



GUIDANCE
Disclosure of Ingredient Concentrations and
Concentration Ranges on Safety Data Sheets
 (July 31, 2015)

1.0 Purpose

The purpose of this document is to provide suppliers with guidance on requirements related to ingredient disclosure and the use of concentrations and concentration ranges on safety data sheets (SDSs), as specified under the *Hazardous Products Regulations*.

2.0 Background

WHMIS is Canada's national hazard communication standard and is implemented through interlocking federal, provincial and territorial legislation. The key elements of the system are hazard classification, cautionary labelling of containers, the provision of safety data sheets (SDSs) and worker education and training programs.

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 workplace 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 The *Controlled Products Regulations* (CPR) and the *Ingredient Disclosure List* of the original WHMIS 1988 were repealed and replaced by the HPR.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 workplace 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.

3.0 Ingredient Disclosure, Concentrations and Concentration Ranges

The HPR and United States' Hazard Communication Standard (HCS 2012) require suppliers to provide information on hazards and safe use and handling of a hazardous product on the SDS and label. A product's SDS must fully disclose all hazardous ingredients in the product, its toxicological properties, any safety precautions workers need to take when using and handling the product, and first aid treatment required in the case of exposure, along with other information specified in Schedule 1 of the HPR.

Table 1 – Comparison of Requirements on Ingredient Disclosure, Concentrations and Concentration Ranges under the CPR, the HPR and the HCS 2012

Canada WHMIS 1988 (repealed CPR)	<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>Section 11 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</p>
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	<p>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.
<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.
<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;



	<p>(d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.</p> <p>For Mixtures In addition to the information required for substances:</p> <p>(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</p> <ol 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. <p>(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> <p>For All Chemicals Where a Trade Secret is Claimed Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.</p>
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Appendix 1 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.

3.1 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.

3.2 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 document and the attached appendix, 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 document and the attached appendix, 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.

3.3 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 would apply (These do not apply to trade secrets, as discussed below):

- 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.

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. This section is similar to the provision in the HCS 2012.

Example: If the manufacturing formula for a mixture calls for 10% of hazardous ingredient A, but due to batch-to-batch variability, the true concentration is expected to vary from 5% to 15%, then the supplier must disclose 5% to 15% 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”. 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 (for example, 10 – 40%) 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.

Textbox: 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.



4.0 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 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 true concentration or true concentration range of a hazardous ingredient, a statement must be provided on the SDS to indicate that a claim was filed, and it must include 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 these circumstances, 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.

5.0 For More Information

For more information on WHMIS, please see WHMIS.org or <http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php>

For more information on the U.S. Hazard Communication Standard (HCS) 2012: <http://www.osha.gov/dsg/hazcom/index.html>