



## PART IV

### CLASSES OF CONTROLLED PRODUCTS

#### *Interpretation*

#### 32. In this Part,

"ACGIH" means the American Conference of Governmental Industrial Hygienists; (*ACGIH*)

"acute lethality" means death of animals immediately or within 14 days after a single administration of or exposure to a toxic substance; (*léthalité aiguë*)

"aerosol container" means a disposable container designed to release pressurized contents by means of a manually operated valve which forms an integral part of the container; (*contenant aérosol*)

"ASTM" means the American Society for Testing and Materials; (*ASTM*)

"chronic toxic effect" means an adverse effect to the health of a person or test animal that develops

(a) over time, following a single exposure to a toxic substance, or

(b) from prolonged or repeated exposure to a toxic substance under conditions that do not produce that effect from a single exposure; (*toxicité chronique*)

"dust" means solid airborne particles that are mechanically generated; (*poussières*)

"flame projection" means the ignited discharge of the pressurized contents of an aerosol container; (*projection de la flamme*)

"flashback" means that part of a flame projection that extends from its point of ignition back to the aerosol container; (*retour de flamme*)

"flash point" means the minimum temperature at which a liquid gives off vapour in sufficient concentration to ignite in test circumstances; (*point d'éclair*)



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"fume" means solid particles in the air that are generated by condensation from the vapour of a solid material; (*fumée*)

"IARC" means the International Agency for Research on Cancer; (*CIRC*) **[SOR/97-543, s. 19]**

"mist" means liquid droplets suspended in the air that are produced by the dispersion of a liquid or by the condensation of a vapourized liquid; (*brouillard*)

"NACE" means the National Association of Corrosion Engineers (U.S.A.); (*NACE*)

"normal atmospheric pressure" means an absolute pressure of 101.325 kilopascals (1.00 atmosphere) at 20°C (68°F); (*pression atmosphérique normale*)

"OECD" means the Organization for Economic Co-operation and Development; (*OCDE*)

"OECD Test Guideline" means a test published in the OECD Standard entitled *OECD Guidelines for Testing of Chemicals*; (*ligne directrice de l'OCDE*)

"respiratory tract sensitization" means the development in a non-atopic person of severe asthma-like symptoms on exposure to a substance to which the person has previously been exposed; (*sensibilisation des voies respiratoires*) **[SOR/2001-254, s. 9]**

"skin sensitization" means an immunologically-mediated, cutaneous reaction in a non-atopic person or animal on exposure to a substance to which the person or animal has previously been exposed; (*sensibilisation de la peau*) **[SOR/2001-254, s. 9]**

"statistically significant" means shown by statistical procedures to have a high probability of being due to something other than chance; (*statistiquement significative*)

"vapour" means the gaseous form of a substance that is found in a solid or liquid state at normal atmospheric pressure. (*vapeur*)

### INTERPRETATION / DISCUSSION of SECTION 32

Part IV of the *Controlled Products Regulations* lists the scientific criteria which define controlled products; (see sections 34 to 66).



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Definitions for terms used throughout the *CPR* are found in section 2. Definitions related to classification under WHMIS and, hence, used only in Part IV of the *CPR*, are found in section 32.



### *Manner of Establishing Classification*

**33.(1) For the purpose of establishing that a product, material or substance is included in a class listed in Schedule II of the Act or falls into a division of a class, the supplier shall use, subject to subsection (2),**

**(a) results from testing that he has carried out with respect to the product, material or substance in accordance with sections 34 to 66, as applicable; or**

**(b) evidence based on established scientific principles with respect to **[SOR/2010-38; s. 2]****

**(i) the product, material or substance, or**

**(ii) where appropriate, a product, material or substance that has similar properties.**

**(2) For the purpose of establishing that a product, material or substance is or is not included in Class D - Poisonous and Infectious Material, the supplier may use, in place of the evidence referred to in subsection (1), one or more of the following:**

**(a) results of other testing with respect to the product, material or substance;**

**(b) if appropriate, results of testing with respect to a product, material or substance that has similar properties; and**

**(c) other evidence based on studies or epidemiological data with respect to**

**(i) the product, material or substance, or**

**(ii) if appropriate, a product, material or substance that has similar properties.**

**[SOR/2010-38; s. 2]**

**(3) If the evidence referred to in paragraph (1)(b) results from toxicological studies, the studies shall have been carried out in accordance with **[SOR/2010-38; s. 2]****

**(a) the applicable OECD Test Guideline referred to in this Part; or **[SOR/97-543; s. 20]****

**(b) where there are no tests carried out in accordance with the applicable OECD Test Guidelines referred to in this Part, one of the following tests or methods:**



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- (i) in the case of a 90 day test or a chronic test, a test or method described in U.S. Food and Drug Administration (FDA) guidelines or U.S. Environmental Protection Agency (EPA) guidelines, as published in the *Federal Register* and as amended from time to time,
- (ii) in the case of a test for skin or eye irritation, the Draize Test as described in volume 82 of *The Journal of Pharmacology and Experimental Therapeutics*, dated 1944, at pages 377 to 390,
- (iii) in the case of a test for teratogenicity, a test or method described in *Principles for the Testing of Drugs for Teratogenicity*, Technical Report Series Number 364, published in 1967 by the World Health Organization,
- (iv) in the case of a test for mutagenicity, a test or method described by the U.S. Environmental Protection Agency (EPA) in "Proposed Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Human and Domestic Animals", as published in volume 43 of the *Federal Register* (No. 163), dated 1978, at pages 37,336 to 37,403, or
- (v) any other test or method that is carried out in accordance with generally accepted standards of good scientific practice at the time the test is carried out.

### DISCUSSION of SECTION 33

To determine if a product is included in one or more WHMIS classes, the supplier must use the procedures set out in this section of the CPR. If the product is specified by the CPR to fall into one of the classes listed in Schedule II to the HPA, it is a controlled product. The term "controlled product" is defined in section 2 of the HPA. The CPR does not allow a supplier to make the choice as to whether or not the product should be classified into WHMIS. The supplier or importer of the product has the legal responsibility to determine whether the product is a controlled product.

**Professional judgement:** The extent to which professional judgement is used by a supplier will depend on the specific criteria being considered. The guidelines, which can be accessed from the "CLASSIFICATION" page of the Government of Canada WHMIS Web site, ([www.whmis.gc.ca](http://www.whmis.gc.ca)), provide guidance on the use of professional judgement in the classification of controlled products under WHMIS.

**Structure-activity relationships:** If no toxicological information is available for a hazardous substance, a Quantitative Structure Activity Relationship (QSAR) system may be used to obtain information about the potential toxicity of the substance. Data thus obtained can be used for the toxicological classification of a substance about which no toxicological information is available. Where a supplier has access to information generated by a QSAR system, and the information is relevant to the hazardous properties of a substance, the supplier should evaluate that information; {ref.: PIS No. 74}.



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**Sufficiency of evidence:** The CPR does not require a supplier to research all of the literature or examine all of the tests that have been carried out. Where a supplier carries out his/her own tests pursuant to paragraph 33(1)(a), he/she must do so in accordance with sections 34 to 66 which, for the most part, set out objective tests. Where, pursuant to paragraph 33(1)(b), a supplier uses evidence based on established scientific principles, he/she must base his/her decision on a reasonable evaluation of test results. "Reasonableness" should be assessed on the basis of a reasonably competent individual knowledgeable in the appropriate science necessary to evaluate the product, material or substance.

**Testing requirements:** Neither the HPA nor the CPR impose a requirement for the testing of materials in order to classify them for any of the WHMIS Classes. For example, a supplier is not obliged to conduct additional toxicological testing of a product in order to assess its potential hazard. As a fundamental principle, during the development of WHMIS, all stakeholders agreed that nothing in the hazard criteria, nor any part of WHMIS would require additional toxicological testing. Rather, the WHMIS program was designed to make the best use of existing toxicological data.

**Untested mixtures:** A classification system based on cut-off presumes that a mixture is hazardous if it contains a hazardous ingredient at a concentration exceeding a specified cut-off. The use of cut-offs is administratively straightforward and can be applied by using available data on the toxicology of ingredients of the mixture. The cut-off values agreed to for WHMIS are:

0.1% for teratogens, embryotoxins, carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens; and

1.0% for all other toxicological effects and tissue corrosivity.

Since WHMIS is an information system, the use of cut-off values appeared justifiable as a means of consistently communicating information about hazardous ingredients as contrasted with providing a hazard evaluation of an untested mixture. The numerical values of the cut-offs, however, are necessarily arbitrary and were chosen largely for consistency between Canada and the United States.<sup>1</sup> Upon transition to the GHS in WHMIS, the cut-off values for the classification of untested mixtures for health hazards should be harmonized with those of Canada's major trading partners with no reduction in the level of worker protection.

**Weight of evidence approach:** Well conducted, credible studies could point to different conclusions regarding whether the product, material or substance is a controlled product. The supplier must assess the impact of deciding that the product is not a controlled product versus the impact of deciding that it is a controlled product. In the final analysis, the supplier's decision should be both reasonable (in light of the scientific evidence) and responsible (in light of the fact that the supplier is selling or importing potentially hazardous material for use in the workplace). Similar considerations are required when deciding what information should be disclosed on an MSDS. The weight of evidence approach is a cumulative and qualitative (as opposed to quantitative) evaluation of a body of data.

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<sup>1</sup> Report of the [WHMIS] Project Steering Committee, 1985; p.14.



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Definitions for "reliability", "relevance" and "adequacy" of data have been proposed in the article "A systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data"; (ref.: H.-J. Klimisch et. al.; Regulatory Toxicology and Pharmacology 25, 1-5 (1997); article no. RT961076).

For some of the CPR criteria, a weight of evidence approach would not be considered to be appropriate. If, for example, as per subparagraph 61(a)(l) of the CPR, an animal assay carried out in accordance with the specified test produced a response in 30 per cent of the rats tested, even if the same test conducted on mice and guinea pigs elicited responses in less than 30 per cent of each population, it is not appropriate to use a weight of evidence approach in the classification of this substance under the CPR. The three studies do not constitute "replicate studies", i.e., identical species and route. In this case, as this CPR criterion specifies "an assay", i.e., a singular assay, the supplier must consider the product as falling within the criteria for skin sensitization as the CPR criteria do not consider lesser results obtained from additional assays.

#### **Subsection 33(1):**

Subsection 33(1) is applicable to all WHMIS classes. A supplier of any product must evaluate his/her product against all of the criteria for controlled products (sections 34 to 66) to determine which criteria, if any, the product meets (unless the product is already exempted under section 12 of the HPA). This section describes the ways that determine whether a product is included in one or more WHMIS classes.

Paragraph 33(1)(a) states that a supplier may test a product according to the test method, if specified in a criterion, and use the results to determine if his/her product meets that criterion.

Paragraph 33(1)(b) enables a supplier to evaluate whether a product meets the criteria without actually testing the product on the following condition: the supplier must base the decision on evidence generated according to established scientific principles such as test results with respect to the product or, where relevant, a product with similar properties. For example, the supplier may use test data published in scientific literature on the product or he/she may, **if** it is appropriate to the criterion, extrapolate published data on the ingredients of a mixture to estimate a property for the mixture. A supplier would not be expected to test for the flashpoint of a product that has no flammable ingredients or to test whether an aqueous solution is a Class A - Compressed Gas.

Subsection 33(1) had stated that "the supplier shall use, subject to subsection (2) evaluation and scientific judgment based on test results with respect to (i) the product, material or substance or (ii) where appropriate, a product, material or substance that has similar properties." The SJCSR concluded that "evaluation and scientific judgment" is too subjective and exceeds the legislative authority of the HPA. To address this issue, this subsection was amended through SOR/2010-38, effective February 23, 2010. As indicated in the Regulatory Impact Analysis Statement that accompanied this and related amendments (which were exempted from pre-publication in Part I of the *Canada Gazette*):

"...They [the amendments] will not change the scope of the HPA/CPR nor what is encompassed by the term "controlled product." They do not provide extra powers to the Government nor do they increase the burden for the regulated community".



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### Subsection 33(2):

Subsection 33(2) applies to Class D only. This subsection allows a supplier to use test data (including results from testing conducted in accordance with scientifically valid methods other than those specified in sections 34 to 66) and other types of evidence, such as human case reports and epidemiological data, to determine whether or not a product, material or substance should be included within Class D. In the case of a material (pure substance or tested mixture) which does not meet any of the criteria for Very Toxic Material or Toxic Material, but for which there is valid documented evidence based on established scientific principles that the material causes an adverse effect in humans following occupational exposure, this fact, by itself, is sufficient to include that material within this class. In this context, "adverse effects" mean injury to humans resulting from occupational exposure including any reversible or irreversible material impairment to health or irreversible diminished functional capacity.<sup>2</sup>

A supplier does not have to undertake toxicological testing of a product if there is no toxicological data available. However, the supplier should be aware of relevant information from published technical literature, from the Canadian Centre for Occupational Health and Safety and from publications of regulatory agencies, industry or trade associates and labour organizations that are related to occupational health and safety; {ref.: PIS No.9}. Human evidence is also information of which a supplier ought to be aware.

Depending upon the species tested and the route of administration, the toxicological response to a given test substance may vary to a large degree. As a result, it is possible that a test substance may elicit a positive result in the rat via the oral route and a negative result in the mouse via the dermal route. Such results are considered to be neither contradictory nor conflicting. Therefore, the positive result in the rat study should form the basis for determining the appropriate WHMIS classification.

Subsection 33(2) had stated that "the supplier may use information of which the supplier is aware or ought reasonably to be aware in place of the criteria set out in subsection (1)." Similar to what had been their conclusion on subsection 12(11), the SJCSR concluded that the HPA does not provide the authority for the CPR to state "aware or ought reasonably to be aware". To address this, subsection 33(2) was also amended through SOR/2010-38.

### Subsection 33(3):

As for subsection 33(2), subsection 33(3) is also applicable only to Class D. In many cases toxicological testing of a product will not have been carried out in accordance with the OECD Test Guidelines referred to in the criteria for Class D. This section ensures that the wealth of toxicological information derived from testing carried out prior to the establishment of these OECD tests may still be used. However, the testing must have been carried out in accordance with generally accepted standards of scientific practice at the time it was conducted. Subparagraphs 33(3)(b)(i) to (iv) are examples of tests or methods that were considered to be "generally accepted standards of good scientific practice" when they were published. Tests or methods that have been derived from these

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<sup>2</sup> Report of the [WHMIS] Project Steering Committee, 1985; page 61.



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listed tests or methods are also acceptable. Subparagraph 33(3)(b)(v) also allows the use of "any other test or method that is carried out in accordance with generally accepted standards of good scientific practice at the time the test is carried out."

The deletion of the term "test results" in paragraph 33(1)(b) through SOR/2010-38 necessitated the amendment to subsection 33(3) to replace "Where the test results referred to in paragraph (1)(b)" with "If the evidence referred to in paragraph (1)(b)...".



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**CPR Section 34 - CLASS A -- COMPRESSED GAS**

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#### CLASS A – COMPRESSED GAS

**34. Any product, material or substance contained under pressure, including compressed gas, dissolved gas or gas liquefied by compression or refrigeration, that has any of the following characteristics shall be included in Class A - Compressed Gas listed in Schedule II to the Act:**

- (a) a critical temperature of less than 50°C (122°F);**
- (b) an absolute vapour pressure greater than 294 kilopascals (2.90 atmospheres) at 50°C (122°F);**
- (c) an absolute pressure in the cylinder or other pressure vessel in which it is packaged greater than 275±1 kilopascals (2.71±0.01 atmospheres) at 21.1°C (70°F) or 717±2 kilopascals (7.07±0.02 atmospheres) at 54.4°C (130°F); or**
- (d) in a liquid state, an absolute vapour pressure exceeding 275 kilopascals (2.71 atmospheres) at 37.8°C (100°F) as determined by the *Standard Test Method for Vapor Pressure of Petroleum Products (Reid Method)*, ASTM D323-82, dated August 27, 1982. **[SOR/97-543; s. 21]****

#### INTERPRETATION / DISCUSSION of SECTION 34

The controlled products in this class include non-liquified compressed gases (e.g. nitrogen, air); compressed gases liquified under pressure (e.g. butane); compressed gases liquified under refrigeration (e.g. liquid nitrogen); and dissolved gas (e.g. acetylene is dissolved in acetone in a porous material in the acetylene cylinder).

All compressed gases in a cylinder are hazardous because of potential energy due to compression. For example, the force within a "standard" cylinder with an area of 0.954 m<sup>2</sup> (1500 in<sup>2</sup>) and pressurized to 17,240 kPa (2500 psi) is 16.5 x 10<sup>6</sup> Newtons (3.8 x 10<sup>6</sup> pounds). If this expansive force was suddenly released in an accidental or uncontrolled way, such as through the shearing of a valve, a tremendous amount of energy would be released.

Any one of the four criteria can be used to determine whether a product, material or substance is a compressed gas including the "critical temperature" which is the temperature above which a gas cannot be liquified. The "critical pressure" is the pressure required to liquify a gas at its critical temperature.

Because compressed gases may also possess other hazards, the criteria for the other classes should also be examined.

**Fire extinguishers:** By virtue of paragraph 12(f) of the *HPA*, a product, material or substance included in Part II of Schedule I to the *HPA* and packaged as a consumer product is not subject to WHMIS supplier



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MSDS nor label requirements. The "manufactured article" exemption does not apply to fire extinguishers because, during normal conditions of use, these products do not meet the third criteria in the definition of manufactured article, i.e., that they "will not release or otherwise cause a person to be exposed to a controlled product"; {ref.: PIS No. 39}.