

DRAFT FOR COMMENT

PESTICIDE REGISTRATION (PR) NOTICE 2000-XX

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Indoor Residential Insecticide Product Label Statements

This Notice sets forth the U.S. Environmental Protection Agency's (EPA) guidance with respect to labeling statements for indoor residential insecticide products. The purpose of this guidance is to provide users of indoor residential insecticides with clear and concise information which they can understand and follow. The labeling statements suggested in this document are intended to reduce the potential for exposure of humans and pets to indoor residential insecticides. The EPA also provides recommendations regarding formulation and packaging to further insure consumer safety while handling pesticide products.

I. BACKGROUND

In recent years, the Agency has made a concerted effort to reduce indoor residential pesticide exposure and improve the safety of indoor residential pesticides. This effort came in response to concerns expressed by the general public, state and local governments, and non-government organizations regarding pesticide exposure and risk, indoor air quality, and ambiguity in residential pesticide product use directions.

The Agency continuously reviews information on incidents related to residential use pesticides. For example, the 1997 report of the National Pesticide Telecommunications Network (NPTN), a cooperative effort of Oregon State University and the Agency, indicates that of the known locations where adverse pesticide incidents occurred, the majority were related to residential use. A review of incident data from the American Association of Poison Control Centers (AAPCC) indicates that from 1993 to 1996, 90% of all reported accidental pesticide exposures were residential, and 50% of those involved insecticides.

Under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), August 3, 1996 EPA is required to consider aggregate exposure and cumulative effects from food use pesticides in both the diet and from non-occupational (e.g., consumer-residential) sources. By clarifying the maximum number of treatments and minimum application intervals, this Notice will help provide the Agency with an additional method for estimating residential exposure.

This PR Notice is a continuation of the Agency's efforts to reduce pesticide exposure and clarify pesticide labeling. In the case of indoor residential insecticides, the Agency believes that a few "common sense" modifications to current labeling, formulation and packaging could achieve significant results.

II. SCOPE

This Notice applies to the labeling of insecticide products registered for indoor residential use by the consumer or homeowner and by professional (i.e., commercial) applicators (such as liquids, aerosols, sprays, granules and dusts). This Notice **is not** applicable to residential insecticides that are formulated as baits, resin strips, impregnated tapes or other similar products. Similar notices may follow, as appropriate, for products such as those designated for residential use outdoor, fungicides used indoors, and products applied inside residences by professional applicators. Please note that the guidance in this PR Notice should not be viewed as a substitution for the policies required when completing residential risk assessments (SOPs for Residential Exposure Assessments).

III. POLICY

Registrants should review and, as necessary, modify their product labels for insecticides registered for indoor residential use to include additional or revised use directions and other statements, and take related actions as described in this Notice. The Agency intends to establish consistency in the labeling of indoor residential insecticides. The Agency believes that by including the statements described in this Notice, exposure to humans and pets associated with such products will be reduced. To further reduce exposure and the potential for consumer incidents when mixing, diluting, or handling concentrated liquid insecticides, the Agency encourages registrants to formulate products for residential use as Ready-to-Use products.

Since this Notice is a guidance document, the Notice itself does not impose binding obligations on either the pesticide registrants or EPA. However, because the Agency believes that the labeling changes set forth in this Notice will help reduce exposure of humans and pets to indoor residential insecticides, EPA may in the future initiate regulatory action based on the rationale provided herein. Registrants are encouraged to voluntarily modify product labeling as provided for in this Notice.

The Agency believes the incremental cost of such actions is outweighed by the health benefits of having appropriate labeling statements which help assure the proper use of residential indoor insecticide products.

IV. LABEL STATEMENTS

EPA requests that all end-use insecticide products registered for indoor residential use be modified, as appropriate for each product, to include the following types of statements. The intent is to reduce unnecessary applications and exposure. EPA will not, however, approve the following exemplary labeling statements as replacement for more restrictive statements or information currently required on labels. The Agency will consider suggestions for alternative label language based on appropriate data, information or logic.

- A. **Presence of Occupants/Re-entry** - The Agency encourages registrants to amend labels to include a statement as to when human occupants and pets must leave a treated area and indicate the time interval necessary prior to re-entry into the treated area. The interval specified should be based on the physical, chemical and toxicological properties of the pesticide product. The following are examples of acceptable language for pesticide labels, as appropriate to the type of product and use pattern.
1. “Keep people (especially children) and/or pets out of treated areas during and immediately following treatment for (insert time frame) minutes/hours. Cover fishbowls and tanks before treatment.”
 2. “Do not allow people (especially children) and/or pets to lie, sleep or remain in treated areas during or immediately following treatment and do not allow access until after treated area is dry.”
 3. “Do not apply or place product where individuals (especially children) and/or pets are likely to come in contact with the pesticide”.

For space sprays, the following language is suggested.

4. “Children's toys/personal items must be removed from the treatment area before application.”

B. **Application Rates and Intervals** - Label language stating to “Apply/Repeat as necessary” could contribute to overuse of a pesticide, and result in unnecessary exposure and risk. The Agency strongly encourages registrants to modify labels to assure that the labels clearly specify maximum rates or numbers of application and minimum intervals between applications. Application rates and intervals should be based on efficacy data and the physical, chemical, and toxicological properties of the insecticide product. Examples of statements regarding application rates and intervals that should be included on pesticide labeling follow:

1. “Do not apply more than (insert appropriate number) treatments per week/month/year.”
2. “Apply in two second bursts of spray per foot of area being treated.”
3. “Do not repeat treatment more than once every (insert appropriate number) hours/days/weeks.”
4. “Avoid excess application. Dampen surface, but not to the point of saturation or soaking.”
5. “If reinfestation occurs, repeat treatment but do not repeat treatment more frequently than every (insert appropriate number) days”

For products that are not designed to be used as a preventive treatment (i.e. with regularly scheduled applications), please insert the following labeling language:

6. “This product is not designed for preventive use and should only be applied when pests appear. Do not apply this product more than (insert appropriate time) times per week/month/year.”

C. **Ventilation** - Some indoor pesticide labels need clear directions regarding ventilation. As may be applicable, i.e., for liquid and pressurized residential insecticides such as foggers, aerosols and space spray applications, the following statement should be added:

“Upon reentry, immediately open windows and leave area. Keep windows open for at least (insert appropriate time frame) before humans and pets are allowed to remain in the treated area.”

If no ventilation period can readily be proposed, a minimum period of 2 hours is suggested.

- D. **Broadcast Prohibition Language** - If a product is labeled as a crack and crevice or spot treatment, or otherwise does not explicitly include a broadcast or space spray use, the label should include the following statement:

“For crack and crevice or spot treatment only. Use only in the areas described. Do not use this product as a fogger or apply it in the air.”

- E. **Expiration Dates** - EPA regulations at 40 CFR section 156.10(g)(6)(I) require pesticides that change chemical composition significantly to bear an expiration date for sale and use in a prominent position on the label. EPA determines the appropriateness and need for an expiration date based on storage stability data, efficacy data and other appropriate information. In most instances, these dates are based upon data or other information demonstrating a change in composition over a relatively short time period. However, given the likelihood that many indoor residential products may be kept (or left behind) by consumers in homes and businesses for many years after purchase, EPA believes that an expiration date is generally appropriate for all indoor residential products. For this reason, EPA strongly encourages registrants to propose an expiration date for any indoor residential product using the following terminology: "Not for sale or use after [date]." EPA is not at this point proposing any specific "default" expiration date, but will evaluate proposed dates based on available data, the nature of the product and any rationale provided by the registrant.

- F. **Food Contamination** - To minimize contamination of food, food contact surfaces, and food utensils, the label should include the following statements:

- 1) “Exposed food (including pet food and water dishes) must be removed during application”.
- 2) “Food utensils should be removed before application. All food processing/food contact surfaces must be covered during application and thoroughly washed with soap and water before re-use”.
- 3) “Do not apply to areas or surfaces which will contact food”.
- 4) “Food utensils such as teaspoons and measuring cups must not be used for food purposes after use with pesticides”.

- G. **Read Entire Label** - Purchasers and users of any pesticide product should be directed to read the entire label by inserting

“READ ENTIRE LABEL BEFORE EACH USE”

in bold, capital letters in the “Directions for Use” section. The statement should appear directly under the Federal Misuse statement (“It is a violation of Federal law to use this product in a manner inconsistent with its labeling”). Contact the Registration Division if you need clarification.

V. USE OF CONCENTRATES

In recent years, the Agency has been discouraging the registration of concentrated insecticide products intended for indoor use. The Agency believes products that are designed for use in a “ready-to-use” form (such as pump sprayers or aerosol formulations) pose fewer hazards than those which must be diluted or handled in concentrated form. Ready-To-Use (RTU) packaging reduces potential exposure to children and pets from ingesting/contacting the pesticide stored or kept in non-labeled containers such as coffee cans or nonpesticide spray bottles which are commonly used by homeowners. Using containers other than the labeled product container to apply the pesticide defeats the purpose of label instructions, precautions, and first aid treatment, since the information would not be readily available for use should exposure occur. For this reason, the Agency encourages registrants to formulate products for residential use as Ready-to-Use products.

Please note that an existing registered concentrate formulation may not be changed to a RTU product by amendment or notification. An application for new product registration must be submitted. However, since the Agency is encouraging the use of RTU products, these new product applications will be processed expediently.

VI. HOW TO MODIFY LABELING

EPA requests that registrants who are subject to this Notice submit an application for amended registration. This application must include the following items: EPA application form 8570-1 (filled in), five copies of the draft label (highlighting the changes made), and a description on the application, such as, "Amended in accordance with PR Notice 2000-XX." **All such submissions must pertain only to this PR Notice. Additional unrelated amendments and/or changes to the product must be submitted as a separate action or the submission will not be reviewed and the entire submission will be returned to the registrant as unacceptable.** The Agency will attempt to process correctly submitted applications within 90 days.

Registrants should send applications for amendment to the following addresses:

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 (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Hand-Carried/Courier 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 (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

VII. EFFECTIVE DATES

EPA requests that products subject to this Notice that are released for shipment by registrants after October 1, 2001 bear labeling that is consistent with this Notice. EPA requests that all products subject to this Notice that are distributed or sold by registrants and supplemental distributors after October 1, 2002 bear labeling that is consistent with this Notice. EPA requests that all products subject to this Notice that are distributed or sold by dealers and distributors after October 1, 2003 bear labeling that is consistent with this Notice. Please note that some states conduct label reviews prior to approving a modified product. Various states' requirements should be taken into consideration when deciding on the timing of your amendment submission to EPA. Some states may require a review of the modified label by EPA prior to submission to the state for state approval purposes.

Notwithstanding the foregoing, instances where a risk concern has been identified will be assessed on a case by case basis. Finally, in the event that the Agency identifies a risk concern associated with any indoor residential insecticide, these dates could change and/or additional regulatory measures may become necessary.

VIII. FOR FURTHER INFORMATION

If you have questions regarding this Notice, please contact Mark Dow (Telephone 703-305-5533; e-mail dow.mark@epamail.epa.gov) or Tracy Keigwin (Telephone 703-305-6605; e-mail keigwin.tracy@epamail.epa.gov) of Registration Division, Office of Pesticide Programs.

-

James J. Jones, Director
Registration Division