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Guidance for Registration and Labeling of Section 25(b) Minimum Risk Pesticides

To avoid delays in the registration process submit a complete application with the following:

- A complete and signed Application for Registration of Pesticides ([AGR 630-4216](#))
- Product Label (searchable PDF format, unprotected, and optimized)
- Confidential Statement of Formula(s), required to be submitted on form [AGR 707-4139](#)
- Registration fee of \$390 per product for 2 years (\$195 if registered during 2nd year of cycle)
- Safety Data Sheet (SDS).
- Efficacy Data (upon request or as required).

Pesticide registration forms and guidance documents are available on the WSDA web site at agr.wa.gov/PestFert/Pesticides/ProductRegistration.aspx.

Products must comply with EPA's six conditions to qualify for exemption as a Section 25(b) Minimum Risk Pesticide and in order for the product to be registered by WSDA.

Condition 1: Active Ingredients Must be Only Those Listed in 40 CFR 152.25(f)(1). Products intended for use on food/feed crops (including most aquatic sites) can only include eligible active ingredients listed at <http://www.epa.gov/sites/production/files/2015-12/documents/minrisk-active-ingredients-tolerances-2015-12-15.pdf> with applicable tolerance exemptions in [40 CFR 180](#). For example, acetic acid and corn cob are not permitted as active ingredients.

Condition 2: Inert Ingredients Must be Only Those Listed in 40 CFR 152.25(f)(2). Products intended for use on food/feed crops (including most aquatic sites) can only include inert ingredients with applicable tolerance exemptions in 40 CFR 180. The only inert ingredients that may be used are those that EPA has classified as:

- o Commonly consumed food commodities [40 CFR 180.950(a)].
- o Animal feed items [40 CFR 180.950(b)].
- o Edible fats and oils [40 CFR 180.950(c)].
- o Specific chemical substances listed in www.epa.gov/sites/production/files/2016-11/documents/minrisk_inert_ingredients_w_tolerances_2016-11-16.pdf.

Condition 3: All Ingredients (Active and Inert) Must be Listed on the Label using the EPA label display name.

- o Active ingredients must be listed on the label with individual percentage(s) in descending order (WAC 16-228-1400).
- o Inert (or "other") ingredients must be listed on the label with a cumulative percentage.
- o The total percentage of active and inert ingredients must equal 100%. The statement "Total = 100%" must be listed below active and inert ingredients.

Pursuant to the final rule published in the [Federal Register](#) on December 28, 2015, the compliance date for the requirement to label ingredients with a label display name is February 26, 2019.

Condition 4: The Label Cannot Include Claims to Control or Mitigate Organisms that Pose a Threat to Human Health, or insects or rodents carrying specific diseases. For instance, the label may not state: "Controls ticks that carry Lyme disease;" or "Controls mosquitoes that can transmit malaria or encephalitis." In addition, the label cannot include implied health or safety claims that are not allowed by EPA, such as "sterilize," "disinfect," "sanitize," "kill germs," "prevent infection," "stop the spread of germs and disease," "germ-free," "kill influenza," "clinically proven," "certified germ killer," "mold remediation," or "mold control."

Condition 5: The Name and Address of the Producer or the Company for Whom the Product was Produced must be displayed prominently on the product label.

Condition 6: The Label Cannot Include any False or Misleading Statements or Claims, as describes in 40 CFR 156.10(a)(5)(i)-(viii). Examples are available at www.epa.gov/minimum-risk-pesticides/conditions-minimum-risk-pesticides#tab-6:

- Statements concerning the composition of the product, such as “*Chemical-free.*”
- Statements about the effectiveness of the product as a pesticide, such as “*Kills all insects.*”
- Any statement directly or indirectly implying that the pesticide is recommended or endorsed by any agency of the federal government, such as “*Recommended by EPA as safe and exempt.*”
- Use of certain statements that may imply review or acceptance of the minimum risk product by EPA, when such review has not occurred. Examples: “It is a violation of federal law to use this product in a manner inconsistent with its labeling,” or “EPA registration number”.
- Statements referring to the Worker Protection Standard (WPS) and Agricultural Use Requirements are not allowed because Section 25(b) pesticides are not subject to the requirements of FIFRA. Restrictions and Precautions normally found in the Agricultural Use box (such as Personal Protective Equipment and Restricted Entry Interval) may be listed on the label under **Precautionary Statements.**

Additional Washington State Specific Requirements for Minimum Risk Pesticides

Label Elements

Ensure your label is consistent with the Confidential Statement of Formula (CSF). All revised labels for 25(b) Minimum Risk Pesticides must be reviewed and approved before being distributed in Washington State. Do not distribute a revised label unless you have received approval from WSDA.

Required Label Elements (Refer to WAC 16-228-1400 and the sample label at end of this guidance document):

- ① **Product Brand Name**
- ② **Product Function**
- ③ **Ingredient Statement**
- ④ **Keep Out of Reach of Children**
- ⑤ **Precautionary Statements: Pictograms, Signal Word and Hazard Statements**
- ⑥ **Directions for Use**
- ⑦ **Storage and Disposal**
- ⑧ **Net Contents**
- ⑨ **Name and Address of Registrant or Manufacturer**

Optional: Washington Registration Number and Label Identification Code (such as Revision Date)

Label Must Include a Product Function (e.g., insecticide, herbicide, fungicide) that is consistent with product ingredients and label claims.

If the Section 25(b) product is NOT labeled for use on food/feed crops

The label must prohibit use on food/feed crops if it contains any active or inert ingredients not permitted for use on food/feed crops. The following active ingredients are not permitted for use on food/feed crops:

- Cedarwood oil, citronella, citronella oil, dried blood, eugenol, geranium oil, lauryl sulfate, malic acid, 2-phenylethyl propionate, and zinc.
- Putrescent whole egg solids may be used on food/or feed crops in non-contact situations only. Refer to 40 CFR 180.1071 for allowable uses.
- Sodium lauryl sulfate (SLS) is allowed for residential use only. Food crops (such as fruits and vegetables) treated with SLS cannot be offered for sale.

Exception: Lemongrass oil is allowed for use on food/feed crops, per EPA determination.

Label must have an appropriate signal word and precautionary statements

All Section 25(b) minimum risk pesticide product labels must include the statement “KEEP OUT OF REACH OF CHILDREN”.

If the product is intended for commercial/agricultural use, use the applicable label elements found in the Safety Data Sheet (SDS).

If the product is NOT for commercial/agricultural use AND a SDS is available, use the applicable label elements found in the SDS.

If the product is NOT for commercial/agricultural use AND a SDS is NOT available AND toxicity data is available, signal word and precautionary statements will be based on the data.

If the product is NOT for commercial/agricultural use AND a SDS is NOT available AND toxicity data is NOT available, use the table below (unless directed otherwise by WSDA):

Signal Word, PPE and Precautionary Statement	Product Formulation (Composition)
<p>CAUTION Eye protection and gloves</p>	<ul style="list-style-type: none"> Product contains 8.5% or more (not cumulative) of cedarwood oil, cinnamon oil, clove oil, eugenol, garlic oil, lauryl sulfate, lemongrass oil, mint oil, peppermint oil, 2-phenethyl propionate, potassium sorbate, rosemary oil, sodium lauryl sulfate, thyme oil, or white pepper.
<p>WARNING Eye protection and gloves</p>	<ul style="list-style-type: none"> Product contains greater than 5% cumulative total of all acids (acetic, citric and/or malic).
<p>CAUTION Dermal sensitization precautionary statements, prohibition against application to the hands of children, and use directions requiring adult supervision during application to children For example: Do not apply this product to children under 3 years old. Do not allow children to apply this product. When using on children, apply to your own hands and then put it on the child. Do not apply near eyes and mouth. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.</p>	<ul style="list-style-type: none"> Products containing cedarwood oil, citronella and/or citronella oil of the Java type (<i>Cymbopogon winterianus</i>, CAS No. 8000-29-1), cloves, clove oil, eugenol, geraniol, geranium oil, peppermint, peppermint oil, rosemary, rosemary oil, sodium lauryl sulfate, thyme or thyme oil <i>intended for topical application to human skin.</i>*
<p>Not for topical application to human skin unless data is submitted and risk is acceptable.</p>	<ul style="list-style-type: none"> Product contains greater than 1% citronella and/or citronella oil of the Ceylon type (<i>Cymbopogon nardu</i>, CAS No. 107-75-5).

*For application to pets a dermal sensitization statement is suggested when applicable.

Label must have Directions for Use that include a description of intended uses and use rates. A statement such as "Treats xx sq. ft. where xx is based on container size, is acceptable for ready-to-use products. If the label includes chemigation uses, the label must include directions for chemigation.

The Ingredient Statement Should appear on the front panel of the label.

Label Must Not allow use on aquatic sites, unless there is aquatic acute data for the product that are adequate to support use on aquatic sites. Aquatic acute toxicity studies are required for fish and aquatic invertebrates if the label includes any aquatic sites, except for the aquatic sites listed in WAC 16-228-1400(2)(a-i).

Label must include an appropriate storage and disposal statement.

Label must include the weight or measure of contents (net contents).

Optional: The state registration number is recommended.

WSDA assigns a two part state registration number to Section 25(b) minimum risk pesticide products. The first part of the product number is the company number assigned to the registrant. This number can be either the EPA company number or a Washington State issued company number. To request an EPA company number, registrants may submit a signed letter on company letterhead and establish an official address with EPA as described in the Agency's guidance "[How to Obtain a Company Number and Register an Official Address](#)". The second part of the product number is automatically generated and assigned by WSDA's database system upon approval. The system assigns a five position number; 2 digits for the year approved followed by a 3 digit number.

Data Must Support Label and Website (Labeling) Claims

- Condition #6 in [40 CFR 152.25\(f\)\(3\)\(iv\)](#) is that the pesticide labeling not include any false and misleading statements. To meet this condition, all claims, such as a claim that the product repels mosquitoes and ticks or eliminates bedbug infestation, should be substantiated in accordance with the [Federal Trade Commission's guidelines for substantiating advertising](#).
- Efficacy data is required for the following pests that may affect public health of humans: mosquitoes, ticks, and bedbugs.
- Topical insect repellents with claims for ticks and mosquitoes (vectors of human disease) should demonstrate >90% efficacy. Spatial repellents with claims to repel mosquitoes should demonstrate >75% efficacy.
 - Efficacy data should be submitted for *Anopheles*, *Aedes*, or *Culex* for label claims against mosquitoes and should address Complete Protection Time (CPT) for mosquito repellents.
 - Efficacy data should be submitted for blacklegged tick, American dog tick, brown dog tick, or lone star tick for label claims against ticks.
- Pesticides with claims to kill or repel bed bugs or other pest of significant public health importance should demonstrate >90% efficacy. Data for pests, which are not considered of public health importance, should demonstrate >80% efficacy.
- Data should show ≥90% knockdown within 10 seconds to make “knockdown”, “quick kill”, or “kills on contact” claims for wasps or bees and within 30 seconds for all other insects or spiders.
- Data must be credible and should be independently collected, reproducible, and replicated.
- WSDA may consider alternative “soft claims” on a case-by-case basis for products when the data does not meet efficacy guidelines.

Examples:

 - The effectiveness of this product may not meet the level of protection required for EPA-registered pesticides.
 - This product has not been shown to protect people from biting mosquitoes for at least 2 hours.
 - Reduces or may reduce (name of pest).
 - Suppresses or aids in the suppression of (name of pest).

Additional Information

Products intended for use on Cannabis (marijuana and industrial hemp)

WSDA will accept labels with directions for use on Cannabis (marijuana and industrial hemp). Washington State considers Cannabis (marijuana and industrial hemp) to be food crops, therefore all ingredients must be allowed for use on food/feed crops.

WSDA's Organic Material Registration is a separate application. If you wish to have the product reviewed for compliance with the National Organic Standards (see agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx).

WSDA Contact Information

Phone: (360) 902-2025

Email: pestreg@agr.wa.gov

Web: agr.wa.gov/PestFert/Pesticides/ProductRegistration.aspx

Inquiries regarding the availability of this information in an alternative format should be directed to the WSDA Receptionist at (360) 902-1976, or Telecommunications Device for the Deaf (800) 833-6388.

