

April 11, 2000

PESTICIDE REGISTRATION (PR) NOTICE 2000-3

**NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, AND
REGISTRANTS OF PESTICIDE PRODUCTS**

ATTENTION: Persons Responsible for the Registration of Pesticide Products

SUBJECT: First Aid Statements on Pesticide Product Labels

This notice announces a change to EPA guidance regarding the format and content of first aid statements on all pesticide product labels. The guidance in this notice is intended to update the first aid language on all pesticide product labels. This PR Notice is effective immediately.

Although registrants are not required to revise their labels or to respond to this notice at this time, the Agency will begin to use this guidance immediately, and expects that registrants of existing products will begin to revise their labels accordingly. It is the Agency's goal that all product labels be revised by October 1, 2001.

I. BACKGROUND

The Agency's regulations require that pesticide products be labeled with first aid statements which provide important information concerning appropriate first aid in the event accidental exposure to a pesticide occurs (see 40 CFR 156.10 (h)(iii)). First aid statements generally provide initial first aid steps to take when accidental exposure occurs and may inform physicians and emergency responders of appropriate medical procedures for victims of poisoning. First aid statements are required when a product has been classified as Toxicity Category I, II or III, but are optional for products classified as Toxicity Category IV. The Label Review Manual (LRM) discusses requirements and guidance on first aid statements. The LRM may be found on the Agency's web site at www.epa.gov/oppfead1/labeling/lrm. In brief, current regulations emphasize:

A. Placement of first aid statements. The first aid statements for all products classified as Toxicity Category I for oral, dermal or inhalation toxicity (systemic effects only) must appear on the front panel of the label. The Agency, may however, permit reasonable variations in the

placement of the statement as long as a reference “See first aid/statement of practical treatment on back panel” appears on the front panel near the word “Poison” and the skull and crossbones. On September 17, 1999, the Agency proposed (FR vol. 64, no. 180, pg 30702) to broaden the requirement so that the first aid statements for all Toxicity Category I products, including those for eye and skin irritation effects, not just systemic effects, be placed on the front panel. First aid statements for other than Toxicity Category 1 products may appear on the front, side or back panel of the label. Any time first aid statements appear on the side or back panel of the label, a referral statement such as “See Side/Back panel for additional precautionary statements” must appear on the front panel of the label in close proximity to the signal word. First aid statements appearing on the side or back panel of the label should be grouped near the other precautionary labeling, yet be set apart or distinguishable from the other label text. Finally, first aid statements should be organized so that the most severe routes of exposure are listed first.

B. Content of first aid statements. First aid statements should be easy-to-understand by all readers and include distinctions in treatment for children vs. adults.

The purpose of this PR Notice is to encourage registrants to adopt the improved statements and format on the label.

EPA has previously issued first aid statements for fumigants in Attachments A-K of PR Notice 84-5, “Label Improvement Program for Fumigants.” Registrants should review those older statements, along with the statements in this notice, to ensure the most appropriate statements are being used. This notice supersedes PR Notice 80-2, “Label Improvement Program - Deletion of Salt Water Emesis Statements.”

In this notice, EPA is recommending generic first aid statements for all products. However, these statements may not always be medically appropriate for a particular product. There are situations where, during reregistration, unique acute effects are identified that we believe necessitate additions to the standard precautionary statements or changes to the generic first aid statements. For example, if a product is a cholinesterase inhibitor, an additional statement identifying the product as such, is required in the first aid statements. If the first aid statements in the Registration Standard/Reregistration Eligibility Decision (RED) document are more restrictive/protective than the first aid statements in this PR Notice, the first aid statements from the Registration Standard/RED should be used.

II. CHANGES RECOMMENDED BY THE CONSUMER LABELING INITIATIVE

In early 1996, the Office of Pesticide Programs (OPP) drafted first aid statements that were intended to be easier to understand and medically up-to-date. It also began a Consumer Labeling Initiative (CLI), which has as its goal the improvement of pesticide labels on consumer products. In the first phase of the CLI, interviews were conducted with users of household pesticides and non-pesticide products used to clean hard surfaces. Consumers indicated that the phrase “first aid” was easier to understand than “statement of practical treatment.” Further,

stakeholders indicated that first aid information needs to be technically accurate. The CLI recommended that EPA should encourage registrants to voluntarily use the term “first aid” in place of the term “statement of practical treatment.”

Draft first aid statements were revised and shown to consumers in the summer of 1997 as part of the CLI research. As a result of those interviews, additional changes were made. The revised statements were then reviewed by, among others, the American Red Cross, the American Association of Poison Control Centers, the Pesticide Program Dialogue Committee and the Consumer Product Safety Commission. Many of those organizations provided suggestions which were incorporated into the first aid statements in this notice.

In the summer of 1998, EPA sponsored research on consumer’s reactions to different formats for pesticide labels. This research indicated that consumers clearly preferred that important information, such as first aid statements, be placed within a box which sets that text apart from the rest of the label. The consumers interviewed also preferred that information not be presented in a narrative format, but rather be shown as brief statements, individually marked with a symbol such as a hyphen or other type “bullet” along the left margin. Consequently, EPA recommends that first aid information on pesticide labels be placed in a box, using a non-narrative format for statements within each specific route of potential exposure. Section III.J. of this notice provides an example of such first aid statements in a “boxed” format. EPA also recommends that an appropriate toll-free phone number to be contacted in case of a medical emergency be placed close to the box which presents the first aid statements. Section III.J. provides an example of a hot-line statement.

III. POLICY

A. First aid heading. As suggested in PR Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments, registrants are encouraged to use the term “First Aid” as the section heading on their labels and discontinue the use of “Statement of Practical Treatment” or “Practical Treatment.”

B. Medically up-to-date language. Since first aid statements provide vital information to pesticide users, physicians, and emergency response personnel, pesticide labels should be updated to reflect changes in medical procedures and treatment. Updated first aid statements (i.e., specific time frames and removing directions to induce vomiting) were provided by poison control centers and the medical community.

C. General statement for each route across all toxicity categories. To improve comprehension by consumers and medical personnel, EPA has revised the first aid statements. The statements for each route of exposure (oral, dermal, inhalation, and eye) are the same for Toxicity Categories I to III. Registrants are encouraged to use the first aid statements in section IV of this notice. These statements should be used unless they are medically incorrect for the product. First aid statements are optional for Toxicity Category IV.

D. Poison control centers. Product labels should direct the user to call a poison control center first when there is an incident. Poison control centers are more likely to have information on effective treatment for pesticide exposures.

E. Induce vomiting only if instructed. Inducing vomiting, as a standard first aid instruction, is no longer universally recommended. For some chemicals, inducing vomiting may actually be harmful. Examples of instances where vomiting especially should not be induced, unless advised to do so by a poison control center or doctor, are:

- 1) pesticides containing zinc phosphide;
- 2) pesticide products which are corrosive (pH < 2 or > 11.5); and,
- 3) products containing $\geq 10\%$ petroleum distillates.

The need to induce vomiting for products having any of these characteristics should be weighed against the potential danger of doing so. The poison control center will tell the person calling how to induce vomiting; the label need not do so.

F. Zinc Phosphide. The first aid statement for products containing zinc phosphide remains as follows:

“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.”

G. Petroleum Distillates. After discussion with medical experts, EPA has determined that having the person sip or drink water or milk after ingesting a product containing petroleum distillates, in any amount, generally is unwarranted. Therefore, the first aid statement recommended for products containing petroleum distillates has been changed. However, if registrants have data to show there is benefit in drinking water or milk after ingesting their product(s), they may submit alternate wording via amendment. In all other cases, the following statement should be used:

“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.”

H. Contact lenses. Contact lens wearers are instructed to first rinse eyes with water, remove contact lenses, and then continue to rinse eyes. Several organizations and doctors commented that it is preferable to reduce the amount of contaminant first, then remove the contacts, and then rinse more thoroughly. In some cases of exposure, the eye muscles tend to hold the eye shut, so removing contacts first may not actually be possible. In EPA’s revised language, the words “hold eye open” are included to reduce consumer confusion.

I. Telephone numbers. EPA encourages registrants to include a company telephone number or toll-free hotline number on the pesticide label as first suggested in PR Notice 97-4, Consumer Access Numbers on Pesticide Labels. If a number is included, it should include a phrase or statement indicating the kinds of information the number should be used for, or if it may be used for all information, a simple lead-in phrase. The explanatory statement may include hours of service. For example:

For emergency information on [product, usage, etc.], call 1-800-555-0000,
Monday through Friday, 9 a.m. to 5 p.m. After 5 p.m. call your poison control center.

or, more simply,

Questions? 1-800-555-0000.

J. Box format. Below is an example of a recommended boxed and “bulleted” format for first aid statements for pesticide products in Toxicity Categories I, II, or III. The first aid statements associated with the exposure route of greatest concern for the product being labeled should appear at the top of the box, followed by the statements pertaining to other potential routes of exposure. If appropriate, a registrant may want to include a statement in the note as to the common name(s) of the active ingredient(s).

Other formats that highlight the information and present it in a clear, easy-to-use fashion are acceptable. For example, increased white space, larger fonts, and different colors and graphics may all help to make the first aid information easier to follow. Format changes may be made by non-notification (refer to PR Notice 98-10 for non-notification requirements).

BOXED FORMAT EXAMPLE

FIRST AID	
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •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 further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> •Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call 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 the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.	
NOTE TO PHYSICIAN	
[Insert appropriate information here.]	

IV. THE “NOTE TO PHYSICIANS”

There have been no changes to any of the previous requirements for this section.

A. When required. The Agency requires a “Note to Physician” for:

- All products in Toxicity Category I.
- Any product which is corrosive or placed in Toxicity Category I due to effects on eyes or skin.

- Products that contain $\geq 10\%$ petroleum distillate should include the following statement: "Contains petroleum distillate - vomiting may cause aspiration pneumonia."
- Any product that produces physiological effects requiring specific antidotal or medical treatment such as: Cholinesterase Inhibitors (e.g., carbamates and phosphorothioates, and organophosphates); Metabolic Stimulants (e.g., dichlorophenols); Anticoagulants (e.g., warfarin).
- For "Note to Physician" for fumigants refer to PR Notice 84-5 or Reregistration Eligibility Decision Documents.

B. Contents of note. For Toxicity Category I eye and skin irritants, use the following Note to Physician:

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

In other cases make certain that the Note to Physician addresses the following information:

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

Registrants may want to refer to the "Recognition and Management of Pesticide Poisonings," 5th edition, 1999 at the Agency's web site at <http://www.epa.gov/oppfead1/safety/healthcare/handbook/handbook.htm>, for potentially relevant information.

C. Location. The "Note to Physician" should be located in close proximity to the "First Aid Statements," but should be clearly distinguished from them.

V. REVISED FIRST AID STATEMENTS

Route of Exposure	Toxicity Category	First Aid Statement ¹
Ingestion	1, 2 and 3	<p>If swallowed:</p> <ul style="list-style-type: none"> -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.
Ingestion	4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
Dermal exposure, skin irritation	1, 2, and 3	<p>If on skin or clothing:</p> <ul style="list-style-type: none"> -Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
Dermal exposure, skin irritation	4	Statement is not required. Registrants may use category 1-3 statements if they choose.
Inhalation	1, 2, and 3	<p>If inhaled:</p> <ul style="list-style-type: none"> -Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice.
Inhalation	4	Statement is not required. Registrants may use category 1-3 statements if they choose.
Eyes	1, 2, and 3	<p>If in eyes:</p> <ul style="list-style-type: none"> -Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.
Eyes	4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
<p>General statement to include with the first aid statement(s) (at beginning or the end):</p> <p>“Have the product container or label with you when calling a poison control center or doctor, or going for treatment.”</p> <p>An emergency phone number may also be included at the end of the sentence.</p>		

¹/These statements should be used unless medically incorrect for the product.

EPA will initiate rulemaking to revise its labeling regulations in 40 CFR 156.10 to conform to these policy changes.

VI. WHAT REGISTRANTS SHOULD DO

EPA will begin using these statements immediately in reviewing all new applications for registration and products submitted for reregistration. Registrants should incorporate these label changes by October 1, 2001. Once the first aid statements are approved by the Agency, the registrants will generally have up to eighteen (18) month from the date of the new, approved label, to distribute and sell products bearing old labels/labeling. Persons other than the registrant may continue to distribute or sell such products until their supplies are exhausted. The Agency may deviate from this stated policy as necessary or on a case-by-case basis. EPA also encourages registrants and applicants for pesticide registration to use the format shown in section III.J. of this notice or a similar format to display first aid information on their product labels.

It is the registrant's responsibility to ensure that each product bears EPA-approved text in its first aid statements. If a registrant believes that alternate text is medically more appropriate, the company should submit an amendment to the Agency with the proposed text. If approved, the company may then use the alternate text. If your product has already been amended to include the specific statements, no action is needed.

All submissions, whether the exact (word for word) label statements specified in this PR Notice or alternative label statements should be submitted by amendment in accordance with the provisions of this Notice, and EPA regulations at 40 CFR 152.44. Amendments should be directed to the appropriate Product Manager. This application should include the following items: EPA application form 8570-1 (completed), five copies of the draft label, and a description on the application, such as, "Response to PR Notice ____."

Registrants should send applications for amendment to the appropriate following address:

U.S. Postal Service Deliveries

The following official mailing address should be used for all correspondence or data submissions sent to OPP by mail:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

Personal/Courier Service Deliveries

The following address should be used for all correspondence or data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

VII. FOR FURTHER INFORMATION

For information on this notice, contact Amy Breedlove, Field and External Affairs Division, at 703-308-9069, or by e-mail to breedlove.amy@epa.gov.

_____/signed/_____
Marcia E. Mulkey
Director
Office of Pesticide Programs