

http://www.epa.gov/pesticides/biopesticides/regtools/25b_list.htm Last updated on Wednesday, February 16, 2011 Pesticides: Regulating Pesticides

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Biopesticides Registration Tools

Minimum Risk Pesticides

Minimum risk pesticides are a special class of pesticides that are not subject to federal registration requirements because their ingredients, both active and inert, are *demonstrably* safe for the intended use. These Web pages provide detailed information for pesticide companies who want to register minimum risk pesticide products.

Criteria for FIFRA 25(b) Exemption

Minimum risk pesticides that meet certain criteria are exempt from federal registration under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The U.S. Environmental Protection Agency (EPA) does not review or register pesticides that satisfy the 25(b) criteria, though registration is required by most states. For information on minimum risk pesticides in your state, please contact your state's pesticide registration office.

To satisfy the conditions required for federal minimum risk status, all five of the following conditions must be met:

Minimum Risk Pesticides

- Criteria for FIFRA 25(b) Exemption
- Permitted Inerts
- State Pesticide Registration Contacts EXIT Disclaimer
- Pesticide Registration Notice (11 pp, 132 K, about PDF)
- Frequent Questions

Related Information

- Regulating Biopesticides
- Registration Tools
- Recent Enforcement Actions
- CSPA's letter of June 11, 2007, (6 pp, 3.45 MB, about PDF)
- EPA's response letter (2 pp, 25 K, about PDF) responds to that letter as well as the March 15 petition.
- Condition 1: The product must contain only <u>active</u> <u>ingredients that are listed in the table</u> below. The active ingredient of a product is the ingredient that kills, destroys, mitigates, or repels pests named on the product label.
- **Condition 2:** The product must contain **only** those inert ingredients that have been classified by EPA as List 4A "Inert Ingredients of Minimal Concern." An explanation of the Inert Ingredients of Minimal Concern and links to List 4A are available on EPA's <u>Permitted Inerts</u> Web page.
- **Condition 3:** All of the ingredients (both active and inert) must be listed on the label. The active ingredient(s) must be listed by name and percentage by weight. Each inert ingredient must be listed by name.
- **Condition 4:** The label cannot include any false or misleading statements, and claims that minimum risk pesticides protect human or public health are prohibited. For example, since these products are exempt from federal registration, label language implying federal registration, review or endorsement, such as "It is a violation of federal law to use this product in a manner inconsistent with the label," or the use of an EPA registration or establishment number is not allowed.
- **Condition 5:** In general, public health claims are prohibited. Minimum risk pesticide labels may not bear claims to control rodent, insect or microbial pests in a way that links the pests with any specific disease. EPA recommends that anyone considering manufacturing,

distributing, or selling minimum risk antimicrobial pesticide products first <u>contact the</u> <u>Pesticide Program's Antimicrobial Division ombudsman</u>, who can assist in ensuring that proposed antimicrobial minimum risk products meet the strict requirements for exemption from registration.

Additionally, EPA requires the establishment of <u>maximum residue limits</u>, <u>which EPA calls</u> <u>tolerances</u>, <u>or exemptions from the requirement of a tolerance</u> for all pesticides intended for use in a manner that may result in residues in food or feed.

Active Ingredients Exempted Under 25(b) of the Federal Insecticide, Fungicide, & Rodenticide Act

^{*} indicates exempt active ingredients that are also exempt from pesticide residue tolerance requirements

Castor oil (U.S.P. or equivalent)*	Linseed oil
Cedar oil	Malic acid
Cinnamon and cinnamon oil*	Mint and mint oil
Citric acid*	Peppermint and peppermint oil*
Citronella and Citronella oil	2-Phenethyl propionate (2-phenylethyl propionate)
Cloves and clove oil*	Potassium sorbate
Corn gluten meal*	Putrescent whole egg solids
Corn oil*	Rosemary and rosemary oil*
Cottonseed oil*	Sesame (includes ground sesame plant) and sesame oil*
Dried Blood	Sodium chloride (common salt) *
Eugenol	Sodium lauryl sulfate
Garlic and garlic oil*	Soybean oil
Geraniol*	Thyme and thyme oil*
Geranium oil	White pepper
Lauryl sulfate	Zinc metal strips (consisting solely of zinc metal and impurities)
Lemongrass oil	

Products Intended for the Control of Public Health Pests Must Be Effective

EPA received a petition from the Consumer Specialty Products Association (CSPA) dated March 15, 2006, requesting that the Agency exclude from the minimum risk pesticide exemption those pesticides that claim to control "pests of significant public health importance" and require an abbreviated registration for minimum risk products that are to be used for the control of public health pests. On September 13, 2006, EPA published in the Federal Register a Notice of Availability and Request for Comments on the petition allowing a 60-day comment period. On December 6, 2006, EPA reopened the comment period for an additional 30 days at the request of CropLife America. During the public comment period, the Agency received approximately 60 comments, both in support of and in opposition to the petition.

EPA has analyzed the comments on the petition and concluded that public health products must be supported by evidence that they are effective against the target pest. EPA is now looking at options to ensure that minimum risk public health pesticides that are otherwise exempted from regulation are effective. <u>CSPA's letter of June 11, 2007</u>, (6 pp, 3.45 MB, <u>about PDF</u>) suggested that EPA engage in expedited rulemaking, including promulgating an interim final rule without notice and comment. <u>EPA's response letter</u> (2 pp, 25 K, <u>about PDF</u>) responds to that letter as well as the March 15 petition.