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

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A chemical is 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 US OSHA, suppliers can determine the carcinogenicity of a product by:

Conducting their own hazard classification; OR

If they classify as carcinogenic with IARC and/or NTP, then the supplier must be able to provide any data and justification it has for their own classification.

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 US OSHA, suppliers can determine the carcinogenicity of a product by:
- Conducting their own hazard classification; OR

Please note: Any classifications provided by IARC and NTP must be listed on an OSHA-compliant SDS in Section 11 whether the supplier will use these carcinogenicity rankings for classification or not (OSHA Directive CPL 02–02–077; Appendix C).

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.

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

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 HP Act 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 AGEM (American Conference of Governmental Industrial Hygienists) as Group A1 (confirmed human carcinogen), A2 (suspected human carcinogen) or A3 (confirmed animal carcinogen with unknown potential for exposure) in the AGEM classification, then the supplier should be provided a carcinogen by the NTP. The equivalent IARC classification is not clearly defined, and so classification should be determined using the literature/data the AGEM classification used for its rating.

For the substance to have been assigned an IARC or NTP carcinogenicity classification and an AGEM classification, the IARC or NTP carcinogenicity classification would take precedence over the AGEM classification.

Safety data sheet and workplace labels must list all carcinogenic substances to which 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 hazard statement is not “probable” or “as is reasonably anticipated to be a cancer risk.” OSHA has determined the classification of the overall mixture on the safety data sheet and label if a Category 2 carcinogen is present in the mixture at this concentration.

A Category 1 carcinogen is a substance that meets the definition of a carcinogen as provided in the US OSHA Hazard Communication Standard (29 CFR 1910.1200). An OSHA-compliant SDS for each carcinogenic component must be included for a Category 1 carcinogen. A Category 2 carcinogen is a substance that has been assigned a carcinogenicity classification for a certain jurisdiction (e.g., IARC, NTP, AGEM) but is not listed as a carcinogen by IARC or NTP. A Category 2 carcinogen is a substance that is not a Category 1 carcinogen and that is not listed as a carcinogen by IARC or NTP. A Category 2 carcinogen may be present in the mixture at any concentration except for those default concentration limits (EU CLP Article 10.1; Canada HPR 2.5 (1)(2)).

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

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