

January 16, 2001

PESTICIDE REGISTRATION (PR) NOTICE 2001-3

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

ATTENTION: Persons Responsible for Federal Registration and Reregistration of
Pesticide Products

SUBJECT: Insect Repellents: Labeling Restrictions for Use on Infants and Children and
Restrictions on Food Fragrances and Colors

This notice announces EPA's approach to insect repellents bearing claims for use specifically on infants and children. Such products have sometimes borne statements such as, "Outdoor Protection for Kids" or "...for children" or "...for kids" or graphics featuring pictures of children. EPA believes that claims targeted to children as well as pictures of food or items predominantly associated with infants and children (e.g., toys) may be misleading. EPA believes that the label changes and policy clarification set forth in this PR Notice will reduce risks associated with the improper use of insect repellents and will improve consumer understanding. Additionally, this PR Notice states EPA's current position on insect repellents formulated to contain colors and fragrances predominantly associated with food (e.g., grape, watermelon, or orange). The Centers for Disease Control and Prevention (CDC) has reviewed and concurred with this notice.

EPA believes that the approach set forth in this notice best assures that insect repellent labels avoid misleading statements or inappropriate signals to consumers and assures that these interpretations are applied even-handedly and promote a "level playing field" throughout this industry sector. This notice provides guidance to EPA personnel and decision-makers, members of the regulated community, and to the public. The guidance in this notice is not binding on either EPA or any outside parties. Although this guidance document provides a starting point for EPA decisions, EPA will depart from this policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that this policy is not appropriate for a specific pesticide or that the specific circumstances demonstrate that this policy is not applicable.

I. BACKGROUND

A. Label Claims Targeted for Infants and Children

A pesticide is considered misbranded if its labeling is false or misleading in any particular including pesticidal and non-pesticidal claims [FIFRA Section 2(q)(1)(A)]. False or misleading statements include claims as to the safety of the pesticide or its ingredients [40 CFR

156.10(a)(5)(ix)]. Products bearing false or misleading claims may be subject to enforcement action under Sections 12 and 13 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Insect repellents that are labeled specifically for use on infants and children may be interpreted to imply that these pesticides are specially formulated for children. This can be misleading to the consumer because these products are not formulated differently for children than they are for adults. Further, EPA is concerned that packaging and labeling specifically targeted to children may encourage inappropriate handling and use of such products by children notwithstanding the presence of label language prohibiting handling or use by children.

EPA initially stated its position on this issue in the DEET Reregistration Eligibility Decision (RED), published December 1998. In the DEET RED, which applies only to DEET products, EPA stated that any repellent products containing DEET with child safety claims are ineligible for reregistration because the Agency regards such claims as misleading.

The Agency is also concerned that the labels of concern may encourage children to apply repellents themselves. An EPA fact sheet entitled “How to Use Insect Repellents Safely” (NTIS No. 735-F-93-052R) was published in April 1998 and outlines seven key recommendations on using insect repellents safely. In the fact sheet, EPA recommends the following precautions when using insect repellents:

- ▶ Repellents should be applied only to exposed skin and/or clothing (as directed on the product label). Do not use under clothing.
- ▶ Never use repellents over cuts, wounds, or irritated skin.
- ▶ Do not apply near eyes and mouth, and apply sparingly around ears. When using sprays, do not spray directly into face; spray on hands first and then apply to face.
- ▶ Do not allow children to handle this product, and do not apply to children’s hands. When using on children, apply to your own hands and then put it on the child.
- ▶ Do not spray in enclosed areas. Avoid breathing a spray product, and do not use it near food.
- ▶ Use just enough repellent to cover exposed skin and/or clothing. Heavy application and saturation is unnecessary for effectiveness; if biting insects do not respond to a thin film of repellent, apply a bit more.
- ▶ After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days. Also, wash treated clothing before wearing it again.

B. Food Fragrances

Since food or food-like fragrances (e.g., fruit, food flavorings) could be attractive to children and create opportunities for misuse, a Policy and Criteria Notice (No. 2155.1) was published November 20, 1975 establishing that pesticides with food or food-like fragrances are unacceptable for registration. This notice found other fragrances such as pine or floral not to create the same type of problem and to be acceptable for registration.

However, in a memorandum dated September 24, 1993, the Registration Division rescinded the food fragrance policy established in 1975. The memorandum stated that there was no clear data that food fragrances increase ingestion and that many of the pesticide products which are most likely to be ingested by children (i.e., antimicrobials and bait-type rodenticides) were specifically exempted from the proscriptions of the earlier policy. In February, 2000, the Office of Pesticide Programs issued a memorandum that determined that given the concern for potential unnecessary exposure to children, it is appropriate to modify the 1993 decision such that references to food or food-like substances would be discouraged by EPA and may be considered unacceptable if printed on an insect repellent label. Since insect repellents are a household item used on children, there is a greater concern for accidental ingestion if the fragrance is predominately associated with a food (e.g., grape, watermelon, orange).

II. RATIONALE WHY INSECT REPELLENTS SHOULD NOT BE LABELED SPECIFICALLY FOR INFANTS, CHILDREN, OR KIDS

The Agency believes there is no factual basis to support a claim that implies that some insect repellents pose significantly lower risk to infants and children or that they are more efficacious for infants and children. Since product performance studies do not demonstrate that insect repellents are safer or more efficacious for infants and children, the Agency considers any statement on the label implying that a product is formulated for kids or children to be potentially misleading. A statement that a repellent offers specific protection for infants and children would also not be acceptable because it may be construed as an implied safety claim. EPA regulations specify that safety claims for pesticides are false or misleading [40 CFR 156.10(a)(5)(ix)]. The Agency believes there is no factual basis to support a claim that implies that certain products pose significantly lower risk to infants and children than products without such statements. If parents believe that such products are safer than adult products, they may, for example, allow children to use them without adequate supervision or may overuse the products on their infants and children.

III. RATIONALE WHY FOOD COLORS AND FRAGRANCES SHOULD NOT BE INCORPORATED INTO INSECT REPELLENT PRODUCTS

The Agency believes that insect repellent products formulated with food fragrances may attract children to overuse, handle, or ingest the product. Therefore, EPA expects that manufacturers of insect repellents avoid fragrances associated with food (e.g., grape, watermelon, orange). EPA also expects that references to food or food-like substances also be avoided on an insect repellent label. Statements, words, or graphics that mention or picture any type of food (e.g., grape, berry, or melon) may mislead a consumer, particularly a child, that the pesticide is

edible. Similarly, EPA interprets the labeling requirements to mean that advertisements reflecting food scents or pictures would also not be used on insect repellent labels; such advertisements may increase the likelihood that consumers will think it is acceptable to ingest these products. Similarly, insect repellents should not be labeled with food-related terms or phrases. Colors may be used in a repellent formulation and printed on the label if they are not referred to as or commonly associated with a food. For example, to state that the repellent is purple would not present this problem; to say it is grape color would.

IV. WHAT REGISTRANTS SHOULD DO

A. Statements and Graphics That EPA Interprets as Unacceptable on the Label

EPA expects that products with statements, words, pictures, or graphics on the label specifically targeted for infants or children would be avoided. Also, pictures of infants or children (without adults) on the label as well as statements such as "For Kids" would be avoided. EPA expects registrants to remove all direct or implied claims of child safety from the label of insect repellent end-use products. Similarly, statements, graphics, fragrances, and names of colors associated with food products such as grape, berry, or melon would not appear on the label.

B. Statements That May be Appropriate on the Label

Statements such as "This repellent may be used for the entire family," "This repellent is suitable for the entire family," or "For use on the whole family," are appropriate to appear on the label, provided that the "Directions for Use" section includes appropriate instructions for use that are applicable to both adults and children. The "Directions for Use" section should also include a statement such as "Do not allow children under 10 to apply this product" or "An adult should apply this product to children under 10." This type of statement will help ensure children do not misapply or misuse insect repellents.

To minimize potential overexposure of children, EPA would, on a case-by-case basis, expect appropriate restrictions for application frequencies to the skin and/or clothing. Such limitations will also be part of the "Directions for Use" section of the label. Examples of statements that would be acceptable under the "Directions for Use" are: "Do not apply more than X times per day to children" or "Do not use on children under X years old." A registrant who wishes to prohibit use on infants and children is encouraged to include such a statement on a revised label.

Pictures of children with adults or an entire family may be printed on the label. Graphics that do not illustrate food or items related to children (such as toys) are appropriate on an insect repellent label. References to, or use of colors such as purple or blue are appropriate; by contrast, references to grape or berry colors may entice a child to apply, handle, or ingest the product.

C. Procedure

Registrants of insect repellents bearing claims targeted to protect infants and children are expected to amend their labels to delete or amend such statements according to this notice. Registrants with inappropriate food flavors or colors are expected to amend their formulations or to change the graphics and wording on the label. To do so, registrants should submit EPA Form No. 8570-1 Application for Pesticide Registration/Amendment and five copies of the revised label to EPA for approval. The application should indicate compliance with PR Notice 01-?. This application should be sent to:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460-0001

V. IMPLEMENTATION

1. Effective immediately, EPA does not intend to approve new or pending applications for registration that make claims that EPA deems to be misleading because they are inappropriately targeted to infants and children. Inappropriate targeting to children could include explicit labeling claims, or the inclusion in the product of inappropriate colors or fragrances that could be attractive to children, as described in this Notice.
2. Products subject to reregistration will be reviewed on a case-by-case basis against the guidance in this notice, and may be found ineligible for reregistration if they bear inappropriate claims targeted to children, or contain colors or fragrances that would be attractive to children.
3. As discussed above, however, EPA will depart from this policy where the facts or circumstances warrant. As of March 1, 2001, EPA will use this guidance on a case-by-case basis as one of the factors in determining whether currently registered products continue to meet the misbranding standard of FIFRA. Registrants of existing products are encouraged to review their product composition and labeling and make needed revisions before that date.

All applicants for registration of new products should consider adopting the labeling statements in this Notice, if appropriate. Registrants of currently registered products to which this Notice is applicable should consider taking the following action as appropriate.

Registrants who have previously submitted labels targeting children or products formulated with food fragrances and/or colors that have been reviewed and accepted by the Agency, and who are taking steps to fit within the interpretations set forth in this Notice, should submit an application for amended registration for each product. The application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label, a description on the application, such as, "Amended consistent with PR Notice 2001-03", and appropriate citation of any data in support of the amendment.

The Agency expects that all products released for shipment by registrants after March 1, 2002 can bear labeling that is consistent with this notice. After March 1, 2002, EPA will begin monitoring pesticide products to determine whether they are labeled in accordance with the regulation at 40 CFR 156.10(h)(2)(ii)(E). It is the responsibility of registrants to submit applications in a timely manner. Registrants should allow adequate review time for acceptance of amendments, which could be several months for EPA's review and additional time for states' reviews. After receiving approval for amended labeling of each product, registrants should submit final printed labeling in accordance with PR Notice 82-2, before distributing the product in commerce.

VI. SCOPE OF POLICY

This Notice is intended to provide guidance to EPA personnel, pesticide registrants and applicants, and the public. Consistent with EPA's obligations under the Administrative Procedure Act, the policy set forth in this guidance document 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. Subject to FIFRA Section 3(f)(2), if EPA believes that a product does not meet the requirements of 40 CFR Part 156, the Agency may find the product to be misbranded.

VII. FOR ADDITIONAL INFORMATION

If you have questions regarding this PR Notice, contact:

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