



US Environmental Protection Agency Office of Pesticide Programs

Pesticide Registration (PR) Notice 2000-6

Minimum Risk Pesticides Exempted under FIFRA Section 25(b)
Clarification of Issues

May 7, 2000

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PESTICIDE REGISTRATION (PR) NOTICE 2000-6

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Minimum Risk Pesticides Exempted under FIFRA Section 25(b)
Clarification of Issues

I. PURPOSE

Please Note: List 4A, "Minimal Risk Inerts" (Appendix B of this notice) is updated on a continuing basis. Current versions are available on the Pesticides Web site at http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.

This notice clarifies several aspects of the exemption for minimum risk pesticides by the FIFRA Section 25(b) rule, including composition, labeling, food tolerances, and state regulation. It is being issued to answer questions frequently asked of EPA about such products.

II. BACKGROUND

Section 2(u) of FIFRA defines a "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer." Except in very limited circumstances, any substance falling within this definition of a pesticide must be registered by EPA before it can be legally sold or distributed. One such exception to the registration requirement is for those pesticides that the Administrator, under section 25(b) of FIFRA, has determined "to be of a character which is unnecessary to be subject to this Act," and that have been exempted from the requirements of FIFRA by regulation.

In 1996, EPA exempted certain minimum risk pesticides from FIFRA requirements if they satisfy certain conditions. EPA exempted the products described in 40 CFR section 152.25(g) in part to reduce the cost and regulatory burdens on businesses as well as the public for pesticides posing little or no risk, and to focus EPA's limited resources on pesticides which pose greater risk to humans and the environment. This exemption provision is located in section 152.25(g) of Title 40 of the Code of Federal Regulations.

To qualify for an exemption as a minimum risk pesticide, each active ingredient in the pesticide product must be listed in 40 CFR 152.25(g)(1). Appendix A is a list of these ingredients. Currently, this list contains more than 30 active ingredients. In addition, 40 CFR 152.25(g)(2) provides that these pesticide products may only contain minimal risk inert ingredients listed in the most current List 4A. Appendix B is the most current list of these inert ingredients. Additionally, to be exempted and remain exempted, products must also meet a series of exemption

conditions described in 40 CFR 152.25(g)(3).

EPA does not review or issue notices of exemption for products which meet the conditions for exemption. Sale or distribution of a pesticide product meeting all the criteria in 40 CFR 152.25(g) without a federal registration is not a violation of FIFRA. However, if a product does not meet all of the exemption criteria, the product is not exempt from FIFRA and its sale or distribution if not registered would be a violation of FIFRA.

How to Determine if a Product Qualifies for Exemption as a Minimum Risk Pesticide Under 40 CFR 152.25(g).

QUESTION: How can I tell if my product qualifies for the minimum risk pesticide exemption?

ANSWER: To qualify as a minimum risk pesticide under 40 CFR 152.25(g) (and be exempt from pesticide registration), a product must meet certain conditions. These conditions fall into the following two categories.

1. Composition:

- active ingredients: may contain only those active ingredients that are listed in 40 CFR 152.25(g)(1) and shown in Appendix A.
- other (inert) ingredients: may contain only List 4A inerts, including commonly consumed foods. (See Appendix B).

2. Labeling:

- All ingredients in an exempted product must be listed on its label:
 - Active ingredients must be listed by name and percentage (by weight).
 - All other ingredients must be listed by name (see above for inerts).
- No false or misleading statements under 40 CFR 156.10 (a)(5)(i)-(viii) may appear on an exempted product's label.
- Labeled Uses:

The product may not bear any claims to control or mitigate microorganisms in a way that links the microorganism to a threat to human health (including but not limited to disease transmitting bacteria or viruses) or claims to control rodent or insect pests in a way that links the pest to *specific* diseases (for example, the label may not say "controls ticks that carry Lyme disease" or "controls mosquitoes that can transmit

malaria or encephalitis," but can say "controls ticks," or, "controls mosquitoes," etc.).

It is important to note that even if a pesticide product meets the conditions for exemption from regulation under FIFRA, it is still subject to any applicable requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) if its use results in pesticide chemical residues on or in food commodities or animal feed. In addition, producers of pesticides must meet any applicable state registration or other regulatory requirements. Each state has its own statutes and regulations concerning pesticide registration and regulation, and the states are not required to permit the sale of an exempted product simply because it meets the 40 CFR 152.25(g) conditions for minimum risk exemption. An address and telephone list of the state agencies which regulate pesticides may be found at:

<http://aapco.ceris.purdue.edu> and at

<http://www.epa.gov/pesticides/biopesticides/otherdocs/statelist.htm>. You may also call (703) 305-7973 to obtain a paper copy.

III. COMPOSITION OF "MINIMUM RISK PESTICIDES"

1. Active Ingredients

QUESTION: What active ingredients may be used in an exempted pesticide product?

ANSWER: Only active ingredients listed in 40 CFR 152.25(g)(1) may be in exempt products. Appendix A to this PR Notice lists all of the active ingredients which are currently permissible ingredients in exempt products.

QUESTION: Can other active ingredients be added to this list? How?

ANSWER: The Agency may modify this list in the future, but any additions (or deletions) would have to be accomplished through rule making. Companies cannot obtain an exemption on an ad hoc basis as part of the application process. EPA cannot exempt an ingredient or product as part of the application process without having completed the required rule making.

2. Other Ingredients

QUESTION: What other ingredients may be used in exempted products?

ANSWER: The only other ingredients an exempt product may contain are listed in the most current List 4A inert ingredients, which the Agency last published in the *Federal Register* of September 28, 1994. List 4A inert ingredients are considered to be minimal risk inert ingredients, and are recognized as safe for use in pesticide products. The current List 4A minimal risk inerts are listed in Appendix B to this PR Notice.

QUESTION: Can common foods be used as inert ingredients in exempted products?

ANSWER: Yes. EPA's policy is that "commonly consumed foods" are considered List 4A inerts of minimal concern, even if they are not already included on the list of minimal risk inerts. (See 59 FR 49400, September 28, 1994) "Inert Ingredients in Pesticide Products; List of Minimal Risk Inerts."

QUESTION: Will additions to the List 4A be possible?

ANSWER: Yes. Additions to List 4A are being considered by the Agency. Any changes will be published in the *Federal Register*.

QUESTION: If a List 4A minimal risk inert has active, pesticidal properties, am I allowed to use it as the active ingredient in an exempt product?

ANSWER: No. The two lists are not interchangeable. In other words, you may not use a List 4A inert ingredient as an active ingredient, and you also may not use one of the active ingredients listed in 40 CFR part 152.25(g)(1) as an inert. Only if the ingredient is included on both lists can it be used without regard to its active or inert function. Even then, the ingredient must be designated on the label as either active or inert (See Labeling below).

IV. LABELING OF MINIMUM RISK PESTICIDES

QUESTION: What should I include on my product's label?

ANSWER: In order to qualify for the minimum risk pesticide exemption, the pesticide product must meet certain labeling conditions. These conditions, all of which must be met in order to qualify for exemption, are as follows:

1. The pesticide product containing permissible substances must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient;
2. The product may not bear any claims to control or mitigate microorganisms in a way that links the microorganisms to a threat to human health (including but not limited to disease transmitting bacteria or viruses) or claims to control rodent or insect pests in a way that links the pest to *specific* diseases (for example, the label may not say "controls ticks that carry Lyme disease" or "controls mosquitoes that can transmit malaria or encephalitis," but can say "controls ticks," or, "controls mosquitoes," etc.);

and

3. The product must not include any false or misleading labeling statements prohibited by 40 CFR 156.10 (a)(5) (i)-(viii). To follow is a list of unacceptable types of statements that Agency regulations provide are false or misleading, along with some examples:
 - a. A false or misleading statement concerning the composition of the product;
 - b. A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
 - c. A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
 - d. A false or misleading comparison with other pesticides or devices;
 - e. Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

Example: “Recommended by EPA as safe and exempt.” This kind of statement leads the consumer to believe that the Federal Government has made such a determination for a particular product. Because exempted products are not reviewed by EPA, this kind of statement is misleading.

Example: “It is a Violation of Federal Law to Use this Product in a Manner Inconsistent with its Labeling.”

Example: “EPA Registration No.” or “EPA Establishment No.”

The latter two examples are false or misleading because they imply that the product is registered by EPA.

Example: An example of a statement that the Agency would likely consider acceptable would be: “This product has not been registered by the United States Environmental Protection Agency. [The name of the company] represents that this product qualifies for exemption from registration under the Federal Insecticide, Fungicide, and Rodenticide Act.”

- f. The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more, but not all such principal active ingredients, even though the names of the other ingredients are stated elsewhere in the labeling;
- g. A true statement used in such a way as to give a false or misleading impression to the purchaser;
- h. Label disclaimers which negate or detract from labeling statements required under the act and these regulations, including as conditions of exemption.

QUESTION: I have found mosquito and tick repellents on the market shelf that do not have EPA registration numbers. I thought that exempted pesticide products could not be labeled to control these kinds of pests?

ANSWER: Claims that the exempted pesticide controls these kinds of *pests* are allowed, but no claims may be made to make the consumer believe that they would be protected by using the product from a *disease* that these insects can carry, such as Lyme disease. ***Remember: the claim may only be for the pest, as a pest, and not as a disease vector.***

Example of an appropriate claim: “repels mosquitoes and ticks.”

Examples of an inappropriate claim: “repels mosquitoes that can transmit malaria,” or, “Will repel ticks that cause Lyme disease.”

QUESTION: I have seen products that say they are "the natural way to control pests," or "safe for kids and pets." Aren't these considered by EPA to be false and misleading claims?

ANSWER: No, not for exempted minimum risk pesticides. Products that meet the criteria for exemption from regulation may make safety claims if true. On the other hand, claims cannot be worded in such a way that implies or states endorsement by EPA or another federal agency or department.

V. FOOD TOLERANCES FOR "MINIMUM RISK PESTICIDES"

QUESTION: What are the requirements if my product is to be used on or around food, food crops, food contact surfaces, or animal feed?

ANSWER: Even if a product is exempt under FIFRA, it must have a tolerance or tolerance exemption under FFDCA, if the product is to be used on food, food crops, food contact surfaces, or animal feed commodities.

The minimum risk pesticide exemption, 40 CFR 152.25(g), only exempts qualifying pesticide products from certain requirements of FIFRA. The use of pesticides on food, food crops, food contact surfaces, and animal feed can result in residues of pesticide products on or in treated foods or foods which come into contact with treated surfaces. Tolerances are maximum legally permissible levels of pesticide residues, including active and inert ingredients, which may be found in foods. In some instances, pesticides are exempted from the requirement of a tolerance, because the pesticide is considered to be safe enough for use at any level. Tolerances and exemptions from tolerance are established and regulated by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), not FIFRA. The pesticide label may bear only those food uses for which there are tolerances or exemptions from tolerances for the active and inert ingredients. If the tolerance exemption is for all food commodities, then any food crops, food surfaces, or animal feed can be listed on the label.

QUESTION: How can I find out if my active and inert ingredients have tolerances or are exempt from the requirement of a tolerance?

ANSWER: Tolerances and exemptions for foods are listed in Parts 180, 185, and 186 of Title 40 of the Code of Federal Regulations for each active ingredient and inert ingredient. Appendices A and B can be used to identify which actives and inerts are exempt from tolerances on all crops as of the date of this notice. In addition, tolerances and exemptions are published throughout the year in the Federal Register. This source is frequently more up-to-date than the latest version of 40 CFR and thus, needs to be checked to verify that no changes have occurred since the last printing of the 40 CFR.

QUESTION: How do I get a tolerance if I need one?

ANSWER: The first step to receive a tolerance is to petition the Agency by following the guidelines found in 40 CFR section 180.7 (see www.gpo.gov). Additional guidance can be found at www.epa.gov/PesticideApplication. The Agency will then announce the receipt of the petition in the Federal register. Tolerance fees are required, but may be waived on a case-by-case basis.

VI. STATE REGULATION OF "MINIMUM RISK PESTICIDE" PRODUCTS

QUESTION: What must I do to meet any applicable state registration requirements?

ANSWER: Even if a pesticide product is exempt from FIFRA requirements, the product may not be exempt from state registration or other regulatory requirements. Each state has its own statutes and regulations concerning pesticide registration and regulation. A pesticide product exempted from federal regulation is not automatically exempt in a state. It is important that you contact the state agencies responsible for pesticide regulation in those states in which you would like to sell your product, so you can find out what you need to do in order to satisfy their

requirements for pesticide registration if required. An address and telephone list of the state agencies which regulate pesticides is available online <http://www.epa.gov/pesticides/biopesticides/otherdocs/statelist.htm>. You may also call (703) 305-7973 to obtain a paper copy.

QUESTION: What happens if a state won't accept my product as an exempted pesticide?

ANSWER: You may:

1. Comply with the State's requirements in order to sell and distribute the product; or
2. Not sell or distribute the product in that state; or
3. You may register the product with the EPA if EPA determines that your product meets all the health and safety standards and all other applicable requirements. You must also meet any applicable State requirements for your product.

If a pesticide product does not meet the conditions for minimum risk pesticide exemption, or if states will not accept the product without an EPA registration, a registration kit may be obtained by calling 703-305-6549. The kit is also available on our website, at www.epa.gov/pesticides/registrationkit.

Please note that the sale or distribution of a pesticide without an EPA registration that does not meet the conditions for a minimum risk pesticide and does not fall within any other exemption from FIFRA is a violation of FIFRA. (See, e.g., FIFRA section 12(a)(1).)

VII. FOR FURTHER INFORMATION

If you have any further questions, please contact Brian Steinwand at (703) 305-7973 (e-mail: steinwand.brian@epa.gov).

Marcia E. Mulkey, Director
Office of Pesticide Programs

Appendix A
PR Notice 2000-6

Active Ingredients Which May Be in Minimum Risk Pesticide Products Exempted under section 25(b) of FIFRA

1. Castor Oil (U.S.P. or equivalent)
2. Cedar Oil
3. Cinnamon* and Cinnamon Oil *
4. Citric Acid*
5. Citronella and Citronella Oil
6. Cloves* and Clove Oil*
7. Corn Gluten Meal*
8. Corn Oil*
9. Cottonseed Oil*
10. Dried Blood
11. Eugenol
12. Garlic* and Garlic Oil*
13. Geraniol
14. Geranium Oil
15. Lauryl Sulfate
16. Lemon grass Oil*
17. Linseed Oil
18. Malic Acid*
19. Mint* and Mint Oil*
20. Peppermint* and Peppermint Oil*
21. 2-Phenethyl Propionate (2-phenylethyl propionate)
22. Potassium Sorbate
23. Putrescent Whole Egg Solids (See 180.1071)
24. Rosemary * and Rosemary Oil*
25. Sesame* (includes ground Sesame plant stalks) (See 180.1087) and Sesame Oil*
26. Sodium Chloride (common salt)*
27. Sodium Lauryl Sulfate
28. Soybean Oil
29. Thyme* and Thyme Oil*
30. White Pepper*
31. Zinc Metal Strips (consisting solely of zinc metal and impurities)

* These active ingredients are exempt for use on all food commodities from the requirement of a tolerance on all raw agricultural commodities at 40 CFR 180.1164(d).

Appendix B
PR Notice 2000-6

Please Note: List 4A, "Minimal Risk Inerts" (Appendix B of this notice) is updated on a continuing basis. Current versions are available on the Pesticides Web site at http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.