A Product Is Classified as a Carcinogen in the United States, But Not in Another Jurisdiction... Why?

Jeremy Long and Elizabeth Dederick, PhD

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US OSHA Guidelines for Evaluating Carcinogenicity

- A chemical regulated as a carcinogen by 29 CFR 1910 Subpart Z: Toxic and Hazardous Substances must be treated as a carcinogen when determining the classification of a product.
- According to the HCS, suppliers can determine the carcinogenicity classification of a product by:
  - Conducting their own hazard classification; OR
  - Relying on the classifications determined by IARC "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest edition) or the NTP "Report on Carcinogens (RoC)" (latest edition).
- **Please note:** Any classifications provided by IARC and NTP must be listed on an OSHA-compliant SDS in Section 11 whether the supplier chooses to use these carcinogenicity ratings for classification or not (OSHA Directive CPL 02-02-079; Appendix C).
- If a supplier classifies differently than the classification provided by IARC and/or NTP, then the supplier must be able to provide any data and justification it has for their own classification.

Approximate equivalences between carcinogen classification schemes

(Sources: Appendix F to 29 CFR 1910.1200 [US]; Technical Guidance for HPR [Canada])

International Agency for Research on Cancer (IARC)	Hazard Communication Standard (HCS)	National Toxicology Program (NTP) "Report on Carcinogens"	Health Canada Hazardous Products Regulations
Group 1: The agent is carcinogenic to humans when there is sufficient evidence of carcinogenicity in humans OR when evidence of carcinogenicity in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans.	**Category 1A:** Known to have carcinogenic potential for humans	Known to be a human carcinogen	Category 1A
Group 2A: The agent is probably carcinogenic to humans when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.	**Category 1B:** Presumed to have carcinogenic potential for humans	Reasonably anticipated to be a human carcinogen	Category 1B
Group 2B: The agent is possibly carcinogenic to humans.	**Category 2:** Suspected human carcinogens		Category 2

Abstract

In order to expand a product line, a foreign supplier may choose to export their industrial chemical product to the United States, but they are often surprised that cancer-specific precautionary information must be added to the product's US-compliant safety data sheets (SDSs) and workplace labels even if the corresponding non-US SDSs and labels do not report a carcinogenic health hazard. This scenario illustrates why, even though the US Hazard Communication Standard (HCS) published by the Occupational Safety and Health Administration (OSHA) is aligned with the United Nation's Globally Harmonized System of Classification and Labelling of Chemicals (GHS), it is important to understand the specific differences between HCS guidelines regarding carcinogenicity classification and the guidelines in other jurisdictions such as the European Union (EU) and Canada. For example, using OSHA-approved resources such as the International Agency for Research on Cancer (IARC) as the sole means of establishing that a substance is a carcinogen can lead to varying classifications between jurisdictions. A supplier may also need to take into account particular product-specific physical or chemical characteristics when determining the carcinogenicity classification to use in a certain jurisdiction.

Product-specific issues that affect carcinogenicity classification

- The HCS applies when a carcinogenic chemical "is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency" (29 CFR 1910.1200(b)(2)). OSHA has interpreted this language as excluding "substances for which the hazardous chemical is inextricably bound or is not readily available, and therefore, presents no potential for exposure" (OSHA Standard of Interpretation: 1910.1200; No. 14, 02/10/2015).
- Some carcinogenic agents only pose a risk when workers are exposed to the chemical by a specific route of exposure. For example, IARC classifies nitrates as "Group 2A: Possibly carcinogenic to humans" if ingested (oral exposure). However, if the risk of oral exposure of certain nitrates (e.g., sodium nitrate) at levels that exceed an exposure threshold in a supplier's workplace is not applicable, the IARC classification may not be pertinent even though nitrates may induce cancer when ingested.
- For mixtures, US, Canada, and EU regulations allow classifiers to use their own specific concentration limits that may differ from the default concentration limits specified in the applicable chemical regulations if the chemical still presents a carcinogenic hazard below the default concentration limits (EU CLP Article 10.1; Canada HPR 2.5 (1)(2)).

OSHA Directive CPL 02-02-079: Inspection Procedures for the Hazard Communication Standard (HCS 2012)
OSHA Hazard Communication: Hazard Classification Guidance for Manufacturers, Importers and Employers
Health Canada Hazardous Products Regulations (HPR)
Technical Guidance on the Requirements of the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR) - WHMIS 2015 Supplier Requirements

knoell USA, LLC
3070 McCann Farm Drive, Suite 112 Garnet Valley, PA 19060
Tel +1 610 558 3001 Fax +1 610 558 6025 jlong@knoellusa.com
www.knoellusa.com

According to Health Canada's Technical Guidance on the Requirements of the Hazardous Products Act and the Hazardous Products Regulations:

- A chemical should be considered carcinogenic under the HPR if it has been determined to be carcinogenic by IARC or the NTP.
- If a substance is not listed by IARC or NTP, but it is listed by ACGIH (American Conference of Governmental Industrial Hygienists) as Group A1 (confirmed human carcinogen), A2 (suspected human carcinogen) or A3 (confirmed animal carcinogen with unknown relevance to humans), it should be considered a carcinogen under the HPR. The equivalent HPR classification is not clearly defined, and so classification should be determined using the literature/data the ACGIH classification used for its rating.
- "If the substance has both an IARC or NTP classification for carcinogenicity and an ACGIH classification, the IARC or NTP classification would take precedence over the ACGIH classification."

US OSHA guidance recommends additional factors (weight-of-evidence) that can be used in determining the carcinogenic potential of chemicals and evaluating tumor studies:

- Tumor type and background incidence
- Reduced tumor latency
- Progression of lesions to malignancy
- Multiple responses
- Whether responses are in single or both sexes
- Whether responses are in a single species or several species
- Responses in multiple animal experiments
- Structural similarity to a chemical(s) for which there is good evidence of carcinogenicity

Source: OSHA Hazard Classification Guidance for Manufacturers, Importers, and Employers

Concentration limits of components classified as a carcinogen that will trigger classification of the overall mixture on the safety data sheet and label

	Cut-off/concentration limits triggering classification of a mixture as:	
Ingredient classified as:	**Category 1 carcinogen**	**Category 2 carcinogen**
Category 1 carcinogen	≥ 0.1%	
Category 2 carcinogen	–	≥ 0.1% Please note: For both the US and EU, labeling of the product as a carcinogen is optional when the ingredient is present in the mixture between 0.1% and 1%. Canadian suppliers must label the product as a carcinogen if the ingredient is present at ≥ 0.1%.
		≥ 1.0% All jurisdictions which have adopted GHS require carcinogenicity information on the SDS and label if a Category 2 carcinogen is present in the mixture at this concentration.

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