.1(1) If a screening officer determines under paragraph 13(1)(b) that a safety data sheet or label to which a claim for exemption relates does not comply with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, the screening officer may send an undertaking to the claimant setting out the measures that are required to be taken for the purpose of ensuring compliance with those provisions, except to the extent that they would require the claimant to disclose the information in respect of which the claim is made, in the manner and within the period specified in the undertaking.

Agreement by claimant

(2) If the claimant agrees with the measures set out in the undertaking, the claimant shall sign the undertaking and return it to the screening officer together with the amended safety data sheet or label.

Notice

(3) On receipt of the signed undertaking, if the screening officer is satisfied, after reviewing the safety data sheet or label, that the claimant has taken the measures set out in the undertaking in the manner and within the period specified in it, the screening officer shall send a notice to the claimant confirming their compliance with the undertaking.

Deemed compliance

(4) A claimant to whom the notice is sent is, for the purposes of the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, deemed to have complied with those provisions.

In the case where a non-compliance with the HPA and/or HPR is identified with the SDS and/or label, the claimant is normally given an opportunity to first comply voluntarily. A section of the Statement of Decision is dedicated to this option and claimants are invited to sign the declaration of undertaking, and return it together with the amended SDS and/or label, typically within thirty days of the date of the decision. Upon receipt of the undertaking and a properly amended SDS and/or label, Health Canada will confirm that the SDS and/or label reviewed as part of the claim

has been deemed compliant. Where the risk to worker health and safety warrants it, Health Canada may pursue other options, in lieu of voluntary compliance, to seek to obtain necessary corrective measures more rapidly.

Order re material safety data sheet

HMIRA 17(1) If the screening officer does not receive the signed undertaking, or is not satisfied that the claimant has taken the measures set out in the undertaking in the manner and within the period specified in it, the screening officer shall order the claimant to comply with the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, except to the extent that they would require the claimant to disclose the information in respect of which the claim is made, in the manner and within the period specified in the order.

No retrospective effect

(2) No order made under subsection (1) shall have retrospective effect.

Compliance with order

(3) Every claimant to whom an order made under subsection (1) is directed shall comply with the requirements specified in the order in the manner and within the period specified in the order.

Deemed compliance

(4) Every claimant who complies with an order under subsection (1) in the manner and within the period specified in the order shall, for the purposes of the provisions of the *Hazardous Products Act*, the provisions of the *Canada Labour Code* or the provisions of the Accord Act, as the case may be, be deemed to have complied with those provisions.

When a claimant does not voluntarily make the corrections required to the SDS and/or label, Health Canada will issue an order for the claimant to do so. In such cases, the claimant is given a grace period of normally 30 days after the expiry of the appeal period following the publication of the decision and order in the *Canada Gazette* of the decision to satisfy the obligations specified in the order. Once the grace period has expired no sale or import of the product associated with the order(s), or use of the product in the workplace in the case of an employer's claim, may occur in Canada until such time as the SDS and/or label has been amended to be in compliance with the HPA and its regulations or, if applicable, the provisions of the *Canada Labour Code* or the provisions of the Accord Act. Upon receipt of an amended SDS and/or label, as per the order (i.e., in the manner and within the period specified in the order), Health Canada will confirm that the SDS and/or label has been deemed compliant. Contravening or failing to comply with any provision of the HMIRA and its related regulations or any order made under that Act may result in further compliance and enforcement actions.

The potential consequences of contravening or failing to comply with any provision of the HMIRA and its related regulations or any order made under that Act are provided in section 49 of the HMIRA.

A person who contravenes or fails to comply with any provision of the HMIRA and its regulations or any order made under that Act may be imprisoned for up to six months and/or liable to a fine of up to one hundred thousand dollars in the case of a summary conviction. In the event of proceedings by way of indictment, imprisonment could increase to up to two years and/or a fine of up to one million dollars.

Furthermore, failure to comply with the provisions of the HPA or its regulations is an offence under that Act, and the extent of punishment is provided in section 28 of the HPA. A person who contravenes a provision of the HPA may, in the case of a summary conviction, be imprisoned for not more than six months and/or liable to a fine of up to two hundred and fifty thousand dollars for a first offense and may be imprisoned not more than eighteen months and/or liable to a fine of up to five hundred thousand dollars for a subsequent offence. In the event of proceedings by way of conviction on indictment, a person may be imprisoned for not more than two years and/or liable to a fine of not more than five million dollars.

Notice

HMIRA 18(1) The Chief Screening Officer shall cause to be published in the *Canada Gazette*

(a) in respect of each decision made under section 15 and each order made under section 16 or 17

(i) a notice containing prescribed information, and

(ii) a notice containing any information that, in the opinion of a screening officer, should have been disclosed on any safety data sheet or label reviewed by the screening officer; and

(b) in respect of each undertaking for which a notice has been sent under subsection 16.1(3)

(i) a notice containing prescribed information, and

(ii) a notice containing any information that has been disclosed on any safety data sheet or label in compliance with the undertaking.

Copies

(2) The Chief Screening Officer shall make copies of any notice published in the *Canada Gazette* under subsection (1) available to any person on request in writing.

Restriction

(3) No notice referred to in subsection (1) shall disclose any information in respect of which a claim for exemption has been made.

The decisions on claim validity and SDS compliance (and label compliance, if applicable) and any required corrective measures (i.e., orders and undertakings) are made publicly available by Health Canada in Part I of the *Canada Gazette*. These public notices do not, however, contain the same level of detail as the Statement of Decision, and no CBI is disclosed through them. Each public notice does initiate and specify the period within which the decision, order or undertaking, as applicable, may be appealed. The status of the claim and the date of the decisions rendered on a claim (i.e., claim validity and SDS and label compliance) are published in the *Canada Gazette,* and the expiry date of the HMIRA Registry Number are listed on the Health Canada website in the table of active claims for exemption: http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/hmira-lcrmd/exemption-derogation/active_claims-actives_avis/index-eng.php

B: The Claim for Exemption Review and Decision Process

Exemption

HMIRA 19(1) Every person who files a claim for exemption in accordance with section 11 is, until the final disposition of the proceedings in relation to the claim for exemption, exempt from the requirement in respect of which the exemption is claimed.

Idem

(2) Where the final disposition of the proceedings in relation to a claim for exemption is that the claim or a portion of the claim is valid, the claimant is, for a period of three years beginning on the final disposition of the proceedings, exempt from the requirement in respect of which the claim or portion of the claim is determined to be valid.

Definition of "proceedings"

(3) In this section, "proceedings", in relation to a claim for exemption, means any proceedings under this Act in relation to that claim for exemption and includes proceedings commenced in the Federal Court and proceedings on any appeal from any decision of that Court.

The full claim for exemption review and decision-making process occurs following the registration of the claim for exemption. Upon issuance of a HMIRA Registry Number, a temporary exemption is granted until such time as a decision on the validity of the claim is made. If the claim is found invalid, the temporary exemption ceases. If the claim for exemption is found to be valid, an exemption is granted for three years following the end of the appeal period (i.e., after the decision is issued, published and the appeal period is over). A list of active claims is maintained on the Health Canada website at:
http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/hmira-lcrmd/exemption-derogation/active_claims-actives_avis/list-liste-eng.php

Should a claimant choose not to re-apply upon expiry of the exemption period, the Registry Number associated with the product claim is no longer valid and cannot be used or referenced. There are two options for expired claims:

- Disclose the CBI and replace any Generic Chemical Names with true chemical names and CAS registry numbers (if applicable) and concentrations where applicable, and remove the HMIRA Registry Number and the date of decision from the SDS and, where applicable, from labels; or
- Withdraw the product from the Canadian market and/or the workplace (in the case of an employer claim).

C: The Appeal Process

Right of appeal

HMIRA 20(1) A claimant or an affected party may appeal any decision or order made under section 15, 16 or 17, and an affected party may also appeal any undertaking in respect of which a notice has been published in the *Canada Gazette*.

Procedure on appeal

(1.1) An appeal shall be brought by filing with the Chief Appeals Officer, within the prescribed period, a statement of appeal setting out the grounds on which the appeal is made and any submissions in support of the appeal.

Manner of filing appeal and fee payable

(2) A statement of appeal shall be in such form and shall be filed in such manner as is prescribed and shall be accompanied by the prescribed fee or a fee calculated in the manner prescribed.

Stay of order

(3) An appeal instituted pursuant to subsection (1) in relation to an order of a screening officer made under section 16 or 17 shall stay the operation of the order.

An appeal can be filed by a claimant who makes a claim for exemption or by any affected party, as defined in subsection 2(2) of the HMIRR.

An appeal can relate to:

- decisions and orders on the validity of a claim for exemption;
- decisions and orders on the compliance of an SDS or label related to a claim for exemption; and,
- an undertaking between Health Canada and a claimant to voluntarily correct safety and health information on an SDS and/or a label found to be non-compliant.

Claimants and affected parties have 45 days to launch an appeal from the date that the Notice of Decision, Order, or Compliance Undertaking is published in the *Canada Gazette*. The procedure for dealing with appeals and conducting appeal hearings is established by the *Hazardous Materials Information Review Act Appeal Board Procedures Regulations*.

The length of the appeal process varies with the complexity of the case. For each appeal filed, a notice of appeal is published by the Appeal Board in the *Canada Gazette* to provide affected parties an opportunity to make representations to the Appeal Board.

When an appeal is launched, the requirement to comply with the decisions or order originally made about the claim is held in abeyance, pending the outcome of the appeal (see subsection 19(1), and (3) and 20(3) of the HMIRA).

The final outcome of the process in the context of the mandate of the Appeal Board is a decision by the Appeal Board to either:

- dismiss the appeal and confirm the decision, or order of the screening officer;
- allow the appeal and either vary or rescind the decision or order being appealed;
- dismiss the appeal regarding an undertaking; or
- allow the appeal regarding an undertaking and make an order that the Appeal Board considers appropriate.

In addition, an Appeal Board may order a claimant to disclose information with respect to a claim for exemption - to certain affected parties, in confidence - for reasons of health and safety in a workplace.

D: Confidentiality

Information privileged

HMIRA 46(1) Subject to this Act and any regulations made under it, all information obtained from a supplier or employer for the purposes of this Act is privileged and, despite the *Access to Information Act* or any other Act or law, no person who has obtained information from a supplier or employer for the purposes of this Act shall knowingly, without the written consent of the person who provided the information,

(a) communicate the information, or allow it to be communicated, to any person; or

(b) allow any person to inspect or to have access to any book, record, writing or other document containing that information.

Exception - administration or enforcement of Act

(1.1) A person who has obtained information from a supplier or employer for the purposes of this Act may communicate the information or allow it to be communicated, or allow inspection of or access to any book, record, writing or other document containing that information for the purposes of the administration or enforcement of this Act.

Exceptions

(2) A person who has obtained information from a supplier or employer for the purposes of this Act may communicate the information or allow it to be communicated, or allow inspection of or access to any book, record, writing or other document containing that information, to or by

(a) [Repealed, 2012, c. 31, s. 278]

(b) [Repealed, 1996, c. 8, s. 24]

(c) any official of the Department of Employment and Social Development, any appeals officer within the meaning of subsection 122(1) of the *Canada Labour Code*, or any person to whom powers, duties or functions have been delegated by the Minister of Labour under subsection 140(1) of that Act, or under an agreement entered into under subsection 140(2), of that Act, for the purposes of the administration or enforcement of Part II of that Act;

(c.1) any health and safety officer as defined in subsection 205.001(1) of the *Canada-Newfoundland and Labrador Atlantic Accord Implementation Act,* for the purposes of the administration and enforcement of Part III.1 of that Act or any health and safety officer as defined in subsection 210.001(1) of the *Canada-Nova Scotia Offshore Petroleum Resources Accord Implementation Act,* for the purposes of the administration and enforcement of Part III.1 of that Act;

(d) any official of the Department of Transport, for the purpose of making the information available in cases of medical emergency through the Canadian Transport Emergency Centre (CANUTEC) of the Department of Transport; and

(e) any official of the government of a province, for the purposes of the administration or enforcement of any law of the province relating to occupational safety and health where under the law of that province similar provisions exist to protect the confidentiality of the information obtained as a result of such communication, inspection or access.

Other exceptions

(3) A person who has obtained information from a supplier or employer for the purposes of this Act may communicate or disclose the information or cause it to be communicated or disclosed to any physician or prescribed medical professional who requests that information for the purpose of making a medical diagnosis of, or rendering medical treatment to, a person in an emergency.

Conditions

(4) No person who obtains any information pursuant to subsection (2) or (3) shall knowingly disclose that information to any other person or knowingly allow any other person to have access to that information, except as may be necessary for the purposes mentioned in that subsection.

Definition of "official"

(5) In this section, official means any person employed in or occupying a position of responsibility in the service of Her Majesty, or any person formerly so employed or formerly occupying such a position.

Any information submitted to Health Canada to support a claim will be kept confidential by Health Canada, and is not subject to the *Access to Information Act* or any other Act or law. The information will not be disclosed, except in a few key instances, including:

- The information may be used and shared for the purposes of administering or enforcing the HMIRA. This use includes, for example, sharing the product composition with a designated Health Canada toxicologist, or sharing the outcome of an evaluation of a claim (namely the information published in the *Canada Gazette*) with an inspector designated under the HPA, for enforcement actions.
- The information may also be given to the Canadian Department of Transport for the purpose of making the information available in cases of medical emergency through the Canadian Transport Emergency Centre (CANUTEC) of the Department of Transport, or in the case of a medical emergency to a physician or health professional requesting the information to make a medical diagnosis or to render medical treatment.

Transition to WHMIS 2015 as it relates to the CBI process

The transition to Workplace Hazardous Materials Information System (WHMIS) 2015, which implements the Globally Harmonized System of Classification and Labelling of Chemicals in WHMIS, does not alter the elements of the claim for exemption evaluation and process as they relate to the validity of a claim. However, the criteria used to determine the compliance of a (material) safety data sheet ((M)SDS) and label have changed significantly as the HPA has been amended, and the *Controlled Products Regulations* (CPR) have been repealed and replaced with the HPR. In addition, consequential amendments have been made to both the HMIRA and the HMIRR to reflect and support the revised HPA and HPR.

Transition began the day that the amended HPA and new HPR came into force (February 11, 2015). To allow stakeholders adequate time to prepare for the new system, a top down approach with three main phases of implementation was adopted.

Claims with a validity period beginning before the transition period remain valid for the established duration. There is no need to refile a claim with Health Canada during the validity period. There is also no need to refile a claim with Health Canada when the claimant makes the transition from WHMIS 1988 compliance to WHMIS 2015 compliance.

The claims process has not changed as a result of the transition to GHS. However, some of the forms have been amended to support the implementation of the HPR and the transition period. Of note, during the transition phase, it is necessary to indicate on the application form whether the SDS and label with the claim submission are intended to be compliant with WHMIS 1988 or with WHMIS 2015.

Note: For a certain time period, suppliers and employers making claims for exemption under the HMIRA may file claims with (M)SDS(s) and labels complying with either WHMIS 1988 or WHMIS 2015. However,

- For claims received as of **June 1, 2016**, Health Canada will only assess **supplier claims** under the HMIRA for compliance with WHMIS 2015; and
- For claims received as of **December 2017**, Health Canada will only assess **employer claims** for compliance with WHMIS 2015.

References

29 CFR 1910.1200, Hazard Communication

Hazardous Materials Information Review Act, R.S.C. 1985, c. 24 (3rd Supp.), Part III

Hazardous Materials Information Review Regulations, SOR/88-456

Hazardous Materials Information Review Act Appeal Board Procedures Regulations, SOR/91-86

Hazardous Products Act, R.S.C., 1985, c. H-3

Hazardous Products Regulations, SOR/2015-17

Appendix A-1: Developing a Generic Chemical Name (GCN)

Introduction

A claimant may seek an exemption from disclosing the identity of an ingredient. In such cases, the claimant must disclose a generic chemical name (GCN) on the SDS in lieu of the chemical identity. A GCN is a chemical name which is less specific than the chemical identity but no more general than is necessary to protect the supplier from disclosing the Confidential Business Information (CBI). A claimant should be able to explain or justify the extent of name modification necessary to protect the CBI and it must be no more general than necessary.

Guidance on Developing a Generic Chemical Name (GCN)

1.0 Purpose

The intent of this document is to provide suppliers with guidance on developing a generic chemical name (GCN) for the purpose of ingredient disclosure on safety data sheets (SDSs), for use under the *Hazardous Products Regulations* (HPR) and *Hazardous Materials Information Review Act* (HMIRA). A GCN may also be used for a non-hazardous ingredient (not required for disclosure on an SDS) so long as the SDS makes clear that the ingredient is not hazardous, or not controlled under the *Hazardous Products Act* (HPA).

2.0 Background

A supplier or employer may seek an exemption from the requirement to disclose the name of a confidential ingredient on an SDS under the HPR by filing a claim for exemption with Health Canada under the HMIRA. In such cases, the claimant must disclose a GCN on the SDS in lieu of the chemical name (HPR 5.7 (5)). The GCN also must be submitted to Health Canada as part of the claim for exemption filed under the HMIRA.

The subject of developing a GCN has produced many questions by claimants seeking to apply for an exemption.

3.0 Guidance for the derivation of a GCN

A GCN is a chemical name which is less specific than the true chemical name but no more general than is necessary to protect the Confidential Business Information (CBI). A GCN should be unique and unambiguous, and a claimant should be able to explain or justify to Health Canada, upon request, the extent of the name modification that is necessary to protect the CBI. The GCN, like all other information in the SDS, is subject to the prohibition in section 14.2 of the HPA, and as such, must not convey false or misleading information about the nature of the chemical.

3.1 Strategy for developing a GCN

Several sources for a chemical name can be used as the starting point to develop a GCN. Most chemical names are derived using systematic nomenclature such as the one developed by the International Union of Pure and Applied Chemistry (IUPAC) or from the Chemical Abstracts Service (CAS). Several sources are available to obtain systematic chemical names, such as ChemID through the National Library of Health (1), the CRC Handbook of Chemistry and Physics (2) and the Merck Index (3).

One method of developing a GCN is to use the approach set out by the *Masked Name Regulations* under the *Canadian Environmental Protection Act, 1999*. This method is useful in that it is very systematic and its application to develop a GCN as required under the HPR and HMIRA is considered acceptable by Health Canada.

A less systematic method is to mask the identity, position or number of functional groups on the chemical molecule. For example:

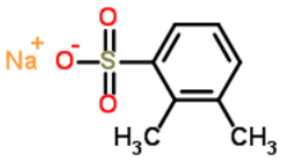
- The position and/or number and/or type of constituents can be masked;
- The parent structure and its primary functional group can be masked;
- The presence and number of other functional groups can be masked.
- Any combination of the above mentioned options

IUPAC has published documents on class names (4) which can be used to replace the parent structure and functional groups on the molecule.

The GCN should retain some aspect of the chemical structure, as well as one or more functional groups or radicals. For example, a salt should be identified and not masked if there are hazards very specific to its metal cation which are required to be disclosed on the SDS or label.

3.2 Examples of GCNs based on the outlined strategies

1. CAS Name: Sodium dimethylbenzene sulphonate (CAS no: 1300-72-7)

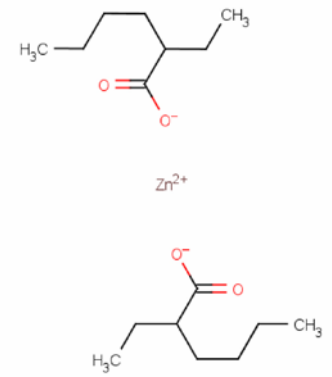


The GCN could be developed by starting with the CAS name and masking the following:

- Na+: the presence of the cation, or salt
- The two CH3 groups (alkyl groups): the specific constituents, the number of constituent groups, position of the constituent groups (positions “5” and “6” on the benzene ring), or even the presence of the constituent groups
- Benzene ring (aryl group): the parent compound

Possible GCNs include: dimethylbenzene sulphonate (salt)
dialkylbenzenesulphonate sodium salt
dialkylarylsulphonate sodium salt
dialkylarylsulphonate (salt)
alkylarylsulphonate (salt)
substituted arylsulphonate (salt)
dimethylbenzene inorganic acid, sodium salt

2. CAS Name: Hexanoic acid, 2-ethyl-, zinc salt (CAS no: 136-53-8): $2(2\text{-}(C_2H_5)C_6H_{10}O_2)Zn$



The name Hexanoic acid, 2-ethyl-, zinc salt could be used to start, or zinc bis(2-ethylhexanoate), where the bis indicates two ethylhexanoate components could be used, and the following could be masked:

- Zn^{2+}: the presence of the cation, or salt.
- The ethyl (C_2H_5) group (alkyl group): the specific constituent, position of the constituent group (the "2" position), or even the presence of the constituent groups
- Hexanoic acid (carboxylic acid group): the parent compound

Possible GCNs include: salt of an alkyl substituted carboxylic acid
alkylcarboxylic acid, zinc salt.

Keeping the identity of zinc salt would allow the linking of hazards to the organic functional group and structural features of the compound.

3.3 Common errors in developing a GCN

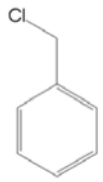
(a) Terms for product/chemical use

Terms such as dye, surfactant (even if qualified with the type such as anionic, cationic, or nonionic), catalyst, binder, colorant, emulsifier, inhibitor, or organic solvent are descriptors of product use and do not provide sufficient information on the chemical itself.

(b) Pseudo chemical names or misleading names

Syllables or masked syllables from the conventional chemical nomenclature may misrepresent a chemical structure. This includes using prefix and suffix syllables in the GCN, when these radicals or functional groups are not present in the molecule.

Juxtaposing a series of simple chemical terms such as "oxo-alcohol ether sulfate" or using creative phrases such as "oxygenated ketone" could cause confusion when considering the chemical functionality.



The order of the components of the name should usually relate to the actual chemical name. For example:

"alkylaryl halide" for chloromethylbenzene would be confusing as it indicates the halide is on the aryl (benzene) group (in this case, the GCN would be more correctly arylalkylhalide or haloalkylarene).

Where the precise structure of the reaction product is known, developing a GCN based on precursor or starting ingredient(s) of a reaction would be too ambiguous.

(c) Long descriptive phrases or a list of atoms.

Long descriptive phrases may be too general. For example, referral to a specific chemical ingredient as a "long chain hydrocarbon containing sulphur and nitrogen" gives no indication of whether the hydrocarbon is saturated, unsaturated, branched or linear; does not indicate whether the sulphur and nitrogen only have hydrogen attached to them or something more complex; and does not indicate whether sulphur or nitrogen is the main functional group, such as an amide or imide, or sulfonate or sulfoxide.

4.0 References

1. ChemID, National Library of Medicine, National Institute of Health. Available at: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
2. CRC Handbook of Chemistry and Physics, 96th Edition, Published by CRC Press, Editor(s):William M. Haynes, 2015
3. The Merck Index, 15th Edition, Royal Society of Chemistry, 2013
4. International Union of Pure and Applied Chemistry, (1995) Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure. Pure &App/. Chem., Vol. 67, Nos 819, pp. 1307-1375.

Appendix A-2: Guidelines for the Completion of the Claim for Exemption under the HMIRA Application Form

A 'complete application package' consists of the following:

- A current Health Canada Claims for Exemption Application form is used
  Note: Using the Health Canada Application form is not a mandatory requirement of the Hazardous Materials Information Review Act (HMIRA); however, the information communicated regarding a claim for exemption must clearly and consistently convey what is being claimed as CBI and address the requirements addressed in the HMIRA and the Hazardous Materials Information Review Regulations (HMIRR) (subsections 11(3)(4) of the HMIRA and sections 3, 4, 5, 6, 7 and 8 of the HMIRR).
- Product Identifier on the Claim for Exemption Application (Part III of application) must match the product identifier listed on the submitted Safety Data Sheet (SDS) and label (where applicable)
- Generic Chemical Name(s) (GCN) listed on the Claim for Exemption Application (Part VII of application) must match the Generic Chemical Name(s) used on the SDS
- What is being claimed for exemption and the basis for the claim must be clear (Part III and Part VII of the application form must match the SDS and/or label, and no essential information can be missing on the form: e.g., validity boxes must all be checked)
- Product composition must be complete (no missing chemical names, concentration totals add up to 100% or span 100% where concentration ranges are used)
- The SDS and the Claim for Exemption Application form must be complete (e.g., all pages of the SDS must be included)
- French translation of Generic Chemical Name(s) is provided
- Information required for payment of the required fee by credit card, or payment in the form of a cheque or money order is present.

The claim for exemption form is designed to capture all of the essential elements required for Health Canada to properly assess the claim. It is separated into seven Parts.

Part I: General information

The first part of the form captures the type of exemption, along with the information about the claimant. Given that the content of the form is determined by the type of claim, the first step should always be to select if the claim is a "Supplier" or "Employer" claim. If a third-party (i.e., consultant) is filing on behalf of the claimant, the third party's contact information must also be provided on the application.

Part II: Subject of Claim

The second part defines what types of applications are available (referred to from here on as the subject of the claim). Each available subject of a claim is represented by a code letter. The letter corresponding to the subject of the claim must be entered in Section III of the form, under

"Subject of the Claim". Where the application form indicates 'Chemical identity', this option encompasses the chemical name of an ingredient together with any applicable synonyms and trade names, the corresponding CAS registry number or any other unique identifier (if applicable), and any corresponding impurities, stabilizing solvents, or stabilizing additives.

Supplier Claim

A. the chemical identity of an ingredient of a hazardous product, and/or;

B. the concentration of an ingredient of a hazardous product, and/or;

C. the name of a toxicological study that identifies an ingredient of a hazardous product.

Employer Claim

D. the chemical name of an ingredient of a hazardous product, and/or;

E. the concentration of an ingredient of a hazardous product, and/or;

F. the name of a toxicological study that identifies an ingredient of a hazardous product, and/or

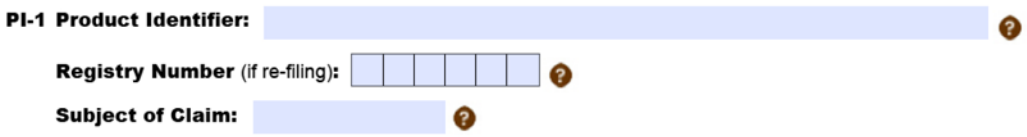
G. the product identifier, being its chemical name, common name, generic name, trade-name or brand name and/or

H. information in respect of a hazardous product, other than the product identifier, that constitutes a means of identification and/or;

I. information that could be used to identify a supplier of a hazardous product.

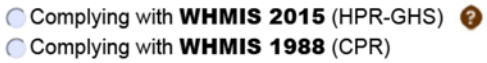
Part III: Hazardous product information

In this section, the form captures the Product Identifier (i.e., the product name), the subject of the claim (i.e., the letter code A, B, C, etc. in Part II of the form), and in case of a refiled claim, the last HMIRA Registry Number assigned to the product in the previous filing of the product.



NOTE: The product identifier must always be the same as the product name on the SDS and/or label.

During the transition period, the application must indicate whether the SDS is meant to comply with WHMIS 2015 (HPR) criteria, or with the former WHMIS 1988 (CPR) criteria.



For new claims, there is also an area to indicate the source of information used to prepare the SDS. This information helps guide Health Canada in the review of the claim. Examples of information to put in this box might be 'based on toxicological data acquired on similar product X', or 'based on publicly available sources of ingredient toxicological data', or 'based on product toxicological studies'.

Please note that all proprietary data that the claimant wishes to have Health Canada consider in their review must be submitted at the time of filing.

For re-filed claims, there is an area to confirm that the SDS and/or label submitted are compliant and reflect any previously required amendments by Health Canada. If changes have been made to the SDS since the previous filing due to availability of new information, then the sources of the new information should be indicated. For example, if a new toxicology study was found on an ingredient that would trigger a product classification change, or if product testing was done since the last filing which would modify ingredient disclosure requirements on an SDS and/or label, those items should be indicated and would explain or justify a deviation from amendments previously required by Health Canada.

Refiled claims are nonetheless a new claim for exemption, and thus a new HMIRA Registry Number is required from Health Canada.

When applying for a claim refile, and while a claim for exemption is under review, Health Canada must be informed in writing of any change in the composition of a product for which a claim has been filed. When applying for a claim refile, Health Canada may request a new filing (charged as an original claim) if the composition changes require a new evaluation of the file, or if the change requires the hazard information on the SDS/label to be revised.

When filing for more than one exemption, additional products may be added to the claim by clicking

Part IV: Information in Support of the Claim for Exemption:

The information provided in this section will be used to assess the claim validity. All information provided to Health Canada in the context of the HMIRA by CBI claimants, including financial estimates, is treated as privileged, subject to the exceptions specified in section 46 of that Act.

Questions 1 and 2 must be answered. This information, at minimum, will be used to assess the confidentiality of the claim. The estimate of the material financial loss and the estimate of the material financial gain to the competitor do not both need to be provided - only one of the two values is required. As the financial value of a product contributes to the overall validity of the claim, the screening officer has the authority to request the information to substantiate the amount indicated.

Claimants are encouraged to submit documentation with their registration package such as an explanation for the financial numbers included in the application, if they would like to streamline the registration process.

1. Is the information which is the subject of each claim considered confidential by the claimant?

○ YES ○ NO

2. Are there measures in place to ensure confidentiality?

○ YES ○ NO

Question 3 is also mandatory and used to assess the financial value of the trade secret. A claimant must either report the potential economic value and material financial loss (3A); or the economic value and the material financial gain to a competitor (3B).

3A. Economic value and material financial loss to the claimant (You must provide a value for both of i and ii below.)

Each Product Identifier (PI) entered in Part III is repeated in this Section.

PI-1

i. Estimate of the actual or potential economic value of the information to the claimant, over the time period indicated, because it is confidential. Time Period (years): Value: $

ii. Estimate of the material **financial loss** to the claimant over the same time period that would result from disclosure of the information. Loss: $

3B. Economic value and material financial gain to the claimant's competitors
(You must provide a value for both of i and ii below.)

Each Product Identifier (PI) entered in Part III is repeated in this Section.

PI-1

i. Estimate of the potential economic value of the information to the claimant's competitors, over the time period indicated, because it is confidential. Time Period (years): Value: $

ii. Estimate of the material **financial gain** to the claimant's competitors over the same time period that would result from disclosure of the information: Gain: $

The financial figures reported are often based on gross profit, contribution margins, operating income, and net income. This information should be strictly related to the business entity which files the claim and the product sales and loss in Canada; however, claimants may append additional applicable data pertaining to sales of the product by the parent company or affiliated companies in other parts of the world. Clear linkages between the claimant and the related entities must be established for the information to be considered.

Question 4 is on research and development costs and is optional. Health Canada would only use this information as evidence to support the validity of a claim.

Part V: Fee Calculation

This part of the form self-populates and is based on information entered in previous parts of the form.

The fees for a claim for exemption are prescribed in section 4 of the HMIRR. Namely:

- $1,800 for an original filing
- $1,440 for a refiled claim

If a claimant has gross annual revenue of not more than three million dollars in the last fiscal year, and employs not more than 100 employees, he is eligible for a 50% reduction. To signal small business status, section 2 of this part of the form must be completed.

Fees are payable in Canadian funds to the “Receiver General for Canada” by credit card, cheque or money order. If paid by credit card, the relevant information is recorded on the form. If paid by cheque or money order, it is important that the cheque or money order is sent with the application.

If Credit Card is the preferred method of payment, the claimant must also complete and submit a “Payment Authorization Form”.

Part VI: Declaration

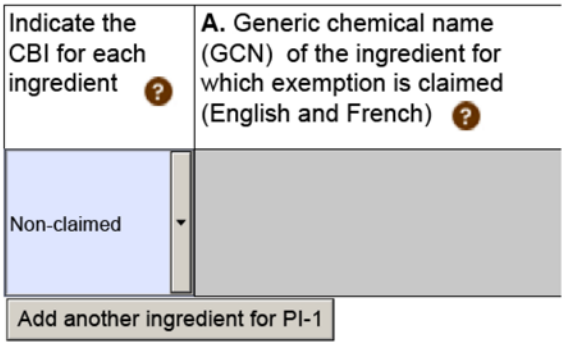
This portion of the form declares that the information is accurate, and has been completed and signed by the claimant or by an authorized representative of the claimant. Although digital signatures are accepted, all fields must be filled for the application to be processed. A third-party (i.e., consultant) filing on behalf of the claimant cannot sign on behalf of the claimant.

Part VII: Confidential Business Information

This section of the form captures the details about the CBI that is the subject of the claim for exemption.

Column 1:

Each ingredient in the product composition must be listed in Column 1 of the table. If more than one ingredient is to be listed, select, the “Add Ingredient” button located at the bottom of Column 1.



For every ingredient in the product composition, there are six categories that identify the possible subject(s) of the claim to choose from in the drop-down menu in Column 1. These categories are as follows:

-Non-claimed
-Chemical ID
-Concentration
-ID & Concentration
-ID & Study Name
-ID Conc. & Study

Non-claimed: This field should be chosen for all ingredients whose identities are not part of the subject of the claim for exemption.

Chemical ID: This option should be selected when a claimant wishes to protect the chemical identity of an ingredient. If the claimant is filing to protect the identity of multiple ingredients, this option would be selected for each ingredient to which it applies. Note that if a claimant wishes to protect both the identity and the concentration of an ingredient, then the option, “ID & Concentration”, should be selected.

Concentration: This option should be selected when a claimant wishes to protect the concentration or concentration range of an ingredient in a product. Note that if a claimant wishes to protect both the identity and the concentration of an ingredient, then the next option, i.e., “ID & Concentration”, should be selected.

ID & Concentration: This option should be selected for all ingredients for which the claimant wishes to be exempt from disclosing both the identity and concentration or concentration range of the ingredient.

ID & Study Name: This option should be selected when a claimant wishes to protect the identity of the ingredient entered, as well as the name of a study or studies that identify the ingredient.

ID Conc. & Study: Finally, this option should be selected when a claimant wishes to protect the identity and concentration of an ingredient, as well as the name of a study or studies that identify the ingredient.

Column 2:

When the claimant wishes to protect the chemical identity of an ingredient, a Generic Chemical Name (GCN) must be disclosed in place of the actual identity. When an option that includes the chemical identity is selected in Column 1, an adequate GCN in both French and English must be entered in Column 2. The GCN listed on the application form must be identical to the one listed on the submitted SDS. Should two or more of the ingredients have the same GCN, the claimant may:

- number the GCN (e.g., alkylamine 1, alkylamine 2, etc.) if one or more of the ingredients with the same GCN are referred to on the SDS in the discussion of hazards or toxicity; or
- pluralize the GCN: (e.g., alkylamines (3) to indicate that there are three alkylamines in the product). This option applies only if there is no reference on the SDS to any particular ingredient which shares the same GCN.

Column 3 and 4:

The specific chemical identity along with its CAS number, if applicable, must be provided for **all** ingredients in the product. Health Canada requires this information in order to evaluate the claim for exemption, and the compliance of the SDS and/or label.

Column 5:

The amount (in percent) of each ingredient in the product must be disclosed in this column. For an application to be considered complete, the total sum of all the ingredient concentrations listed in Column 5 must equal 100%.

If the concentration of an ingredient in the product varies from batch to batch, the true concentration range may be entered in lieu of an actual concentration, and the added sums must span 100% (e.g., 90-110%).

Column 6:

Finally, if the claimant wishes to protect the identity of a study, then the title of the study must be entered in column 6. Claiming a toxicological study for exemption under the HMIRA does not mean that the toxicological effects are exempt from disclosure. This option means that the specifics of a given study (such as the study name, or source) are CBI. In the event that a claimant has filed or was granted such a claim and receives a request pursuant to section 6.1 of the HPR for the source of information for any toxicological data provided under item 11 of the SDS, the supplier is lawfully allowed to refuse to disclose the sought information. Should all the toxicological studies not fit within the confines of the application form, a reference to an appendix where all the studies are referenced is recommended.

Application checklist:

- A complete claim for exemption form (Part I - Part VII)
- The most recent SDS and/or label, if applicable
- Fee payment based on the number and type of claim (original, refiling, small business)
- 100% composition of all (hazardous and non-hazardous) ingredients present in the product (listed in Part VII in full or submitted separately)

Submitting a Generic SDS:

Note that when submitting a claim with an associated SDS that is a generic SDS, it is imperative that the application clearly indicate to which product the claim relates. Additionally, one claim must be filed for each product, even if two (or more) products for which an exemption is sought share a single generic SDS. Consequently, all HMIRA Registry Numbers relevant to the products listed on the generic SDS must be clearly linked to the product identifiers listed on the SDS.

Submitting your application:

The complete application should be sent to Health Canada by courier or registered mail at:

Claims Registration
Health Canada, Healthy Environments and Consumer Safety Branch
Workplace Hazardous Materials Bureau
269 Laurier Avenue West, 8th Floor (4908B)
Ottawa, Ontario
K1A 0K9
Canada

Or by using the Secure Document Exchange (SDX) system:
https://sdx-edp.hc-sc.gc.ca/english/Account/LogOn

Change in Ownership:

An HMIRA Registry Number is issued to a given hazardous product. A change in the ownership of the hazardous product means a change in the claimant. Health Canada requires written notification of the change in ownership. Please contact Health Canada for further guidance on providing written notification. Upon receipt of such notification, the existing claim (product with HMIRA Registry Number) is transferred to the new owner.

Change in Product Identifier:

Note that if a product identifier is changed, either by reason of change in ownership or for any other reason, a new claim for exemption must be filed.