

January 2, 2001

PESTICIDE REGISTRATION (PR) NOTICE 2001-1

**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 an update to EPA guidance regarding the format and content of first aid statements on all pesticide product labels. This notice is intended to provide guidance for what the Agency believes is the most updated appropriate first aid language for pesticide product labels to ensure that they continue to adequately protect the public. The Agency has received updated information for first aid statements and believes this information is more appropriate than information that may currently be on pesticide product labels and encourages registrants and applicants to update their product labels. This notice supersedes PR Notice 2000-3.

EPA will begin using this guidance immediately in evaluating products submitted for new or amended registration or reregistration. Registrants should review their current labels in light of the guidance in this notice, and, if necessary, make revisions to their labeling before October 1, 2003. As of that date, EPA will use this guidance when determining whether a product is misbranded under FIFRA sec. 12.

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 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 regulatory 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.

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. (40 CFR 156.10(h)(iii)(A))

First aid statements for other than Toxicity Category I 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, EPA expects that a referral statement such as “See Side/Back panel for additional precautionary statements” will 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 would then be grouped near the other precautionary labeling, yet be set apart or distinguishable from the other label text. Finally, first aid statements are to 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, when appropriate.

EPA has previously provided guidance for 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. If in doubt, use the more restrictive text. This notice supersedes PR Notice 80-2, “Label Improvement Program - Deletion of Salt Water Emesis Statements.”

This notice provides guidance on generic first aid statements applicable to most products. However, these statements may not always be medically appropriate for a particular product. There are situations where unique acute effects are identified that necessitate additions to the standard precautionary statements or changes to the generic first aid statements. For example, if a product is a cholinesterase inhibitor, or other class of pesticide, the Agency may require an additional statement in the first aid section identifying the product as such, in order to make the “no unreasonable adverse effects” finding under FIFRA. If the product contains 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:

“Contains an ____ (either organophosphate or N-methyl carbamate) that inhibits cholinesterase.”

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 document are expected to be used.

II. CHANGES RECOMMENDED BY THE CONSUMER LABELING INITIATIVE

In early 1996, the Office of Pesticide Programs (OPP) began updating its recommended first aid statements with the intention that the statements 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. Information from the interviews can be found in the CLI Phase I Report, EPA-700-R-96-001, September 1996. 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 encourage registrants voluntarily to use the term “first aid” in place of the term “statement of practical treatment.”

Draft first aid statements, which the Agency believed to be more accurate, were 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 guidance in this notice.

In the summer of 1998, EPA sponsored research on consumer’s reactions to different formats for pesticide labels. For information on the research, see the CLI Phase II Report, EPA-742-R-99-004, October 1999. This research indicated that consumers clearly preferred 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. Section III., paragraph J. of this notice provides an example of such first aid statements in a “boxed” format. EPA encourages registrants to include an appropriate toll-free phone number to be contacted in case of a medical emergency near the first aid statements. Section III., paragraph I., also provides an example of a hot-line statement.

III. GUIDANCE

A. First aid heading. As suggested in PR Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments, for their residential/household-use products especially, 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” because these terms are not clear to or easily understood by many consumers. However, any of the terms are acceptable on all pesticide products.

B. Medically up-to-date language. Since first aid statements provide vital information to pesticide users, physicians, and emergency response personnel, EPA expects pesticide labels to 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 to EPA by poison control centers and the medical community.

C. General statement for each exposure route for all toxicity categories. To improve comprehension by consumers and medical personnel, EPA is providing guidance on what it believes to be the most updated and appropriate first aid statements. The statements for each route of exposure (oral, dermal, inhalation, and eye) are the same for Toxicity Categories I to III. The first aid statements in Section V of this notice are expected to 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 when there is an incident. Poison control centers are more likely to have information on effective treatment for pesticide exposures.

EPA expects the phrase "Call a poison control center or doctor immediately for treatment advice" to appear as the first line in the statements for the ingestion route of exposure. However, for the other routes of exposure, place the phrase in one of the following three locations in the first aid statements:

1. at the top;
2. at the end; or,
3. for each route of exposure. (Note: The word "immediately" may be deleted for all routes of exposure except for ingestion.)

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. From the information gathered from the poison control centers and the medical community, the following examples are instances where vomiting especially should not be induced, unless advised to do so by a poison control center or doctor:

- 1) pesticides containing zinc phosphide;
- 2) pesticide products which are corrosive (pH < 2 or > 11.5); and,
- 3) products containing \$ 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. If necessary, the poison control center will tell the person calling how to induce vomiting; the label need not do so.

F. Zinc Phosphide. The recommended 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, we believe that the appropriate first aid statement for products containing petroleum distillates is as follows:

“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 their product(s), they may submit alternate wording via amendment.

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, confusion can be avoided by placing emergency numbers with the “First Aid” or “Hot Line Number” text, numbers for chemical spills with the spill cleanup information in the Storage and Disposal section, and numbers for general information elsewhere on the label. 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 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. The optional statement showing the class of pesticide is also shown. 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 [Class of Pesticide] | |
|---|---|
| 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. <p style="text-align: center;"><i>*The statements for products containing petroleum distillates may be different.</i></p> |
| HOT LINE NUMBER [Class of Pesticide] | |
| 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 PHYSICIAN.” In the past, the Agency has found it necessary in making the “no unreasonable adverse effects” finding to require, on a case-by-case basis, that products which are:

- in Toxicity Category I;
- corrosive or placed in Toxicity Category I due to effects on eyes or skin;
- contain \geq 10% petroleum distillate;
- produce physiological effects requiring specific antidotal or medical treatment, such as Cholinesterase Inhibitors (e.g., carbamates, phosphorothioates, and organophosphates);
- metabolic stimulants (e.g., dichlorophenols); or
- anticoagulants (e.g., warfarin)

bear a "Note to Physician" on their labels. There are no suggested changes for this section in this guidance.

A. Contents of Note.

1. For Toxicity Category I eye and skin irritants, the Agency has used the following statement:

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

2. For other toxicity categories or exposure routes, the Note to Physician may address the following information; as appropriate:

- 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.

3. For products that contain \geq 10% petroleum distillate the note would include the following statement: “Contains petroleum distillate - vomiting may cause aspiration pneumonia.”

4. For the appropriate contents of the “Note to Physician” for fumigants, refer to PR Notice 84-5 or Reregistration Eligibility Decision Documents pertaining to the specific pesticide active ingredient.

For potentially relevant information, registrants and applicants 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/oppead1/safety/healthcare/handbook/handbook.htm>.

B. Location. The expected location for the "Note to Physician" is in close proximity to, and preferably below, the "First Aid Statements," but clearly distinguished from it.

V. UPDATED FIRST AID STATEMENTS

| Route of Exposure | Toxicity Category | First Aid Statement ¹ |
|--|-------------------|---|
| Ingestion | 1, 2, and 3 | If swallowed: -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 | If on skin or clothing: -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 | If inhaled: -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 | If in eyes: -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.

VI. IMPLEMENTATION

It is the Agency's intention to implement the guidance of this notice as smoothly as possible, to make the process manageable for both the Agency and the regulated community, and to avoid any disruption or delay to the Agency's programs. Accordingly, the Agency is providing ample time for registrants to bring products into compliance with FIFRA.

(1) **Applications for new and amended registration.** The Agency will apply the guidance in this notice immediately to applications for new and amended registration.

(2) **Pending applications.** The Agency will apply the guidance in this notice to applications that are pending with the Agency, and may require, when making the "no unreasonable adverse effects" finding, that applicants make changes to their labeling before approving the application.

(3) **Reregistration.** EPA will begin applying this guidance immediately in the issuance of Reregistration Eligibility Decision (RED) documents. Registrants of products subject to *reregistration* should anticipate that this guidance will be used in evaluating the acceptability of their product for reregistration.

(4) **Registrants of existing products not covered by current applications.**

As of **October 1, 2003**, EPA will begin evaluating products being sold or distributed to determine that they remain in compliance with FIFRA with respect to the adequacy of their first aid statements. At that time, EPA will consider further action to ensure that all pesticide products reflect appropriate first aid statements.

Registrants of existing products should anticipate this date, and propose revisions to their first aid statements in future applications for amendment. Changes may be made in conjunction with other labeling amendments, or may be submitted as separate applications solely for the purpose of revising first aid statements. Registrants should note that applications for amendment should be submitted with sufficient time for EPA review before October 1, 2003. EPA cannot guarantee that applications received close to this date can be reviewed and approved by October 1, 2003.

Once the first aid statements are approved by the Agency, the registrants will generally have up to eighteen (18) months from the date of the approved label to distribute or sell existing stocks of products bearing old labels/labeling. It is the registrant's responsibility to ensure that their distributors' labels comply with FIFRA and 40 CFR 156.10. Persons other than the registrant may continue to distribute or sell such products until their supplies are exhausted.

VII. HOW REGISTRANTS CAN REVISE THEIR FIRST AID STATEMENTS

All submissions, whether using the exact (word for word) label statements specified in this PR

Notice or alternative label statements proposed by the registrant (accompanied by justification) should be submitted by amendment in accordance with normal amendment procedures. Amendments should be directed to the appropriate Product Manager or Regulatory Action Leader. 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 2001-1"

VIII. SCOPE OF POLICY

This Notice is intended to provide guidance to EPA personnel, pesticide registrants and applicants, and the public. As a guidance document, this policy is not binding on either EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice. Registrants and applicants may propose alternatives to the recommended labeling statements described in this Notice and the Agency will assess them for appropriateness on a case-by-case basis. If a product does not meet the requirements of 40 CFR 156, the Agency may find the product to be misbranded. As stated above, the Agency believes that the statements outlined in this Notice will better protect human health and are appropriate within the meaning of 40 CFR 156.10 (h)(iii).

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

IX. FOR FURTHER INFORMATION

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

Marcia E. Mulkey
Director
Office of Pesticide Programs