

# **Revised March 2018**

# **Label Review Manual**

# **Chapter 7: Precautionary Statements**



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# What's changed in this version?

- ➤ Added *Table of Contents*.
- Added What's changed in this version? section.
- Updated hyperlinks.
- Reformatted text and style to improve readability.
- Added dermal sensitization to acute toxicity categories table (Table 1).
- Reinstated first aid statements per PR Notice 2001-1.
- ➤ Updated location of first aid statements per February 27, 2018 First Aid Guidance Document EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68.
- Removed redundant section on NPIC and referenced Chapter 15 for details.
- Added Note to Physician statement for products containing zinc phosphide.
- > Updated NPIC information in first aid statements example in Table 9.
- Changed Labeling Options section to Modified precautionary statements for diluted products (aqueous solutions only).
- Removed Optional Labeling/Deviations section and moved directions under its respective sections.

# I. Introduction

The precautionary statements provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide, in addition to medical treatment instructions and information to reduce exposure potential. This chapter addresses the signal word, child hazard warning, hazards to humans and domestic animals statement, first aid statement, and personal protective equipment (PPE) information for product labels with uses not subject to the worker protection standard (WPS). Precautionary statements for WPS-PPE, user safety requirements, engineering controls, user safety recommendations, environmental hazards, and physical/chemical hazards are addressed in other chapters.

# II. Documents used to determine precautionary statements

40 CFR 156.62 specifies the criteria for the acute toxicity categories for pesticide products, and 40 CFR 156.70 specifies the typical *Hazards to Humans and Domestic Animals* statement associated with each toxicity category. EPA has historically used the labeling statements in the September 26, 1984 proposed rule *Labeling Requirements for Pesticides and Devices* (49 FR 37960, Number 188) to supplement the precautionary statements in 40 CFR 156.62. 40 CFR 156.70(c) states that specific statements pertaining to the hazards of the product and its uses must be approved by the Agency.

During pesticide reregistration and re-evaluation, the reregistration eligibility decision (RED), interim decision, or final decision documents may also specify required label statements. In cases where these label requirements differ from those determined by the acute toxicity categories, the most protective statements must be employed. The regulations allow use of a signal word for human hazard for a higher product toxicity category when necessary to prevent unreasonable adverse effects on humans and the environment. 40 CFR 156.64(b)(1).

# III. Acute toxicity classification

The signal word, hazards to humans and domestic animals, non-WPS PPE, and first aid statements are typically determined by the results of the six acute toxicity studies performed with the product formulation. The acute oral, acute dermal, and acute inhalation studies evaluate systemic toxicity via the designated routes of exposure. The primary eye irritation and primary skin irritation studies measure irritation or corrosion, while the dermal sensitization study evaluates the potential for allergic contact dermatitis. Except for dermal sensitization, each acute study is assigned to a toxicity category based on the study results (see Table 1 below). The results of these six acute toxicity studies must be known to determine the appropriate precautionary statements.

Table 1. Acute Toxicity Categories						
Study	Category I	Category II	Category III	Category IV		
Acute Oral	LD <sub>50</sub> ≤50 mg/kg	LD <sub>50</sub> >50 –500 mg/kg	LD <sub>50</sub> >500 – 5,000 mg/kg	LD <sub>50</sub> >5,000 mg/kg		
Acute Dermal	LD <sub>50</sub> ≤200 mg/kg	LD <sub>50</sub> > 200 – 2,000 mg/kg	LD <sub>50</sub> > 2,000 - 5,000 mg/kg	LD <sub>50</sub> >5,000 mg/kg		
Acute Inhalation	LC <sub>50</sub> ≤0.05 mg/l	LC <sub>50</sub> >0.05 - 0.5 mg/l	LC <sub>50</sub> > 0.5 – 2 mg/l	LC <sub>50</sub> > 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	Positive		Negative			
Sensitization	Product is a sensitizer sensitization	or is positive for	Product is not a sensit sensitization	izer or is negative for		

# 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) <u>40 CFR 156.64</u>. The signal words and its associated toxicity categories are as follows:

Toxicity Category I	DANGER
Toxicity Category II	WARNING
Toxicity Category III	CAUTION
Toxicity Category IV	None required (or <b>CAUTION</b> 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.

# B. Poison – skull and crossbones symbol

# 1. When required

The word "POISON" and the skull and crossbones symbol are required for products classified as toxicity category I for acute oral, acute dermal, or acute inhalation toxicity studies. 40 CFR 156.64(a)(1). Additionally, if a formulation contains ≥4% methanol, the addition of "POISON" and the skull and crossbones symbol are recommended because of the well-known possible risk of causing blindness.

Table 2. Examples of Signal Word Determination					
Study/Classification	Product A	Product B	Product C	Product D	Product E
Acute Oral	Ш	IV	1	III	III
Acute Dermal	IV	III	III	IV	III
Acute Inhalation	Ш	IV	III	Ш	III
Primary Eye	Ш	II	ı	I	III
Primary Skin	IV	IV	П	IV	III
Special Inert (e.g., methanol)	No	No	No	No	Yes
CORRECT SIGNAL WORD	CAUTION	WARNING	DANGER POISON	DANGER	DANGER POISON

# 2. Location and prominence

If required, the word "POISON" and the symbol must appear in immediate proximity to each other. The word "POISON" must appear in red on a background of a distinctly contrasting color. It should appear near the signal word "DANGER." 40 CFR 156.64(a)(1).

# C. Child hazard warning statement

#### 1. When required

The child hazard warning statement "Keep Out of Reach of Children" is required on all product labels regardless of toxicity category, unless EPA waives the requirement or requires or permits an alternative child hazard warning. The child hazard warning statement requirement may be waived or modified when the registrant adequately demonstrates that the likelihood of contact with children during distribution, storage, or use (e.g., an MUP in some situations) is remote or if the pesticide is approved for use on infants or children.

40 CFR 156.66.

### 2. Location and prominence

The child hazard warning statement must appear on the front panel and on a separate line in close proximity to the signal word. 40 CFR 156.66(a). The Agency prefers the child hazard warning statement to be located above the signal word. The child hazard warning statement should also be oriented in the same direction as other label text.

#### 3. Additional information

Based on the FIFRA unreasonable adverse effects standard, the Agency has not allowed the Precautionary Statements or the Directions for Use to contain any statement which implies that the product may be used by children. For example, draft labels of products intended to repel insects should not contain instructions such as "Do not allow use by small children without close adult supervision." Such labeling creates unacceptable risk issues, as it implies that a child can apply the product if an adult is present.

A modified child hazard warning statement may be used for products where child contact is expected during normal use. For products required or permitted to use a modified statement, the statement should be appropriate for the use pattern (e.g., "Do not allow children to apply product," "Do not allow children to play with pet collar.")

### D. Hazards to Humans and Domestic Animals Statements

#### 1. When required

Hazards to Humans and Domestic Animals statements are required for products classified as toxicity categories I, II, or III, or positive for skin sensitization.

Hazards to Humans and Domestic Animals statements may specify both mandatory actions and advisory information.

### 2. Required header

The Hazards to Humans and Domestic Animals statements must appear under the section heading "Precautionary Statements" and below the subheading "Hazard to Humans and Domestic Animals." Additionally, the signal word must immediately precede the precautionary paragraph. 40 CFR 156.70. The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product. 40 CFR 156.70(a).

### 3. Location and prominence

The Hazards to Humans and Domestic Animals section may appear on any panel. The Agency strongly prefers that the statements be organized so that the most severe routes of exposure (by toxicity classification) are listed first.

# 4. Determining the Hazards to Humans and Domestic Animals statements for fumigant products

Refer to <u>PR Notice 84-5</u>, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

# 5. Determining the Hazards to Humans and Domestic Animals statements for non-fumigant products

Statements from Tables 3-8 below may be selected based on the toxicity category assigned to each route of exposure. Statements from these tables should be combined to form a concise paragraph. Repetitious sentences should be omitted. In cases where the toxicity categories are unknown and a regulatory decision was made, the precautionary labeling must be consistent with the signal word. Refer to Section IV.E. and Chapter 10 of this Manual for selecting the appropriate protective equipment to include for non-WPS products.

# 6. Applicability

Hazards to Humans and Domestic Animals statements must be appropriate for all uses on the label. These statements must be consistent with each use pattern listed on the label. The statement should not include precautionary measures that are reasonably beyond the control of the typical applicator. Hazards to Humans and Domestic Animals statements must not require use of specialized equipment which would not be readily available to the typical user of the product (e.g., specialized respirator equipment for a consumer product).

# 7. Alternative Hazards to Humans and Domestic Animals statements

Registrants may submit Hazards to Humans and Domestic Animals statements which reflect specific hazards. 40 CFR 156.70(c). Such requests must be supported by data (or substantive justification) and approved by EPA (e.g., "Do not remove contact lenses, if worn. Get immediate medical attention.").

# 8. Products containing methanol

If a product contains ≥4% methanol, the following statement should be included to mitigate potential risk:

"Methanol may cause blindness."

Table 3. Typical Statements for Acute Oral Toxicity				
Category	Signal Word	Statement		
I	DANGER POISON \$\mathbb{R}\$	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.		
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.		
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.		
IV	CAUTION (optional)	No statement is required. May use Category III statement.		

Table 4. Typical Statements for Acute Dermal Toxicity				
Category	Signal Word	Statement		
I	DANGER POISON	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (specify appropriate protective clothing). Remove and wash contaminated clothing before reuse.		
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (specify appropriate protective clothing). Remove and wash contaminated clothing before reuse.		
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear (specify appropriate protective clothing, if applicable).		
IV	CAUTION (optional)	No statement is required. May use Category III statement.		

Table 5. Typical Statements for Acute Inhalation Toxicity				
Category	Signal Word	Statement		
I	DANGER POISON 🎘	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist) <sup>1</sup> . Wear ( <i>specify appropriate respiratory protection</i> ). Remove and wash contaminated clothing before reuse.		
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist) <sup>1</sup> . Wear (specify appropriate respiratory protection). Remove and wash contaminated clothing before reuse.		
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor, or spray mist) <sup>1</sup> . Remove and wash contaminated clothing before reuse.		
IV	CAUTION (optional)	No statement is required. May use Category III statement.		

 $<sup>^{\</sup>mathrm{1}}$  Choose the word which appropriately describes the product formulation type during use.

Table 6. Typical Statements for Primary Eye Irritation				
Category	Signal Word	Statement		
I	DANGER	Corrosive <sup>1</sup> . Causes irreversible eye damage. Do not get in eyes or on clothing. Wear ( <i>specify appropriate protective eyewear</i> ). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.		
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear ( <i>specify appropriate protective eyewear</i> ). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.		
III	CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear (specify appropriate protective eyewear, if applicable). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.		
IV	CAUTION (optional)	No statement is required. May use Category III statement.		

<sup>&</sup>lt;sup>1</sup> Required only if corrosive effects were observed during the study.

Table 7. Typical Statements for Primary Skin Irritation				
Category	Signal Word	Statement		
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes, on skin, or on clothing. Wear ( <i>specify appropriate protective clothing and gloves</i> ). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.		
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wear ( <i>specify appropriate protective clothing and gloves</i> ). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.		
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (specify protective clothing and gloves, if applicable).		
IV	CAUTION (optional)	No statement is required. May use Category III statement.		

Table 8. Typical Statements for Dermal Sensitization			
Study Result	Statement		
Positive	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals <sup>1</sup> .		
Negative	No statement is required.		

<sup>&</sup>lt;sup>1</sup> A positive dermal sensitization study for a Category IV product does not trigger PPE requirement.

# E. Personal Protective Equipment (PPE)

PPE requirements are specified for uses covered under the WPS, but there are no regulatory requirements for non-WPS products, products used by residents, or products intended only for manufacturing use. However, to protect human health, the following guidance is offered.

# 1. For non-WPS uses (industrial/commercial)

Label reviewers should ensure that adequate, understandable language regarding the types of PPE that should be worn for the product's hazards is included in any label, whether it is RUP or not. In cases where the reviewers determine PPE would be necessary, the various PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. If there is an applicable regulatory document which specifies PPE requirements based on concerns specific to the active ingredient, then those PPE requirements must be placed on the label.

# 2. For products used by residents/consumers

To protect human health, label reviewers should review the toxicity data and the product's uses to determine whether PPE would be necessary to meet the standards for registration. In cases where the reviewer determines PPE would be necessary, the PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. In some cases, the PPE indicated in these tables may need to be modified; for example, to fit the consumer's ability to acquire it. For instance, "shoes" may need to be substituted for "chemical-resistant footwear," or "safety glasses" may need to be substituted for "protective eyewear." If there is an applicable regulatory document which specifies PPE requirements based on concerns specific to the active ingredient, then those PPE requirements must be placed on the label.

#### F. First Aid statement

#### 1. When required

A first aid statement is required when any acute toxicity study result is classified as category I, II, or III. 40 CFR 156.68. Including the first aid statements for products classified as category IV is acceptable, but not required.

# 2. Appropriate headers

The first aid statements should appear under either the heading "First Aid" or "Statements of Practical Treatment." 40 CFR 156.68(c) and PR Notice 2001-1. The heading "First Aid" is preferred by the Agency. In addition, EPA historically has not allowed the heading "Antidote" in conjunction with the first aid

statements unless a specific antidote is necessary.

### 3. Location and prominence

First aid statements shall appear on the front panel of the label for all products classified as toxicity category I (40 CFR 156.68). The Agency may, however, permit reasonable variations in the placement of the first aid statement as long as the reference statement "See First Aid (or Statement of Practical Treatment) on (*identify appropriate panel*)." appears on the front panel, preferably near "Poison" and the skull and crossbones symbol.

First aid statements for toxicity category II and III products may appear on any panel of the label. The Agency does *not* require the first aid statements for toxicity category II and III products to bear the first aid statements on a *visible* panel. For additional information on the Agency's position regarding the location of the first aid statement, see EPA's February 27, 2018 guidance document *First Aid Guidance Document – EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68* located under docket ID <u>EPA-HQ-OPP-2016-0545</u>. However, any time first aid statements appear other than on the front panel, then a referral statement such as "See side/back panel for First Aid." should appear on the front panel in close proximity to the signal word. Furthermore, first aid statements on the side or back panel should be grouped near other precautionary labeling text, yet set apart or distinguishable from the other label text. The Agency strongly prefers that the statements be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.

# 4. Determining the first aid statements for fumigant products Refer to PR Notice 84-5, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

# 5. Determining the first aid statements for non-fumigant products

Review Table 9 to determine the preferred first aid statements for each route of exposure. Registrants should support alternative first aid statements with medical evaluations of the product. Approval of alternative first aid statements is guided by considerations such as those set out in the "Content and Clarity" section below. The Agency has not approved the use of salt water for emesis as a first aid technique. PR Notice 80-2.

#### a) Content and clarity

First aid statements should be written in brief, clear, simple, and straightforward language so that the average person in an emergency

can easily and quickly understand the instructions. First aid statements should apply to all ages or when necessary, include distinctions between the treatments for different ages (e.g., children vs. adults). Any reasonably competent individual should be able to carry out the instructions in the first aid statements. These statements should not include procedures which must be performed by medical personnel or require specialized equipment. Such procedures belong under the Note to Physician heading (see Section IV.G. below).

#### b) Acute dermal and primary skin irritation

Because both of these studies focus on the dermal route of exposure, any first aid statements required by the results of these two studies can be combined. Use the first aid statement required for the acute dermal toxicity study if the results of both studies place the product in the same acute toxicity category. Use the statements for the more severe acute toxicity category if the results of the studies would place the product in different acute toxicity categories.

#### c) Eye and skin irritation

If the product is corrosive and is in toxicity category I or II for eye or skin irritation, then a first aid statement for ingestion may also be included. First aid statements for ingestion may be more appropriate for products with some potential for ingestion, such as liquid concentrates, but less so for products with low potential, such as aerosol sprays. For Toxicity Category I skin and eye irritants, the Agency has used the statement (PRN 2001-1):

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

# 6. Products that contain an organophosphate or an N-methyl-carbamate

If the product contains either an organophosphate (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase) the following phrase should be included in the first aid statement (PRN 2001-1):

"Contains a/an\_\_\_\_\_ (either organophosphate or N-methyl-carbamate) that inhibits cholinesterase."

# 7. Products that contain zinc phosphide

If the product contains zinc phosphide, the following first aid statement for ingestion is recommended (PRN 2001-1):

"If swallowed: Immediately call a poison control center or doctor or transport the person to the nearest hospital. DO NOT DRINK WATER. Do not administer anything by mouth or make the person vomit unless advised to do so by a doctor."

# 8. Products that contain petroleum distillates

If the product contains ≥10% petroleum distillate, the following first aid statement for ingestion should be used (PRN 2001-1):

"If swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person."

However, if registrants have data to show there is benefit in drinking water or milk after ingesting the product, they may use alternate wording.

# 9. Telephone numbers

EPA encourages, but does not require, registrants to include a company telephone number or toll-free hotline number for emergency information in the first aid section. If a number is included, confusion can be avoided by specifying emergency vs. non-emergency numbers. If a phone number is included, it should include a phrase or statement indicating the kinds of information the number should be used for and it may include hours of service. For example:

"Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information on this product, call (1-XXX-XXXX), Monday through Friday, 9 a.m. to 5 p.m. For medical emergencies, call the poison control center at 1-800-222-1222."

If a registrant does not have its own non-emergency number, the registrant may reference the National Pesticides Information Center (NPIC) (see Chapter 15). Note that the NPIC does not provide emergency medical information.

Table 9. First Aid Statements			
Route of Exposure	Category	Statement <sup>1</sup>	
Ingestion treatment	I, II, III	If swallowed:	
for acute oral toxicity		- Call a poison control center or doctor immediately for treatment advice.	
		- Have person sip a glass of water if able to swallow.	
		- Do not induce vomiting unless told to do so by a poison control center or	
		doctor.	
		- Do not give anything by mouth to an unconscious person.	
	IV	No statement is required. May use statement above.	
Skin exposure	1, 11, 111	If on skin or clothing:	
treatment for acute		- Take off contaminated clothing.	
dermal toxicity and		- Rinse skin immediately with plenty of water for 15-20 minutes.	
primary skin		- Call a poison control center or doctor for treatment advice.	
irritation	IV	No statement is required. May use statement above.	
Inhalation treatment	1, 11, 111	If inhaled:	
for acute inhalation		- Move person to fresh air.	
toxicity		- If person is not breathing, call 911 or an ambulance, then give artificial	
		respiration, preferably by mouth-to-mouth, if possible.	
		- Call a poison control center or doctor for treatment advice.	
	IV	No statement is required. May use statement above.	
Eye exposure	1, 11, 111	If in eyes:	
treatment for		- Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
primary eye irritation		- Remove contact lenses, if present, after the first 5 minutes, then continue	
		rinsing eye.	
		- Call a poison control center or doctor for treatment advice.	
	IV	No statement is required. May use statement above.	

#### General information to include near the first aid statement

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
- For medical emergencies, call the poison control center at 1-800-222-1222.
- For general information on this product, call 1-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at <a href="http://npic.orst.edu">http://npic.orst.edu</a>.

# G. Note to Physician

#### 1. When used

For fumigant products, refer to <u>PR Notice 84-5</u>, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

For non-fumigant products, the following criteria are used to determine whether a Note to Physician is needed:

(a) All products that are classified as Toxicity Category I.

<sup>&</sup>lt;sup>1</sup> Use alternate statements if these are medically inappropriate for the product (e.g. if the product contains zinc phosphide or ≥10% petroleum distillate).

(b) Products which are corrosive or classified as Toxicity Category I for eye or skin. These products must include the following Note to Physician:

"Probable mucosal damage may contraindicate the use of gastric lavage."

(c) Products which contain ≥10% petroleum distillate. These products should include the following Note to Physician:

"Contains petroleum distillate. Vomiting may cause aspiration pneumonia."

(d) Products which contain zinc phosphide. The products should include the following Note to Physician:

"Contains the phosphine-producing active ingredient zinc phosphide. Probable mucosal damage may contraindicate the use of gastric lavage."

(e) Products which produce physiological effects requiring specific antidotal or medical treatment such as: cholinesterase inhibitors (e.g., carbamates, phosphorothioates, and organophosphates); metabolic stimulants (e.g., dichlorphenols); or anticoagulants (e.g., warfarin).

# 2. Location and prominence

The Note to Physician should be located in close proximity to the first aid statements, but should be clearly distinguished from it. It should not be placed within the first aid statements, but should appear below the last first aid statement.

# 3. Contents of Note to Physician

The Agency does not provide specific statements except for the cases described above. However, the Note to Physician should include or address the following information, as appropriate:

- Technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide; and
- a company telephone number to specific medical personnel who can provide specialized medical advice.

# V. Modified precautionary statements for diluted products (aqueous solutions only)

# A. When used

Modified Hazards to Humans and Domestic Animals and first aid statements which correspond with the toxicity categories associated with a product's use when diluted with water may be allowed on product labels provided the following data and label requirements are met. All data and modified precautionary statements for use dilutions must be reviewed and approved by the Agency. 40 CFR 156.70(c).

# **B.** Data requirements

In some cases, use dilution labeling statements triggered by systemic toxicity (i.e., acute oral, dermal, or inhalation toxicity) may be supported by extrapolation from the  $LD_{50}/LC_{50}$  for the concentrate. At a minimum, the following information must be submitted for Agency consideration:

- (a) A slope calculated from at least three, and preferably more, dose levels having partial responses (i.e., a well characterized dose-response);
- (b) Dose groups sufficiently large (>5 per group) to allow for the calculation of confidence limits that fall within the defined toxicity category boundaries;
- (c) Extrapolation to higher toxicity categories will only be applied to water dilutions. It should also be determined that there are no other factors affecting the toxicity of the end-use product (e.g., inert ingredients that enhance the absorption of the active ingredient, promote the active ingredient's toxicity, etc.). Other types of extrapolations will be done on a case-by-case basis.
- (d) Use dilution Hazards to Humans and Domestic Animals statements triggered by skin or eye irritation must be supported by new or cited studies. If another registered diluted product (such as a ready-to-use formulation) has acceptable data and is found similar to the concentrated product after it has been diluted, those data may also be used to support modified labeling.

# C. Labeling requirements

It is not the Agency's intent to allow two sets of Hazards to Humans and Domestic Animals statements and/or first aid statements on the label. Rather, EPA will allow certain modified statements to be added that are applicable for use dilutions. These additional statements, triggered by the toxicity category of the most concentrated use

dilution, must be placed directly after the required statements for the concentrate, and may not substitute the required statements for the concentrate. If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. 40 CFR 156.68(b) and 40 CFR 156.70(c).

If a product label does include modified use dilution statements, the signal word must still reflect the toxicity of the [concentrated] product as distributed or sold.

40 CFR 156.64(b)(2). The following examples show where modified statements (in italics) should appear on product labeling:

Hazards to Humans and Domestic Animals:

"Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. After product is diluted in accordance with the directions for use, goggles or face shield are not required."

#### First Aid:

"If on skin or clothing: Wash with plenty of soap and water. Get medical attention. If product, diluted in accordance with the directions for use, gets on skin, medical attention is not required."

If a registrant with an identical or substantially similar product is relying/citing a product that has modified use dilution precautionary statements, those modified use dilution statements are not required to be on their product. Only the precautionary statements for the concentrated product (as distributed or sold) is required.