



Health Canada WHMIS 2015 Technical Guidance Phase 1

Consumer Product Safety Directorate Healthy Environments and Consumer Safety Branch Health Canada Amira Sultan

Presentation to the Society for Chemical Hazard Communication (SCHC) September 27, 2016

YOUR HEALTH AND SAFETY ... OUR PRIORITY.

Presentation Outline

- Purpose of the Technical Guidance
- Background and Transition Timelines
- Structure
- Content
- Accessing a Copy of Phase 1

Purpose of the Technical Guidance

- To provide guidance on the requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR) to suppliers of hazardous products destined for Canadian workplaces.
- To provide suppliers with information on the Hazardous Materials Information Review Act (HMIRA) and its regulations and the mechanisms to protect confidential business information (CBI) while still disclosing critical hazard information to workers.

It is important to note that in case of discrepancy between the Technical Guidance and the Acts or Regulations, the official versions of the Acts or Regulations will prevail.

Background and Transition Timelines

- On February 11, 2015, the amended Hazardous Products Act (HPA) and the new Hazardous Products Regulations (HPR) came into force, implementing the GHS in Canada
 - The system is now referred to as "WHMIS 2015"
 - The Controlled Products Regulations and Ingredient Disclosure List have been repealed
 - It is now possible to meet Canadian and U.S. requirements using a single label and safety data sheet.
- Both the WHMIS 2015 Regulations and Legislation are complex texts written in legal language.
- On June 29, 2016, Health Canada published Phase 1 of the Technical Guidance on the Requirements of the HPA and the HPR – WHMIS 2015 Supplier Requirements in order to assist suppliers (manufacturers and distributors) in advance of the first phase of transition deadline (June 1, 2017).

Background and Transition Timelines

- Phase 1 of the Technical Guidance focusses on classification principles, hazard communication and Confidential Business Information (CBI). Phase 2 will focus on physical hazard and health hazard classification and is expected to be released in Fall 2016.
- First milestone of transition requires that suppliers be in full compliance with WHMIS 2015 by June 1, 2017. WHMIS 1988 labels and MSDS(s) from suppliers will no longer be considered acceptable after that date. Distributors have an extended period for transition.



Structure of Phase 1 of the Technical Guidance

Phase 1 consists of Sections and an Appendix:

□ 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

□ Appendix A – Confidential Business Information

Note: there are references made in Phase 1 of the Technical Guidance to content that will be made available in the Fall 2016, as a part of Phase 2.

Section A - Introduction

Section A

Introduction

WHMIS Overview

- General information about the purpose of WHMIS in Canada
- Implementation of WHMIS in Canada through a coordinated approach
- Purpose of the guidance
- Authorities under the HPA and the requirements of the HPR
- Health Canada's responsibilities under WHMIS

Further Information

- Disclaimer on discrepancies between the Acts or Regulations and the Technical Guidance.
- References to legislation and guidance pertaining to other Competent Authorities which are made for comparative purposes and are in that context, Health Canada's understanding of the legislation and guidance.
- For compliance purposes and for additional information regarding the legislation and guidance from other Competent Authorities referred to in the Technical Guidance, readers are advised to consult those relevant Competent Authorities.
- Useful links to the Acts, Regulations and Health Canada's WHMIS website.

Content of Phase 1 Section A - Introduction

Structure of the Technical Guidance

- High-level structural overview of the sections and appendix in the Technical Guidance is provided;
- Each statutory or regulatory requirement is followed by a discussion of the particular requirement. Some examples where appropriate are also included;
- All requirements of the HPR are highlighted in blue boxes.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

1

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.

- 34 -

Content of Phase 1 Section A - Introduction

PART 3

Labelling

Structure of the Technical Guidance

 The requirements of the HPA and HMIRA are highlighted in green boxes. 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 baliment 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;

- 66 -

Content of Phase 1 Section A - Introduction

Structure of the Technical Guidance

Variances between Canada and the U.S. are highlighted in orange boxes.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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)

- 69 -

1

Section A - Introduction

GHS Implementation in Canada and WHMIS 2015

- General information regarding GHS in Canada and coming-into-force of the HPR and the amendments to the HPA (February 11, 2015).
- Summary of key changes to WHMIS in Canada
 - 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.
- Summary of the key objectives of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as well the groups of hazards that are covered by the international system (physical, health and environmental).

Supplier Obligations

• Outlines the requirements for Canadian suppliers of hazardous products.

Exclusions

• A list of excluded sectors from supplier requirements under the HPA and HPR.

Section A - Introduction

Canada-U.S. Cooperation under the Regulatory Cooperation Council (RCC)

 General overview of the collaborative work undertaken by Health Canada and U.S. OSHA under the auspices of the RCC.

Transition Timelines to WHMIS 2015

- Timelines for suppliers, employers and workers to adjust to the requirements under WHMIS 2015.
- Implementation of WHMIS 2015 will take place over a three-stage transition period that is synchronized nationally across federal, provincial and territorial jurisdictions.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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	Supp		
		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 <u>WHMIS.org</u>.

Section C – Regulatory Requirements

- Provides comprehensive information concerning the supplier requirements for WHMIS 2015.
- Section C is divided into 8 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

* Parts that are currently not in Phase 1 but will be in Phase 2 of the Technical Guidance.

Content of Phase 1 Section C – Regulatory Requirements *Part 1 - Interpretation*

- Part 1 of the HPR provides the definitions for terms that are used in the regulations.
- Part 1 of the Technical guidance provides additional information and some examples of the application and use of these definitions.
- In some cases, terms are not defined in Part 1 of the HPR, however they are defined in the specific Part or Subpart of the HPR where the terms are used, and this approach was mirrored in the Technical Guidance. For example, the definition of a "flammable solid" would be found in Part 7, Subpart 7.

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 HPR where the defined term is used. Information regarding the terms defined in 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:

- 10 -

- flammable aerosol;
- (2) spray aerosol; and
- (3) foam aerosol.

Content of Phase 1 Section C – Regulatory Requirements *Part 1 - Interpretation*

Noteworthy points

Where appropriate you will find a short comparison between a definition in the HPR and the HCS 2012. This is not a variance but a point for clarification purposes.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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

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

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

"ATE" means an acute toxicity estimate, and includes the LD_{so} and the LC_{so} , 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:

- 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 LD_{e_0} or LC_{e_0} 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 LD_{s0} or LC_{s0} 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.

- 11 -

Section C – Regulatory Requirements

Part 2 – Classification of a Product, Mixture, Material or Substance

- 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 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 HPA.
- It specifies the types of data that must be considered and sets out principles that are relevant to classification of a product, mixture, material or substance (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.

Content of Phase 1 Section C – Regulatory Requirements *Part 2 – Classification of a Product, Mixture, Material or Substance*

Part 2 is further broken down into "themes" for classification requirements:

Part 2 Classification of a Product, Mixture, Material or Substance	29
2 - General	29
2.1 - Material or Substance	39
2.2 - Mixture	42
2.2 - Classification	42
2.3 - Bridging Principles	46
2.4 - Other Principles.	58
2.7 - Product	63
2.8 - Specific Rules	64

Section C – Regulatory Requirements

Part 2 – Classification of a Product, Mixture, Material or Substance

2 – General

• Under this "theme" in Part 2, you will find detailed guidance on for example, situations in which you have two or more distinct PMMS packaged together in an outer container, such as a in a kit.

2.1 – Material or Substance

 Provides guidance on certain requirements that are to be met for when classifying materials or substances with respect to Parts 7 (Physical Hazard classes) and Part 8 (Health Hazard classes) of the HPR. This includes the types of data to be considered and the order of precedence for considering these different types of data.

Section C – Regulatory Requirements

Part 2 – Classification of a Product, Mixture, Material or Substance

2.2 – Mixture

- Guidance is provided on classification, bridging principles and other principles with respect to mixtures. For example, a useful summary table on how to apply bridging principles to Health Hazard classes of the HPR is provided.
- Some other principles that are discussed under mixtures include synergistic and antagonistic effects.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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

	Bridging Principles						
Health Hazard Class	Dilution	Production Batches	Increase in concentration of hazardous ingredient	Interpolation	Substantially similar mixtures	Aerosols	
Acute Toxicity	✓ (see note 1 below)	~	√	~	V	~	
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)

Section C – Regulatory Requirements

Part 2 – Classification of a Product, Mixture, Material or Substance

2.7 – Product

 Guidance is provided on products that are classified in particular physical hazard classes – specifically, Flammable Aerosols, Gases Under Presser, Self-Reactive Substances and Mixtures, and Organic Peroxides. For these classes, the packaging as well as the contents of the packaging must considered for the purposes of classification. TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

Content of Phase 1 Section C – Regulatory Requirements *Part 2 – Classification of a Product, Mixture, Material or Substance*

2.8 – Specific Rules

In this "theme" you will find specific rules. For example, in Subparts 7, 8, 11, 12 and 14 of Part 7, there are is a specific rule that relates 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). As data may be available for different forms of these solids, a supplier may not be aware of which data to use for classification. For example, one may have data on the flammability of solid flakes versus solid granules for a particular solid. Guidance is provided indicating that suppliers must use data that relate to the solid in the same form as the one in which it is to be sold or imported. This is to ensure that the classification reflects the hazards of the product that is being sold or imported.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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 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.

Content of Phase 1 Section C – Regulatory Requirements *Part 3 – Labelling*

- Labels are a key element for hazard communication under WHMIS 2015.
- Part 3 addresses labelling requirements under the HPR and includes detailed guidance on:
 - the required information elements to appear on a label;
 - pictogram(s), signal word(s), hazard statement(s) and precautionary statement (s);
 - supplemental label elements;
 - variances between the HPR and the HCS 2012 with respect to labelling requirements;
 - example of a label which meets the HPR requirements, etc...

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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)

Content of Phase 1 Section C – Regulatory Requirements *Part 3 – Labelling*

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.



í

Content of Phase 1 Section C – Regulatory Requirements *Part 4* – *Safety Data Sheets*

- SDSs are a key element for hazard communication under WHMIS 2015.
- Detailed information on supplier obligations as well as the information required to appear on the SDS is provided.
- Part 4 also provides detailed guidance on:
 - the use of a generic SDS;
 - variances between the HPR and HCS 2012 with respect to SDSs;
 - how to meet the SDS requirements for hazardous products that are classified as Biohazardous Infectious Materials (BIM) only;
 - how to meet SDS requirements for products packaged in multicompartment containers, etc...

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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) 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(les) or subcategory(les) 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.

- 91 -

Content of Phase 1 Section C – Regulatory Requirements *Part 4* – *Safety Data Sheets*

Appendix 1 – Information Elements on Safety Data Sheet – Schedule 1 of the HPR

- Detailed item by item guidance on how to meet the requirements of Schedule 1 of the HPR;
- Variances between the HPR and HCS 2012 with respect to each item on the SDS are clearly identified in orange boxes;
- Highlighting minor nuances between the HPR and the HCS 2012 that would still be acceptable in Canada, 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" under section 2 of the SDS, since the HCS 2012 refers to "Self-Reactive Chemicals"

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

- 110 -

Section C – Regulatory Requirements

Part 4 – Safety Data Sheets

Appendix 2 – Information Elements on Safety Data Sheet – Biohazardous Infectious Materials, Schedule 2 of the HPR

- All hazardous products containing Biohazardous Infectious Materials (BIM) must meet the requirements of Schedule 2 of the HPR;
- Guidance on what type of information is required under each "Section" is described in this appendix;
- A useful link to assist in completing these sections is on the Federal Public Health Agency of Canada's website: <u>www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php</u>

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

- 122 -

Content of Phase 1 Section C – Regulatory Requirements Part 4 – Safety Data Sheets

Appendix 3 – Guidance on the Disclosure of Ingredient Concentrations and Concentration Rages on Safety Data Sheets

- Detailed guidance on how to meet the requirements of the HPR on the disclosure of ingredient concentrations and concentration ranges on SDSs;
- Comparison of the requirements on ingredient disclosure, concentrations and concentration ranges under the *Controlled Products Regulations* (CPR), the HPR and the HCS 2012 is provided;
- This document was provided to stakeholders (Canada and the U.S.) as stand alone guidance in July 2015 and has been added to the guidance for your reference.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

Content of Phase 1 Section C – Regulatory Requirements *Part 4* – *Safety Data Sheets*

Appendix 4 – Comparison of Ingredient Concentration Disclosure and CBI Protection Requirements

Example Ingredient Concentration Chemical Name Volume % Toluene 17% Acetone 32-41%		Regulatory System					
		WHMIS 1988 (WHMIS before GHS)		WHMIS 2015 (GHS in Canada)		HCS 2012 (GHS in U.S.)	
Ingredient Concentration	Concentration (where	True Concentration		True Concentration		True Concentration	
(No CBI)	concentration does not vary)	Chemical Name Toluene	Volume % 17%	Chemical Name Toluene	Volume % 17%	Chemical Name Toluene	Volume % 17%
R (W va ba	Concentration Range	Standardized Concentration Range		True Concentration Range		True Concentration Range	
	(where concentration varies, e.g. batch-to-batch variability)	Chemical Name Acetone	Volume % 30-60%	Chemical Name Acetone	Volume % 32-41%	Chemical Name Acetone	Volume % 32-41 %
	Concentration (where concentration	"Trade Secret" and Registry Number (Range Optional)		"Trade Secret" and Registry Number (Range Optional)		"Trade Secret" (Range Optional)	
	does not vary)	Chemical Name Toluene *HMIRA claim filed June	Volume % Trade Secret* e 1, 2015, RN: 5555	Chemical Name Toluene *HMIRA claim filed Jun	Volume % Trade Secret* te 1, 2015, RN: 5555	Chemical Name Toluene	Volume % Trade Secret
	Concentration Range (where concentration varies, e.g.	"Trade Secret" and I Chemical Name Acetone	Registry Number Volume % Trade Secret*	"Trade Secret" and Chemical Name Acetone	Registry Number Volume % Trade Secret*	CBI Claim Not Supplier must di Concentratio Chemical Name	sclose True
	batch-to-batch variability)	*HMIRA claim filed Jun	e 1, 2015, RN: 5555	*HMIRA claim filed June 1, 2015, RN: 5555		Acetone	32-41 %
Alignment of Ca	nada / U.S. Requi Aligned		Complementary	Not Aligned	Volume % True Concentrat True Concentra Range Disclos	tion	ne % otected

Content of Phase 1 Section C – Regulatory Requirements *Part 6 – Additional Requirements*

- Additional requirements with respect to the information that must be provided on an SDS or label of a hazardous products.
- Part 6 is where you will find guidance on:
 - bilingual requirements where SDSs and labels must be provided in both official languages of Canada (English and French);
 - communication of information with health professionals and under what circumstances;
 - disclosure of the source of information for any toxicological data used in the preparation of an SDS upon request of an inspector, any person or government to which the hazardous product is sold or any user of the hazardous product;
 - how to meet the requirements of "providing" a bilingual SDS with some examples of how this requirement could be met and what would be considered unacceptable;
 - how to meet the bilingual presentation requirements for a label.

TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

- 131 -

Content of Phase 1 Section C – Regulatory Requirements Appendix A – Confidential Business Information

- TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS
- A general overview on the protection of Confidential Business Information (CBI) in Canada, including key CBI legislation.
- In Appendix A, you will find detailed guidance on:
 - variances between the Hazardous Materials Information Review Act (HMIRA) and the HCS 2012;
 - 4 key parts relating to aspects of the CBI claim for an exemption process under the HMIRA as well as helpful examples to assist in completing Section 3 of the SDS :
 - 1. Filing a Claim for Exemption;
 - 2. The Claim for Exemption Review and Decision Process;
 - 3. The Appeal Process; and
 - 4. Confidentiality.

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.

- 138 -

Content of Phase 1 Section C – Regulatory Requirements Appendix A – Confidential Business Information

 In Appendix A-1, you will find detailed guidance On how to develop a Generic Chemical Name (GCN), including suggested strategies and examples as well as common errors when developing a GCN; TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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.

Content of Phase 1 Section C – Regulatory Requirements Appendix A – Confidential Business Information

 In Appendix A-2, you will find detailed guidance on completing the claim for exemption under the HMIRA Application Form as well as how to submit your completed application. TECHNICAL GUIDANCE ON THE REQUIREMENTS OF THE HAZARDOUS PRODUCTS ACT AND THE HAZARDOUS PRODUCTS REGULATIONS

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

Accessing a Copy of Phase 1

Phase 1 of the Technical Guidance is now available upon request at the following link:

http://www.hc-sc.gc.ca/ewhsemt/pubs/occuptravail/technical-guidancewhmis-2015-guidetechnique-simdut/indexeng.php



Accessing a Copy of Phase 1

Once you click on the link you will be asked to complete a short form to obtain a PDF copy of the "Technical Guidance on the Requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR) - WHMIS 2015 Supplier Requirements - Phase 1" publication.

http://www.hcsc.gc.ca/contact/order-pubcommande-eng.php



Thank You!

For further information:

- Health Canada Website:
 - WHMIS.gc.ca
- General enquiry:
 - whmis_simdut@hc-sc.gc.ca
 - 1-855-407-2665