



# 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

## Skin Sensitization

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### How does OSHA HazCom 2012 define Skin Sensitization?

Skin sensitizer means a chemical that will lead to an allergic response following skin contact. (See Appendix A to 29 CFR 1910.1200, section A.4.) In contrast to skin irritation, skin sensitization is an immunological response to previous exposure to a substance which results in an inflammatory skin reaction. An allergic skin reaction is usually presented as a red, itchy, bumpy rash.



Previous exposure to a *specific* substance is necessary for skin sensitization. The first phase is induction (or sensitization) and the second phase is elicitation. In the first phase, development of specialized memory cells in the immune system of an individual occurs following the initial exposure to a skin sensitizer. In the second phase, an allergic skin reaction is produced following subsequent exposure to a skin sensitizer. The specialized memory cells produced in the individual's immune system following the initial exposure respond to the subsequent exposure, i.e., an allergic reaction takes place.

The classification as a skin sensitizer is based on human experience (epidemiology or case studies), human skin sensitization test (patch test or maximization test), or animal testing. Several animal tests exist for the determination of skin sensitization. These include the Mouse Local Lymph Node Assay (LLNA), the Buehler Assay and the Guinea Pig Maximization Test.

### How is a skin sensitizer classified under OSHA HazCom 2012?

A chemical is classified as a skin sensitizer if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or if there are positive results from an appropriate animal test. Skin sensitizers are categorized as Category 1A or 1B. Where data are not sufficient for sub-categorization, skin sensitizers are classified in Category 1.

**Table 1: Hazard and sub-categories for Skin Sensitizers:**

Categories	Category 1A	Category 1B
<b>Description</b>	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.
<b>Symbol</b>		
<b>Signal word</b>	Warning	Warning
<b>Hazard statement</b>	May cause an allergic skin reaction	May cause an allergic skin reaction



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### Important considerations in classifying a substance as a Skin Sensitizer:

Classification of skin sensitization follows a weight of evidence approach. The term “weight of evidence” means that all the available information on the potential of a substance to cause skin sensitization is considered together. This information may include results from human patch testing, human case studies, epidemiological studies and animal studies, and considers the conduct of the study, the severity of the reaction, and the concentration of the chemical. Other data may be considered on a case-by-case basis. Human data should not normally be used to negate positive results from animal studies. Substances meeting the criteria for classification as a respiratory sensitizer may be classified as a skin sensitizer.

### 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, and 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](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 2).

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

Category	Cut-off values/concentration limits triggering classification of a mixture as:
1	≥ 0.1%
1A	≥ 0.1%
1B	≥ 1.0%

### 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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