Produced by SCHC-OSHA Alliance
GHS Information Sheet Workgroup

Carcinogenicity

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What is carcinogenicity?

Carcinogenicity describes the induction of cancer or the increase in its incidence following exposure to a substance or mixture. Substances and mixtures which have caused benign and malignant tumors in well-performed animal tests, are also considered presumed or suspected carcinogens unless strong evidence shows that the mechanism leading to tumor formation is not applicable to humans. (See Appendix A.6 to 29 CFR 1910.1200).

How do I classify for carcinogenicity?

Substance Classification

Carcinogen classification is a process based on specific criteria and requires two interrelated conclusions:

1) Evaluation of *strength of evidence*, and
2) Consideration of all other relevant information (*weight of evidence* analysis).

Carcinogens are classified into the categories in Table 1:

1) Known or presumed human carcinogens (Category 1 – subdivided into 1A or 1B), or
2) Suspected human carcinogens (Category 2)

Table 1: Classification Criteria

Category	Category 1 Known or presumed human carcinogens		Category 2 Suspected human carcinogen
	Category 1A	Category 1B	
Description	Known to have carcinogenic potential for humans – largely based on human evidence	Presumed to have carcinogenic potential for humans – largely based on animal evidence	Evidence from human and/or animal studies is limited

Mixture Classification

Under **Appendix A.0.4.2 to 29 CFR 1910.1200,** mixtures are to be classified using information on the ingredient substances, unless justification can be provided for classifying based upon the whole mixture. Therefore, mixtures are classified via one of the following 3 methods, using 1 as the primary method and 2 and 3 only in case-by-case situations where justification can be made for classification based on the whole mixture:

1. Classify based on cut-off values/concentration limits of the ingredients in a mixture (See Table 2).
   a. If a Category 1 or 2 Carcinogen is present in a mixture at ≥0.1% the mixture must be classified for carcinogenicity.
   b. If there is more than one carcinogenic substance in the mixture above the cut-off limits listed in table 2, the most conservative classification is to be used.

2. On a case-by-case basis, classification can be based upon **conclusive** data on the whole mixture.
   a. Test results for the whole mixture must consider dose and other factors such as duration, observations, and analysis of the test system (e.g., statistical analysis, test sensitivity).

3. Bridging principles can be used when there is sufficient data on both the individual ingredients and similar tested mixtures to provide adequate information on the hazards of the mixture.
   a. See **Appendix A.0.5. to 29 CFR 1910.1200**
   b. The bridging principles permitted are Dilution, Batching and Substantially Similar Mixtures.

Table 2: Cut-off values/concentration limits triggering classification of mixtures:

Ingredient Classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥ 0.1%	-
Category 2 carcinogen	-	≥ 0.1% (Note)

Note 1: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥ 1%, both an SDS and a label are required, and the information must be included on each.

Note 2: Under Appendix A.0.4.3.2 to 29 CFR 1910.1200, If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit in Table 2, the mixture containing that ingredient shall be classified accordingly.

Labeling Elements for Carcinogenicity

Table 3: Hazard Communication Label Elements for Carcinogenicity (29 CFR 1910.1200, Appendix C)

Category	Category 1A	Category 1B	Category 2
Pictogram			
Signal Word	**Danger**	**Danger**	**Warning**
Hazard Statement	**May cause cancer** (*state route of exposure if no other routes of exposure cause the hazard*)	**May cause cancer** (*state route of exposure if no other routes of exposure cause the hazard*)	**Suspected of causing cancer** (*state route of exposure if no other routes of exposure cause the hazard*)

Precautionary Statements	**Prevention**	**Obtain special instructions before use.** **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.
	Response	**If exposed or concerned: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.
	Storage	**Store locked up.**
	Disposal	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

Important considerations during classification

The information in this factsheet is based on **Appendix A (Health Hazard Criteria)** and **Appendix F (Guidance for Hazard Classifications Re: Carcinogenicity (Non mandatory)) to 29 CFR 1910.1200**.

1) Classification should be based on:
   a. Studies using reliable and acceptable methods.
   b. A review of all peer-reviewed published studies and additional data accepted by regulatory authorities.
   c. Consideration of human evidence, animal studies, as well as other factors that may increase or decrease the level of concern.

2) Expert judgment is necessary in applying the classification criteria.

Carcinogen classification is based on strength of evidence, weight of evidence and other considerations:

a. Strength of evidence:
- Sufficient evidence:
  - Causality (cause and effect relationship) between human exposure and development of cancer, or
  - a causal relationship between the substance and increased tumor incidence in animal studies
    → May lead to Category 1A or Category 1B classification.

  - Limited evidence:
    - A positive association between exposure and cancer in humans, without demonstration of a causal relationship, or
    - data from animal studies suggesting a carcinogenic effect, without demonstration of a causal relationship.

    → May lead to Category 2 classification.

(Note: Limited evidence from both human and animal studies may result in a Category 1B classification on a case-by-case basis)

b. Weight of Evidence Analysis
- *Weight of evidence analysis* means that all available information affecting the classification of a hazard should be considered together. It takes your findings of evidence for Carcinogenic potential and determines how much those pieces of evidence should factor into the classification.

- The following are examples of factors that may increase or decrease the overall level of concern:
  - Tumor response factors: tumor incidence and tumor type, number of sites, progression to malignancy, latency, background incidence
  - Experimental study considerations: route of exposure; number of independent studies; adequacy of study design, conduct, or interpretation
  - Additional factors: number of species or strains responding, gender specificity, relevant structure-activity relationships, toxicokinetics/toxicodynamics and mode of action and its relevance to humans (for example, mutagenicity, immunosuppression, etc.)

Under the HCS, where the *weight of evidence* for carcinogenicity does not meet the classification criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the SDS.

3) Inherent Properties of a Substance or Mixture
   a. Under the HCS, classification of a substance or mixture as a Carcinogen is based on its inherent properties. Classification does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

   b. Classification must be present for those substances and mixtures that are carcinogenic, and which under normal conditions of use or foreseeable emergencies are expected to result in employee exposure to the hazardous chemical. OSHA has interpreted exposure to mean any potential exposure. OSHA has further 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."

4) How to use Lists in classifying for carcinogenicity *
   a. If OSHA has determined a chemical to be a Carcinogen in **29 CFR 1910, Subpart Z**, the chemical must be classified as a carcinogen per **Appendix A.6.4.2 to 29 CFR 1910.1200.**
      - See: **29 CFR 1910, Subpart Z, Toxic and Hazardous Substances**
   b. Instead of applying classification criteria using human or animal evidence, the following lists may be used to establish that a substance is a carcinogen (see **Appendix F**).** It is required to state on the SDS (section 11) if a chemical appears on any of these lists.
      - *National Toxicology Program (NTP) "Report on Carcinogens" (latest edition),*
      - *International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)*

* Note: The absence of a chemical from a known Carcinogen list does not exclude it from being classified as a carcinogen.

** See **Appendix F (Guidance for Hazard Classifications Re: Carcinogenicity) to 29 CFR 1910.1200,** for approximate equivalences among classification schemes, and the **Compliance Directive (CPL 02-02-079) Appendix C** for information on how OSHA enforces list-based criteria. for information on how OSHA enforces list-based criteria.

To learn more…

- **OSHA: Hazard Communication**. Available at: https://www.osha.gov/hazcom
  View the HCS 2012 standard, the HCS 2024 standard, the compliance directive, the Hazard Classification Guidance, the *Small Entity Compliance Guide*, , briefs, pictograms, QuickCards™, Frequently Asked Questions, and other resources.

- **UNECE: About the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (from the UN).** Available at: https://unece.org/about-ghs

- ***Globally Harmonized System of Classification and Labelling of Chemicals (GHS):*** *Revision 3 and Revision 7* (also known as "The Purple Book.")
  - **Revision 3:** https://unece.org/ghs-rev3-2009
  - **Revision 7:** https://unece.org/ghs-rev7-2017

  Note: Newer revisions of the "Purple Book" have been developed; however, HCS 2012 follows GHS Revision 3, and the HCS 2024 follows GHS Revision 7 and parts of Revision 8. In some instances, conforming to different revisions may render the user out of compliance with the HCS.

- **OSHA/SCHC Alliance Information Sheets**. Available at:
  - OSHA site: https://www.osha.gov/alliances/schc/schc
  - SCHC site: https://www.schc.org/osha-alliance