



Oregon

Department
of Agriculture

Pesticides Division
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Registration of 25(b) Minimum Risk Pesticides

Currently thirty-one (31) pesticidal active ingredients and a number of inert/other ingredients are exempt from Federal EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 25(b). As of January 1, 2011, the Oregon Department of Agriculture (ODA), Pesticides Division now requires registration of 25(b) Minimum Risk Pesticide products. The intent of this document is to clarify Oregon's registration and labeling requirements and to provide guidance for registrants of 25(b) products.

The following conditions must be met in order for a pesticide product to be registered as a Minimum Risk 25(b) product by ODA:

1. **Active ingredients must** be exactly as listed in 40 Code of Federal Regulations (CFR) 152.25(f)(1) as exempt from the requirement for federal registration (Table 1). For example, garlic must be listed as Garlic or Garlic Oil, not Garlic Juice. The term "Organic" can be used only if it is true. This list can also be found at http://www.epa.gov/opppbd1/biopesticides/regtools/25b_list.htm.
2. **Inert or "Other" ingredients** must be listed on EPA's most current *Minimal Risk FIFRA Section 25(b) Inert Ingredients* list (formerly List 4A) (http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf) or 40 CFR 180.950.
3. Ingredients listed in items #1 and #2 **are not interchangeable** (e.g. actives cannot be inerts and vice versa) except for the few ingredients that are included on both lists.
4. All ingredients (both active and inert/other) must be listed on the label. Each active ingredient must be listed by name and percentage by weight in descending order. Inert/other ingredients must be listed by name and as one cumulative percentage. The combined percentages of active and inert/other ingredients must equal 100%.
5. It is recommended that a statement that the product is EPA exempt appear on the label. Examples of acceptable label wording are:
 - a. "This product is not registered with the U.S. Environmental Protection Agency since it qualifies for exemption under FIFRA section 25(b) as a minimum risk pesticide."
 - b. "This product is exempt from registration with the U.S. Environmental Protection Agency under FIFRA section 25(b) regulations."
6. **Directions for Use:** The label must clearly identify the intended target pest(s), the site(s) where the product is to be used and specific application instructions such as methods, use rates and dilutions.
7. The product label must not include any false or misleading statements. This includes those listed in 40 CFR 156.10(a)(5)(i) through (viii). Examples of such statements include:
 - 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.
 - f. Any false or misleading graphics implying a use that is not permitted.
8. The product label must not make public health claims. For example, the label may refer to controlling ticks, bed bugs or mosquitoes, but may not in any way refer to or claim to control or prevent any microorganisms/pathogens that cause specific diseases carried by those pests, such as West Nile Virus, Bubonic plague, or Hantavirus.
 9. Statements **not allowed** on the label include the following: “EPA Registration Number”; “Recommended by EPA as safe and exempt”; “It is a violation of Federal Law to use this product in a manner inconsistent with labeling”; “Repels mosquitoes that transmit malaria”. It is acceptable, however, to claim, “controls mosquitoes”, etc.
 10. Product labels must not include any aquatic uses. Oregon will not register 25(b) products for direct application to aquatic environments.
 11. A **Storage and Disposal** statement is required: The label must have a statement that provides guidance on how to store and dispose of the container and/or unused product. An example of an appropriate statement: “Store only in original container in a dry place inaccessible to children and pets. Do not reuse empty containers. Offer for recycling if available or discard in trash”.
 12. A **Precautionary Statement** adequate to protect people, pets and the environment is required: An example of an appropriate precautionary statement is, “Keep out of reach of children. Avoid contact with eyes, skin or clothing. If in eyes, flush with water for at least 15 minutes. If on skin, wash with plenty of soap and water. Get medical attention if irritation persists. Do not apply this product undiluted. Do not apply to water”.
 13. Even if a product is exempt under FIFRA section 25(b), each active and inert/other ingredient must have a tolerance or tolerance exemption under the Federal Food, Drug and Cosmetic Act (FFDCA) if the product is to be used on food, food crops, food contact surfaces or animal feed commodities *unless they are exempt under other regulations*. If the product does not qualify for use on food, food crops, food contact surfaces or animal feed commodities it should be clearly stated on the label. An example of acceptable language is, “Do not use on food and feed commodities.”
 14. Name and contact information of registrant is required.
 15. Net contents must be indicated.

Additional References for Information on Section 25(b) Minimum Risk Pesticide Pesticides

- Criteria for FIFRA 25(b) exemption:
http://www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm
- EPA Pesticide Registration (PR) Notice 2000-6 (Minimum Risk Pesticides Exempted Under FIFRA Section 25(b), Clarification of Issues): www.epa.gov/PR_Notices
- Minimum Risk Pesticides FAQ:
www.epa.gov/pesticides/biopesticides/regtools/25b/25b-faq.h

Table 1. 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 metals and impurities)

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*These active ingredients are exempt from pesticide residue tolerance requirements.

ONE-PAGE SUMMARY OF 25(b) MINIMUM RISK PESTICIDE ODA LABELING REQUIREMENTS

Labels for approval in Oregon as 25(b) pesticides must include the following:

- The product brand name
- Ingredients
 - Active Ingredients: (1) only those listed in 40 CFR 152.25 (f)(1) as exempt; (2) in descending order of percentage of composition (% for each active ingredient must be listed).
 - Inert/Other Ingredients: (1) only those from List 4(A) or 40 CFR 180.950; (2) listed by name with the cumulative percentage of all inert ingredients listed.
 - Total percentage of the active and inert/other ingredients must equal 100%.
 - Active and Inert ingredients are **NOT** interchangeable unless they occur on both lists.
- Directions for use must include a description of intended use (target sites and pests) and use rates. Label must not claim to control microorganisms/pathogens that pose a threat to human health.
- A Precautionary statement must include “Keep Out of Reach of Children”, plus any additional statements to protect people, pets and the environment.
- A Storage and Disposal statement.
- If the product does not qualify for use on food, food crops, food contact surfaces or animal feed commodities it should be clearly stated on the label. An example of acceptable language is, “Do not use on food and feed commodities.”
- Name and contact information of registrant or manufacturer. If the registrant’s name appears on the label and the registrant is not the manufacturer, then the registrant’s name must be qualified by appropriate wording such as “Packaged for” or “Distributed by.”
- The net weight or measure of the package contents.