



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

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GHSHazCom Information Sheet Workgroup*

Serious Eye Damage / Eye Irritation

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How does OSHA's Hazard Communication Standard (HCS 2012) define Serious Eye Damage / Eye Irritation?

OSHA's Hazard Communication Standard (HCS 2012) in §1910.1200, defines serious eye damage as the production of tissue damage in the eye, or serious physical decay of vision, following the application of a test substance to the front outer surface of the eye, which is not fully reversible within 21 days of application.

The HCS 2012 defines eye irritation as changes in the eye following application of a test substance to the front outer surface of the eye, which is fully reversible within 21 days of application.

How does HCS 2012 classify Serious Eye Damage / Eye Irritation?

Classification of a substance is based on a review of all available information, including:

- Accumulated human and animal experience
- Information on structurally related compounds
- pH with buffering capacity
- Skin corrosion testing data

Guidance on a tiered approach to the evaluation strategy for serious eye damage and eye irritation is provided in Figure A.3.1 of the HCS 2012. Emphasis shall be placed upon existing human data, followed by animal data, followed by other sources of information. In case the criteria in Section A.3 of Appendix A to §1910.1200 cannot be directly applied, classification is made on the basis of the total weight of evidence, meaning that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.



The criteria for classification of Serious Eye Damage/ Eye Irritation are as follows:

Table 1: Classification Criteria

Category	Description
Category 1	A substance is classified as Serious Eye Damage Category 1 (irreversible effects on the eye) when it produces: <ul style="list-style-type: none"> (a) at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or (b) at least in 2 of 3 tested animals, a positive response of: <ul style="list-style-type: none"> (i) corneal opacity ≥ 3; and/or (ii) iritis > 1.5; calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance.
Category 2A	A substance is classified as Eye Irritant Category 2A (irritating to eyes) when it produces in at least in 2 of 3 tested animals a positive response of: <ul style="list-style-type: none"> (i) corneal opacity ≥ 1; and/or (ii) iritis ≥ 1; and/or (iii) conjunctival redness ≥ 2; and/or (iv) conjunctival edema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.
Category 2B	An eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed for Category 2A above are fully reversible within 7 days of observation.

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

Table 2: Hazard Communication Label Elements for Serious Eye Damage / Eye Irritation

Category	Category 1	Category 2A	Category 2B
Pictogram			No Pictogram
Signal Word	Danger	Warning	Warning
Hazard Statement	Causes serious eye damage	Causes serious eye irritation	Causes eye irritation

Important considerations in classifying a substance as Serious Eye Damage / Eye Irritation

Alternative testing: Alternative testing methods for the assessment of eye irritation and serious eye damage must be validated in accordance with internationally agreed principles and criteria. At present, validated alternative methods for the reliable assessment of reversible eye irritation have not been developed.

How is classification applied to mixtures?

1. Classify based on reliable and good quality evidence on the mixture itself.
2. Use bridging principles (dilution, batching, concentration, interpolation, substantially similar mixtures, and aerosols). See Section A.0.5 of Appendix A to §1910.1200 Health Hazard Criteria for detailed guidance: (http://www.osha.gov/dsg/hazcom/appendix_a.pdf).
3. Classify based on cut-off values/concentration limits of the ingredients in a mixture (Table 3).

Table 3: Concentration of ingredients of a mixture classified as Skin Category 1 and / or Eye Category 1 or 2 that would trigger classification of the mixture as hazardous to the eye:

Sum of Ingredients Classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye or Skin Category 1	≥3%	≥1% but <3%
Eye Category 2		≥10%
(10 x Eye Category 1) + Eye Category 2		≥10%
Skin Category 1 + Eye Category 1	≥3%	≥1% but <3%
10 x (Skin Category 1 + Eye Category 1) + Eye Category 2		≥10%

Note: A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.

Certain chemicals such as acids, bases, inorganic salts, aldehydes, phenols, and surfactants may not be classifiable using the additivity approach above. In these cases, Table 4 is used for classification. For mixtures containing strong acids or bases, the pH should be used as classification criteria since pH will be a better indicator of serious eye damage than the concentration limits. See Section A.3.4.3.4 of Appendix A to §1910.1200 Health Hazard Criteria for detailed guidance: (http://www.osha.gov/dsg/hazcom/appendix_a.pdf).

Table 4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye:

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤2	≥1%	Category 1
Base with pH ≥11.5	≥1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥3%	Category 2

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 HCS 2012 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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