



Respiratory Sensitization

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How does OSHA's Hazard Communication Standard (HCS 2012) define Respiratory Sensitization?

Respiratory sensitizer means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical (See Appendix A to 29 CFR 1910.1200, section A.4.). In contrast to respiratory irritation, respiratory sensitization is an immunological response to previous exposure to a chemical. Hypersensitivity is normally seen as asthma, but other hypersensitivity reactions involving the nose (rhinitis), eyes (conjunctivitis), or lungs (alveolitis) are also considered.

Previous exposure to a specific substance is necessary for respiratory 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 respiratory sensitizer. In the second phase, an allergic respiratory reaction is produced following subsequent exposure to a respiratory 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.

How does HCS 2012 classify Respiratory Sensitization?

A chemical is classified as a respiratory sensitizer if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or if there are positive results from an appropriate animal test. The classification of respiratory sensitizer will normally be based on human experience; recognized and validated animal models for the testing of respiratory sensitizers are not available. Data from animal studies may provide information in a weight of evidence assessment. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperactivity, they should not be considered as respiratory sensitizers.


Respiratory sensitizers are classified as Category 1A or 1B. Where data are not sufficient for sub-categorization, respiratory sensitizers are classified as Category 1. Category 1A is assigned to chemicals with a high potential to cause respiratory sensitization in humans and Category 1B is assigned to chemicals with a low to moderate potential to cause respiratory sensitization in humans.

Table 1: Classification Criteria for Respiratory Sensitization

Category	Category 1A	Category 1B
Description	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered.	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered.

Table 2 shows some of the label elements for Respiratory Sensitization. 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 Respiratory Sensitization

Category	1 (including both sub-categories 1A and 1B)
Pictogram	
Signal Word	Danger
Hazard Statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Important considerations in classifying a substance as a Respiratory Sensitizer:

When considering human evidence, it is necessary that the size of the population exposed and the extent of exposure be taken into consideration. Human evidence includes:

- Clinical history and data from appropriate lung function tests confirmed by:
 - *in vivo* testing (skin prick test); or
 - *in vitro* testing (serological analysis); or
 - studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven (repeated low-level irritation, pharmacologically mediated effects); or
 - A chemical structure related to chemicals known to cause respiratory hypersensitivity.
- Data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

Data from appropriate animal studies includes information which may indicate the potential of a chemical to cause sensitization by inhalation in humans. As stated above, recognized and validated animal models to predict the potential for a chemical to induce respiratory sensitization are not available. Animal evidence includes:

- Measurements of Immunoglobulin E (IgE) and other specific immunological parameters in animals
- Specific pulmonary response in guinea pigs.

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).
3. Classify based on cut-off values/concentration limits of the ingredients in a mixture (Table 3).

Table 3: Cut-off values/concentration limits triggering classification of mixtures (this table will need to be adjusted based on the category):

Ingredient Classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Solid/Liquid	Gas
Category 1 Classification	≥ 0.1%	≥ 0.1%
Category 1A Classification	≥ 0.1%	≥ 0.1%
Category 1B Classification	≥ 1.0%	≥ 0.2%

To learn more...

- OSHA: Hazard Communication: <https://www.osha.gov/dsg/hazcom/index.html>
HCS 2012.
- 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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