



### How does GHS define eye damage/irritation?

#### Eye Damage

The GHS 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.

#### Eye Irritation

The GHS 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.

Table 1: Hazard Communication : Label Elements of Serious Eye Damage / Eye Irritation

	Category 1	Category 2A	Category 2B
Symbol	Corrosion	Exclamation Mark	No symbol
Signal Word	Danger	Warning	Warning
Hazard Statement	Causes serious eye damage	Causes serious eye irritation	Causes eye irritation

### Substance Classification

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
- Skin corrosion testing data

Before there is any *in-vivo* testing for serious eye damage/eye irritation, all existing information should be reviewed. The GHS provides guidance on a tiered approach to the testing and evaluation strategy for serious eye damage and irritation (see Figure 3.3.1 of the GHS) and recommends that generally, primary emphasis should be placed on professional judgment and human experience with the substance, followed by the results of skin irritation testing and of well-validated methods. Animal testing with corrosive substances should be avoided whenever possible.

If animal testing is available, the criteria for classification are as follows:

#### **Eye Irritant Category 1** (irreversible effects on the eye) – a material that produces:

- 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:
  - i. corneal opacity  $\geq 3$ ; and/or
  - ii. iritis  $> 1.5$ ;

calculated as the mean scores, following grading at 24, 48, and 72 hours after instillation of the test substance.

**Eye Irritant Category 2A** (irritating to eyes) – a material that produces:

- a) at least in 2 of 3 tested animals, a positive response of:
- corneal opacity  $\geq 1$ ; and/or
  - iritis  $\geq 1$ ; and/or
  - conjunctival redness  $\geq 2$ , and/or
  - conjunctival edema (chemosis)  $\geq 2$

calculated as the mean scores, following grading at 24, 48, and 72 hours after instillation of the test substance and which fully reverses within an observation period of normally 21 days.

**Eye Irritant Category 2B** (mildly irritating to eyes)

Within the category of 2A, above, when the effects listed are fully reversible within 7 days of observation.

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**Mixtures Classification**

Mixtures are classified for eye irritation as follows:

- Classify based on mixture test data (consider mixture pH as indicated above for substances).
- Use bridging principles (dilution, batching, concentration, interpolation, and substantially similar mixtures and aerosols). See Section 3.3.3.2 of the GHS for detailed guidance.
- Classify based on additivity of the mixture ingredients:

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	$\geq 3\%$	$\geq 1\%$ but $< 3\%$
Eye Category 2/2A		$\geq 10\%$
(10 × Eye Category 1) + Eye Category 2/2A		$\geq 10\%$
Skin Category 1 + Eye Category 1	$\geq 3\%$	$\geq 1\%$ but $< 3\%$
10 × (Skin Category 1 + Eye Category 1) + Eye Category 2A/2B		$\geq 10\%$

Certain chemicals such as acids, bases, inorganic salts, aldehydes, phenols, and surfactants may not be classifiable using the additivity approach above. In these cases, the GHS recommends using the table below. For acids and bases, the pH may be a better indicator of the potential for eye damage (see Note, below).

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

## Notes

An aerosol form of a mixture may be classified in the same hazard category as the tested non-aerosolized form of the mixture provided that the added propellant does not affect the irritation or corrosive properties of the mixture upon spraying. The bridging principles apply for the intrinsic hazard classification of aerosols, however, the need to evaluate the potential for 'mechanical' eye damage from the physical force of the spray is recognized.

pH extremes like  $\leq 2$  and  $\geq 11.5$  may indicate strong local effects, especially in combination with assessment of acid or alkaline reserve, substances exhibiting such physico-chemical properties should be considered as leading to serious damage of eyes (Category 1).

Alternative testing: The GHS text states that these methods must be validated in accordance with internationally agreed principles. Validated alternative methods for the reliable assessment of reversible eye irritation have not yet been developed.

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### To learn more ...

- The GHS, in its entirety (including classification criteria and label and MSDS requirements), can be downloaded at: [http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev03/03files\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html)
- OSHA's Notice of Proposed Rulemaking on the GHS is available at: [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=FEDERAL\\_REGISTER&p\\_id=21110](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=21110)
- A training course on the GHS is offered by the Society for Chemical Hazard Communication (SCHC): <http://www.schc.org/training.php>
- For information sheets on additional GHS topics:
  - OSHA site: <http://www.osha.gov/dcsp/alliances/schc/schc.html#documents> - go to 'Products and Resources'.
  - or SCHC site: [http://www.schc.org/issues.php?start\\_from=5&ucat=&archive=&subaction=&id=&cat=9](http://www.schc.org/issues.php?start_from=5&ucat=&archive=&subaction=&id=&cat=9) - see 'GHS Information Sheets'.
- The OSHA Guide to the Globally Harmonized System of Classification and Labeling of Chemicals is available at: <http://www.osha.gov/dsg/hazcom/ghs.html>

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*The information contained in this sheet is believed to accurately represent provisions of U.S. regulations, consensus standards, and current GHS requirements (Revision 3). 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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