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

WHMIS 2015 Supplier Requirements

Phase 1

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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Guide technique sur les exigences de la *Loi sur les produits dangereux* et du *Règlement sur les produits dangereux* - SIMDUT 2015 Exigences pour les fournisseurs - Phase 1

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Publication date: June 2016

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Cat.: H129-64/2016E-PDF
ISBN: 978-0-660-05613-5
Pub.: 160058

Notice to the reader:

Phase 1 of the Technical Guidance on the Requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR) – WHMIS 2015 Supplier Requirements, includes the following sections:

Section A - Introduction

Section C - Regulatory Requirements

- Part 1 Interpretation;
- Part 2 Classification of a Product, Mixture, Material or Substance;
- Part 3 Labelling;
- Part 4 Safety Data Sheet;
- Part 6 Additional Requirements; and

Appendix A - Confidential Business Information

There are references made in Phase 1 of this Technical Guidance to content that will be made available in the Fall 2016, as part of Phase 2.

Phase 2 will include the following additional sections:

Section B - Requirements of the *Hazardous Products Act*;

Section C - Regulatory Requirements

- Part 5 Exceptions;
- Part 7 Physical Hazard Classes (includes chapters for each of the physical hazard classes in the HPR); and
- Part 8 Health Hazard Classes (includes chapters for each of the health hazard classes in the HPR).

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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 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 LD₅₀ and the LC₅₀, 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 LD₅₀ value;
- an LC₅₀ 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 LD₅₀ or LC₅₀ value of the ingredient, but knows either:

- (1) the range of values within which the LD₅₀ or LC₅₀ of the ingredient falls, or
- (2) the acute toxicity hazard category into which the ingredient falls.

Where there is no specific LD₅₀ or LC₅₀ 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 “LD₅₀” and “LC₅₀”, 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.

"LC₅₀" means the concentration of a mixture or substance in air that causes the death of 50.0% of a group of test animals.

"LC₅₀": The acronym LC stands for the term "Lethal Concentration". The number 50 in the subscript of LC₅₀ means that, in an animal study, 50% of the exposed animal population died, or was expected to have died, at the specified concentration. The LC₅₀ is one way of measuring the short-term poisoning potential (acute toxicity) of a mixture or substance.

LC₅₀ values typically relate to a 4-hour experimental exposure period via inhalation. Where LC₅₀ 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 LC₅₀ 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:

- o Combustible Dusts;
- o Simple Asphyxiants;
- o Pyrophoric Gases;
- o PHNOC;
- o HHNOC; and
- o 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 $\leq 300 \text{ s/m}^3$, 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 that 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

Health Hazard Class	Bridging Principles					
	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 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)

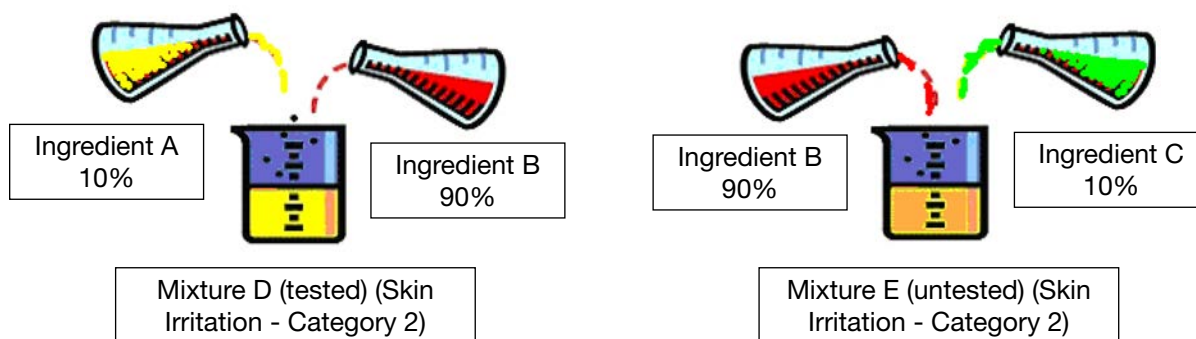
Substantially similar mixtures

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 LC₅₀ 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 is classified in Acute Toxicity – Inhalation - Category 1, 2, 3 or 4 based on the LC_{50} of an emitted gaseous substance (upon contact with water) which falls within one of the LC_{50} ranges for these hazard categories, the substance or mixture which, upon contact with water, emits the gaseous substance (also referred to as Water-Activated Toxicants or WAT) must be classified accordingly and 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 3, and which, in contact with water, releases a gaseous substance with an LC_{50} of 50 ppmV. In accordance with subsection 8.1.1(2) of the HPR, this substance would be classified in Acute Toxicity (Inhalation) - Category 1. That is, the classification would reflect the WAT hazard since the LC_{50} of the emitted gas is lower than the LC_{50} of the substance itself.



The following statements would be required:

Fatal if inhaled.

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

In another 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 LC₅₀ 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 LC₅₀ 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.



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 1 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 (e.g., corrosive to the respiratory tract). 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 LD₅₀. 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

<p>Canada WHMIS 1988 (repealed CPR)</p>	<p>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.</p> <p>Subsections 11(2) and (3) of the CPR (Range of Concentration of Ingredients)</p> <p>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.</p> <p>(3) For the purposes of subsection (2), the ranges of concentration are the following:</p> <ul style="list-style-type: none"> (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.
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<p>Canada WHMIS 2015 (HPR) (came into force on February 11, 2015)</p>	<p>Section 4.5 of the HPR:</p> <p>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.</p> <p>Section 3 of Schedule 1 of the HPR (Information Elements on Safety Data Sheet)</p> <p>(1) In the case of a hazardous product that is a material or substance,</p> <ul style="list-style-type: none">(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 <p>(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,</p> <ul style="list-style-type: none">(a) its chemical name;(b) its common name and synonyms;(c) its CAS registry number and any unique identifiers; and(d) its concentration.
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<p>U.S. HCS 2012</p>	<p>Under item 3 of Table D.1 (Minimum Information for an SDS)</p> <p>Except as provided for in paragraph (i) of §1910.1200 on trade secrets:</p> <p>For Substances</p> <ul style="list-style-type: none"> (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. <p>For Mixtures</p> <p>In addition to the information required for substances:</p> <ul style="list-style-type: none"> (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 <ul style="list-style-type: none"> (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. <p>For All Chemicals Where a Trade Secret is Claimed</p> <p>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.</p>
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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		Regulatory System		
		WHMIS 1988 (WHMIS before GHS)	WHMIS 2015 (GHS in Canada)	HCS 2012 (GHS in U.S.)
Chemical Name	Volume %			
Toluene	17%			
Acetone	32-41%			
Ingredient Concentration (No CBI)	Concentration (where concentration does not vary)	True Concentration Chemical Name Toluene Volume % 17%	True Concentration Chemical Name Toluene Volume % 17%	True Concentration Chemical Name Toluene Volume % 17%
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	Standardized Concentration Range Chemical Name Acetone Volume % 30-60%	True Concentration Range Chemical Name Acetone Volume % 32-41%	True Concentration Range Chemical Name Acetone Volume % 32-41%
CBI Protection	Concentration (where concentration does not vary)	"Trade Secret" and Registry Number (Range Optional) Chemical Name Toluene Volume % Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and Registry Number (Range Optional) Chemical Name Toluene Volume % Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" (Range Optional) Chemical Name Toluene Volume % Trade Secret
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	"Trade Secret" and Registry Number Chemical Name Acetone Volume % Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and Registry Number Chemical Name Acetone Volume % Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	CBI Claim Not Allowed Supplier must disclose True Concentration Range Chemical Name Acetone Volume % 32-41%
Alignment of Canada / U.S. Requirements		Aligned	Not Aligned	Volume % CBI Protected
		Distinct But Complementary	True Concentration / True Concentration Range Disclosed	Volume % CBI Protected



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.



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 offence 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

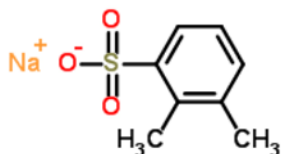
IUPAC has published documents on class names (4) which can be used to replace the parent structure and functional groups on the molecule.

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)

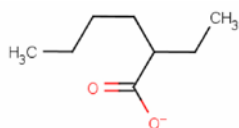
The GCN could be developed by starting with the CAS name and masking the following:



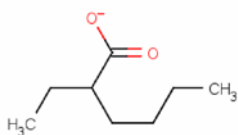
- Na⁺: the presence of the cation, or salt
- The two CH₃ groups (alkyl groups): the specific constituents, the number of constituent groups, position of the constituent groups (positions “5” and “6” on the benzene ring), or even the presence of the constituent groups
- Benzene ring (aryl group): the 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): $2(2-(C_2H_5)C_6H_{10}O_2)Zn$



Zn^{2+}



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

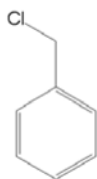
(a) Terms for product/chemical use

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.

PI-1 Product Identifier: ?

Registry Number (if re-filing): ?

Subject of Claim: ?

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.

- Complying with **WHMIS 2015** (HPR-GHS) ?
- Complying with **WHMIS 1988** (CPR)

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

Add Another Product

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.

Indicate the CBI for each ingredient ?	A. Generic chemical name (GCN) of the ingredient for which exemption is claimed (English and French) ?
Non-claimed	
Add another ingredient for PI-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.