Produced by SCHC-OSHA Alliance
GHS Information Sheet Workgroup

Acute Toxicity – Dermal

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What is Acute Dermal Toxicity?

Acute toxicity by the dermal route refers to serious adverse health effects (i.e. lethality) occurring after dermal administration of a single or short-term dose of a substance or mixture. (See Appendix A.1 to 29 CFR 1910.1200).

How do I classify for Acute Dermal Toxicity?

Substance Classification

Substances are classified into one of four hazard categories. Hazard categories are assigned based on acute toxicity values which are expressed as Lethal Dose (LD50) or Acute Toxicity Estimates (ATE). While some in vivo methods determine LD50 values directly, newer in vivo methods (which use fewer animals), consider other indicators of acute toxicity, such as significant clinical signs, to assign a hazard category. For more details on applying these values, refer to the footnotes following Table 1.

Table 1: Classification Criteria (29 CFR 1910.1200 Table A.1.1)

Category	Category 1	Category 2	Category 3	Category 4
Dermal (mg/kg bodyweight) *Notes a and b*	ATE ≤ 50	> 50 ATE ≤ 200	> 200 ATE ≤ 1000	> 1000 ATE ≤ 2000

Note:
(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD50 where available.
(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:
(i) the LD50 where available. Otherwise,
(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or
(iii) the appropriate conversion value from Table 1.2 that relates to a classification category.

Mixture Classification

When classifying mixtures for acute dermal toxicity, the process depends on the amount of available information.

- If the mixture itself has been tested, it is classified based on those results.
- If not, the classification relies on data from individual ingredients or similar tested mixtures.
- If a mixture has not been tested for acute toxicity but there is enough data on its ingredients and similar mixtures, this data is used for classification based on specific bridging principles like dilution, batching, concentration, and similarity to other mixtures (See Appendix A.0.5. to 29 CFR 1910.1200).
- In some cases, additional technical expertise is required to estimate the toxicity accurately.

For mixtures without direct test data, the ATE of the mixture is calculated using the ATE values for all relevant ingredients based on the following formula:

C_i *= concentration of ingredient* ***i***
n *ingredients and* ***i*** *is running from* ***1*** *to* ***n***
ATE_i *= Acute toxicity estimate of ingredient* ***i***

$$\frac{100}{\text{ATEmix}} = \sum_{n} \frac{C_i}{ATE_i}$$

- The cut-off value for Acute Toxicity is ≥ 1% w/w

- If an ingredient at < 1% concentration might impact the mixture's acute toxicity classification, it must be considered relevant, especially for untested mixtures containing Category 1 or 2 ingredients.
- If an ingredient's toxicity is unknown but present at a concentration of 1% or more, the mixture's overall toxicity is calculated based on the known ingredients.
- When a classified mixture is used as an ingredient in another mixture, its actual or derived ATE is used to calculate the classification of the new mixture.
- In some cases, additional technical expertise is required to estimate the toxicity accurately.

If the unknown toxic ingredients is greater than 10% of the mixture, an adjusted formula is applied:

$$\frac{100 - \left(\sum C_{\text{unknown}} \quad \text{if} > 10\%\right)}{\text{ATE}_{\text{mix}}} = \sum_{n} \frac{C_i}{\text{ATE}_i}$$

Labels and safety data sheets must indicate that "x percent of the mixture consists of ingredient(s) of unknown acute dermal toxicity".

If necessary, Acute Toxicity Range Values can be converted to Acute Toxicity Point Estimates:

Table 2: Conversion Criteria for Acute Toxicity – Dermal (29 CFR 1910.1200 Table A.1.2)				
Dermal (mg/kg bodyweight) LD50	0 < Category 1 ≤ 50	50 < Category 2 ≤ 200	200 < Category 3 ≤ 1000	1000 < Category 4 ≤ 2000
Acute Toxicity Point Estimate	**5**	**50**	**300**	**1100**

Labeling Elements for Acute Dermal Toxicity

Table 3: Hazard Communication Label Elements for Acute Toxicity - Dermal (29 CFR 1910.1200, Appendix C)

	Category	Category 1	Category 2	Category 3	Category 4
	Pictogram				
	Signal Word	**Danger**	**Danger**	**Danger**	**Warning**
	Hazard Statement	**Fatal in contact with skin**	**Fatal in contact with skin**	**Toxic in contact with skin**	**Harmful in contact with skin.**
Precautionary Statements	**Prevention**	**Do not get in eyes, on skin, or on clothing.** **Wash ... thoroughly after handling.** . . . Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.** **Wear protective gloves/protective clothing** Chemical manufacturer, importer, or distributor to specify type of equipment is advised where appropriate.		**Wear protective gloves/protective clothing.** Chemical manufacturer, importer, or distributor to specify type of equipment where appropriate.	
	Response	**If on skin: Wash with plenty of water/ ...** **...** Chemical manufacturer, importer, or		**If on skin: Wash with plenty of water/ ...** . . . Chemical manufacturer, importer, or	

		distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**.** **Immediately call a poison center/doctor/ ...** **.** .. Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment *(see* ... on this label)** Reference to supplemental first aid instruction. *- if immediate measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and** **wash it before reuse.**	distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/ ... /if you feel unwell.** **. . .** Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment *(see* ... on this label)** **...** Reference to supplemental first aid instruction. *- if immediate measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**
	Storage	**Store locked up.**	**Store locked up. (not for Category 4)**
	Disposal	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

Important considerations during classification

- Existing test data for chemical classification should be used in lieu of conducting additional tests using animals.
- If data from multiple animal species are available, scientific judgment should be used to select the most appropriate LD50 value from validated tests. The rat or rabbit is the preferred test species for dermal toxicity tests.
- Human data, such as occupational or clinical reports, should also be considered using a weight of evidence approach.
- Use a tiered approach to classification (See Appendix A.1., Figure A.1.1. to 29 CFR 1910.1200).:

To learn more…

- **OSHA: Hazard Communication**. Available at: https://www.osha.gov/hazcom
  View the HCS 2012 standard, the HCS 2024 standard, the compliance directive, the Hazard Classification Guidance, the *Small Entity Compliance Guide*, briefs, pictograms, QuickCards™, Frequently Asked Questions, and other resources.

- **UNECE: About the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (from the UN).** Available at: https://unece.org/about-ghs

- ***Globally Harmonized System of Classification and Labelling of Chemicals (GHS):*** *Revision 3 and Revision* 7 (also known as "The Purple Book.")
  - **Revision 3:** https://unece.org/ghs-rev3-2009
  - **Revision 7:** https://unece.org/ghs-rev7-2017

  Note: Newer revisions of the "Purple Book" have been developed; however, HCS 2012 followed GHS Revision 3, and the HCS 2024 follows GHS Revision 7 and parts of Revision 8. In some instances, conforming to different revisions may render the user out of compliance with the HCS.

- **OSHA/SCHC Alliance Information Sheets**. Available at:
  - OSHA site: https://www.osha.gov/alliances/schc/schc
  - SCHC site: https://www.schc.org/osha-alliance