



Office of Pesticide Programs

Label Review Manual

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Label Review Manual

Chapter 7: Precautionary Statements



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Table 1. Acute Toxicity Categories				
Study	Category I	Category II	Category III	Category IV
Acute Oral	LD ₅₀ ≤50 mg/kg	LD ₅₀ >50 – 500 mg/kg	LD ₅₀ >500 – 5,000 mg/kg	LD ₅₀ >5,000 mg/kg
Acute Dermal	LD ₅₀ ≤200 mg/kg	LD ₅₀ >200 – 2,000 mg/kg	LD ₅₀ >2,000 – 5,000 mg/kg	LD ₅₀ >5,000 mg/kg
Acute Inhalation	LC ₅₀ ≤0.05 mg/l	LC ₅₀ >0.05 – 0.5 mg/l	LC ₅₀ >0.5 – 2 mg/l	LC ₅₀ >2 mg/l
Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)
Dermal Sensitization	Positive		Negative	
	Product is a sensitizer or is positive for sensitization		Product is not a sensitizer or is negative for sensitization	

IV. Determining the precautionary labeling

A. Signal word

1. When required

A signal word is required for all registered pesticide products unless the pesticide product is classified as Toxicity Category IV for all routes of exposure, and is negative for dermal sensitization. If a signal word is used in this case, it must be “CAUTION.” [40 CFR 156.64\(a\)\(4\)](#).

2. Determining the signal word

The signal word is determined by the most severe toxicity category assigned to the five acute toxicity studies (see Table 1) [40 CFR 156.64](#). The signal words and its associated toxicity categories are as follows:

	DANGER
Toxicity Category II	WARNING
Toxicity Category III	CAUTION
Toxicity Category IV	None required (or CAUTION as optional)

Refer to the acute toxicity data review to determine the most severe toxicity category. Also check the Confidential Statement of Formula (CSF) to determine if methanol is present in concentrations of 4% or more. If so, the recommended signal word, regardless of the toxicity categories noted in the acute toxicity review, is “DANGER.”

3. Location and prominence

The signal word must be placed on the front panel as a separate line in close proximity to the child hazard statement “Keep Out of Reach of Children.” [40 CFR 156.60](#). It must also be placed with the heading for the human precautionary statement section of the labeling. [40 CFR 156.64](#). Also, the signal word must be on any supplemental labeling intended to accompany the product in distribution or sale. [40 CFR 156.60](#).

The Agency prefers that the signal word be placed directly below the child hazard statement. The signal word should appear in the Precautionary Statements section immediately below the subheading “Hazards to Humans and Domestic Animals.” In cases where the first aid and “Hazards to Humans and Domestic Animals” statements appear on the front panel, the signal word should be placed directly below the “Keep Out of Reach of Children” statement, but it does not have to be repeated after the “Hazards to Humans and Domestic Animals” statement.

All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to assure that they will not be overlooked under customary conditions of purchase and use. [40 CFR 156.60\(b\)](#). The signal word must appear in all capital letters and should be oriented in the same direction as other label text. See Chapter 3 of this Manual for font size requirements.

4. Related information on California Proposition 65 warnings

Because of the potential for confusion, the Agency historically has not approved labels containing the terms “caution,” “warning,” or “danger,” unless it is the signal word for that label (e.g., “CAUTION: Wash hands before eating or smoking” on a label with the signal word of “CAUTION”). If the Prop 65 term would conflict with the EPA signal word, then registrants should use “Notice” or “Attention” for the Prop 65 statement so that it does not conflict with the EPA signal word.