



Hazard Communication Information Sheet reflecting the US OSHA Implementation of the *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*

Produced by the SCHC-OSHA Alliance
GHS/HazCom Information Sheet Workgroup

Carcinogenicity

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How is Carcinogenicity defined under HazCom 2012?

A carcinogen is a chemical substance or a mixture of chemical substances that induces cancer or increases its incidence. Substances and mixtures that have induced cancer in experimental animal studies are considered to be presumed or suspected human carcinogens unless there is strong evidence to indicate the mechanism of tumor formation is not relevant to humans.

How is Carcinogenicity classified under HazCom 2012?

Carcinogen classification involves two interrelated determinations: evaluation of strength of evidence and consideration of all other relevant information (weight of evidence analysis). Carcinogens are categorized as either known/presumed carcinogens (Category 1) or suspected carcinogens (Category 2). Category 1 is subdivided further based on whether the evidence for classification is mostly from human or animal data (see Table 1 below). The hazard communication label elements for carcinogenicity are presented below in Table 2.

In lieu of application of classification criteria, the following sources may be used to establish that a substance is a carcinogen: 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), and OSHA (29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances). See §1910.1200 Appendix F (Guidance for Hazard Classifications Re: Carcinogenicity) for approximate equivalences among classification schemes.

Table 1: Classification Criteria

Category	Category 1A	Category 1B	Category 2
Description	Known or presumed human carcinogens	Suspected human carcinogen	
	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

Table 2 shows some of the label elements for carcinogens. The precautionary statements are not included due to space limitations of this fact sheet. See §1910.1200 for complete classification and labelling information.

Table 2: Hazard Communication Label Elements for Carcinogenicity

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)

Important considerations in classifying a substance as a Carcinogen:

The information in this section is based on §1910.1200 Appendix A (Health Hazard Criteria) and Appendix F (Guidance for Hazard Classifications Re: Carcinogenicity). Classification should be based on studies using reliable and acceptable methods. All peer-reviewed published studies and additional data accepted by regulatory authorities should be reviewed. Human evidence, animal studies, as well as other factors that may increase or decrease the level of concern should be considered. Carcinogen classification is based on strength of evidence and other considerations (e.g., weight of evidence). Expert judgment is necessary in applying the classification criteria. Under HCS 2012, where the weight of evidence for carcinogenicity does not meet the categorization 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 safety data sheet.

- 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)
- Other considerations (weight of evidence analysis) – Beyond strength of evidence, a number of other factors should be considered that may influence the likelihood an agent may present a carcinogenic risk. 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.)

How is classification applied to mixtures?

1. Classify based on reliable and good quality evidence on the mixture itself: this is done on a case-by-case basis when such data is conclusive and accounts for factors including dose, duration of study, observations, and analysis of the test system (e.g. statistical analysis, test sensitivity).
2. Use bridging principles (dilution, batching, and substantially similar mixtures). See Section A.0.5 of Appendix A to §1910.1200 Health Hazard Criteria for detailed guidance::
3. Classify based on cut-off values/concentration limits of the ingredients in a mixture (Table 3)http://www.osha.gov/dsg/hazcom/appendix_a.pdf.

Table 3: 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: 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 is required and the information must be included on each.

To learn more...

- OSHA: Hazard Communication : <https://www.osha.gov/dsg/hazcom/index.html>
- SCHC site: <http://www.schc.org/osha-alliance>

The information contained in this sheet is believed to accurately represent current OSHA HCS requirements. However, SCHC cannot guarantee the accuracy or completeness of this information. Users are responsible for determining the suitability and appropriateness of these materials for any particular application.

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