

FIFRA Section 25(b) – Minimum Risk Pesticides

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What is a Minimum Risk Pesticide?

- EPA has determined that certain “minimum risk pesticides” pose little to no risk to human health or the environment.
- These products are exempt from registration under FIFRA Section 25.
- The exemption provisions are located in 40 CFR 152.25(f).
- Products must meet 6 conditions to qualify as a 25(b), minimum risk pesticide, and be exempt from registration.

Condition 1: Active Ingredients

- The product's active ingredients must only be those listed in 40 CFR 152.25(f)(1).

Castor Oil	Cedarwood Oil	Cinnamon	Cinnamon Oil	Citric Acid	Citronella
Citronella Oil	Cloves	Clove Oil	Corn Gluten Meal	Corn Oil	Cornmint
Cornmint Oil	Cottonseed Oil	Dried Blood	Eugenol	Garlic	Garlic Oil
Geraniol	Geranium Oil	Lauryl Sulfate	Lemongrass Oil	Linseed Oil	Malic Acid
Peppermint	Peppermint Oil	2-Phenylethyl propionate	Potassium Sorbate	Putrescent whole egg solids	Rosemary
Rosemary Oil	Sesame	Sesame Oil	Sodium Chloride	Sodium Lauryl Sulfate	Soybean Oil
Spearmint	Spearmint Oil	Thyme	Thyme Oil	White Pepper	Zinc

Condition 2: Inert Ingredients

- The product's inert ingredients may only be those that EPA has classified as:
 - Inert Ingredients Approved for Use in Minimum Risk Pesticides - 40 CFR 152.25(f)(2)
 - Other items with minimum risk tolerance exemptions in 40 CFR 180.950
 - Commonly consumed food commodities – 40 CFR 180.950(a)
 - Animal feed items – 40 CFR 180.950(b)
 - Edible fats and oils – 40 CFR 180.950(c)

Condition 3: Ingredients Listed On Label

- All ingredients in a 25(b) product must be listed on the label.
 - All active ingredients must be listed by the label display name and percentage (by weight).
 - All inert ingredients must be listed by the label display name.

Condition 4: Health-Related Claims

- The label cannot state or imply that the product can or will control or reduce organisms that pose a threat to human health, or insects/rodents carrying specific diseases.
- The label cannot bear claims to control or reduce microorganisms such as bacteria or viruses that pose a threat to human health or that could lead to infection or disease in humans.
- Symbols and terms that imply safety or non-toxicity cannot be used as a claim.

Condition 5: Company Name & Contact Information

- The name of the producer, or the company for whom the product was produced, and the company's contact information must be displayed prominently on the product label.
 - Street address.
 - City, State, and Zip code.
 - Telephone number.

Condition 6: Label Statements

- The label cannot include any false or misleading statements, as described in 40 CFR 156.10(a)(5)(i) through (viii).
 - Statements concerning the composition of the product.
 - Statements about the effectiveness of the product as a pesticide.
 - Any statement directly or indirectly implying that the pesticide is recommended or endorsed by any agency of the federal government.
 - The use of certain statements that are required to be on the label of a registered pesticide product that may imply review or acceptance of the minimum risk product by EPA, when such a review has not occurred.

The Issues

- Without Federal registration or review, registration decisions are left to the individual state.
- Every state/territory could have different laws/policies regarding these products.
- Companies may have multiple labels in the channels of trade at the same time to meet each state's requirements.

FIFRA 25(b) Workgroup

- Formed by the Association of American Pesticide Control Officials (AAPCO) in Spring 2017.
- Mission Statement: “To facilitate the collaboration of states and industry in order to share information, provide guidance, foster label consistency, and reduce the duplication of efforts in the review and registration of Minimum Risk Pesticide products.”
- Chair: Erica Millette, New Mexico Dept. of Agriculture
- Co-Chair: Sarah Caffery, Office of Indiana State Chemist

FIFRA 25(b) Workgroup

States

- 41 participants
 - representing 27 states/territories including EPA.
- Conference calls every other month.

Industry

- 43 participants
 - Representing 32 companies including consulting agencies.
- Conference calls quarterly.

State Survey Results

2017

- 41 States require registration of 25(b) products.
 - 5 States require efficacy data
 - 11 States require the Complete Statement of Formula
 - 12 States require the Safety Data Sheet
 - Some states had specific label requirements

2018

- 43 States require registration or review of 25(b) products.
 - 8 States require efficacy data
 - 14 States require the Complete Statement of Formula
 - 17 States require the Safety Data Sheet
- 27 States have adopted some or all of the Label Guidance issued by the workgroup.

FIFRA Minimum Risk Pesticides Label Guidance

- This is a guidance document. Following this document will not guarantee your product will be accepted in all states that require registration.
- Some states may have additional requirements for registration.
- Should aid in companies only needing one label for all states.
- This information is subject to change at any time.

Label Guidance (Cont.)

1. Products must comply with the 6 conditions outlined by EPA.
2. Signal Word and Keep Out of Reach of Children statement are to be located prominently on the front panel of the label.
3. Both Active and Inert Ingredients are to be listed in column form and total 100%.
4. Inert Ingredients are to be listed on the label in order of highest percentage first.

Label Guidance (Cont.)

5. NO images of children are acceptable on labels unless the product is intended for use on children or is a swimming pool product.
6. All claims on the manufacturer's website must comply with the 6 conditions outlined by EPA.
7. Labels are to include specific use site locations.
8. Non-toxic claims are not acceptable.

Label Guidance (Cont.)

9. The terms “Organic” or “Certified Organic” in reference to the 25(b) product are unacceptable.
10. “Natural” claims are not allowed if the product includes synthetic chemicals and those derived synthetically.
11. Claims such as “Safe” or “Safe around children and pets” are acceptable only when accompanied by the qualifier “...when used as directed”.
12. Data may be required to substantiate any claim that appears on the label or labeling.

Future Projects

- Issue data guidance for minimum risk pesticide products.
- Set up an online forum for states and industry to facilitate better communication.
- Collaborative state reviews of minimum risk pesticide product registrations.

Resources

- <https://www.epa.gov/minimum-risk-pesticides> - EPA Minimum Risk Pesticide Information
- <https://aapco.org/2015/07/02/fifra-25b-workgroup/> - AAPCO FIFRA 25(b) Workgroup Site

Contacts

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Questions?
