FIFRA Minimum Risk Pesticides – 25(b) Product Label Guidance

Per FIFRA Section 25(b), U.S. EPA has exempted certain products from federal regulation. However, these products are subject to registration by most states. States are not required to permit the sale of an exempted product simply because it is exempted under federal pesticide law. Each state may have different label requirements, which makes it difficult for companies to comply with all states. For this reason, the Association of American Pesticide Control Officials (AAPCO) created a 25(b) Workgroup. The following list is label guidance put together by the AAPCO 25(b) Workgroup to help companies comply with state requirements. This list is for guidance purposes and does not guarantee that your product will be accepted in all states.

All claims on the manufacturer's website and marketing materials must comply with U.S. EPA's six conditions and AAPCO 25b workgroup label guidance

Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. Labeling means all labels and other written, printed, or graphic matter referencing the pesticide or device or upon any of its containers or wrappers, or accompanying the pesticide or device at any time. In other words, if a claim is not on the label or substantially differs from what appears on the label (or any part of its distribution or sale which for example appears on a brochure), it cannot be made in advertising.

Products must comply with the U.S. EPA's six conditions to qualify for exemption as a Section 25(b) Minimum Risk Pesticide and state labeling requirements (refer to sample labels in Appendices B, C, D):

FRONT PANEL

1. Product Brand Name

1. The product brand name must not be false or misleading

2. Product Function

1. Label must include a product function (e.g., insecticide, herbicide, fungicide) that is consistent with product ingredients and label claims

3. Ingredient Statement

U.S. EPA Condition 1: Active ingredients must be only those listed in 40 CFR 152.25(f)(1). Products intended for use on food/feed crops

can only include eligible active ingredients listed at https://www.epa.gov/minimum-risk-pesticides/conditions-minimum-risk-pesticides#tab-1 with applicable tolerance exemptions in 40 CFR 180. For example, acetic acid and corn cob are not permitted as active ingredients

U.S. EPA Condition 2: Inert ingredients must be only those listed in 40 CFR 152.25(f)(2). Products intended for use on food/feed crops can only include inert ingredients with applicable tolerance exemptions in <u>40 CFR 180</u>. The only inert ingredients that may be used are those that U.S. EPA has classified as:

- 1. Commonly consumed food commodities [40 CFR 180.950(a)]
- 2. Animal feed items [40 CFR 180.950(b)]
- 3. Edible fats and oils [40 CFR 180.950(c)]
- 4. Specific chemical substances listed in https://www.epa.gov/minimum-risk-pesticides#tab-2

U.S. EPA Condition 3: All ingredients (active and inert) must be listed on the label using the U.S. EPA label display name

- Active ingredients must be listed on the label with individual percentage(s)
- 2. Inert ingredients must be listed on the label

Additional State Requirements

- 1. Active ingredients should be listed in descending order
- 2. Inert ingredients should be listed in descending order with a cumulative percentage
- 3. The percentage of active and inert ingredients must equal 100%
- 4. The statement "Total =100% " must be listed below active and inert ingredients

4. Keep Out of Reach of Children is to be prominently displayed on the front panel

5. Signal Word

- 1. Must be prominently displayed on the front panel
- 2. See Appendix A for more information on signal words

Additional State Requirements

Some states require that the signal word on label matches the Safety Data Sheet (SDS), if an SDS is required for state registration.

6. Safety Data Sheets (SDS) and Globally Harmonized System (GHS) Elements

According to OSHA (federal), minimum risk pesticides are subject to EPA's labeling requirements and regulations, thus they need not be <u>labeled</u> under the federal Hazard Communication Standard (HCS). However, a <u>safety data sheet</u> must be provided for these chemicals if they are otherwise covered by the HCS.

Chemicals used in a workplace (i.e. commercial/agricultural products) are covered by the HCS and require an SDS.

Some states may have more stringent requirements, either by law or under a state occupational safety and health program. State requirements vary for SDS submission, label precautionary language, and GHS information

Guidance:

- 1. Required elements (signal word and GHS pictograms) from the SDS must be prominently displayed on the front panel
- 2. In general, commercial/agricultural products require an SDS to comply with federal Hazard Communication Standard. Some states may require the SDS to accompany the product application
- 3. Commercial/agricultural product labels must include the applicable label elements found on the SDS, including the signal word, hazard statements, and GHS pictograms
- 4. See Appendix A for more on precautionary statements

Additional State Guidance

For WA, products that are not for commercial/agricultural use (e.g., home and garden products) do not require an SDS, but should be provided if it is available

- a. If the product is NOT for commercial/agricultural use AND a SDS is available, use the applicable label elements found in the SDS
- b. If the product is NOT for commercial/agricultural use and a SDS is NOT available, follow state guidelines for required label elements and precautionary language

Additional State Requirements

Some states require that the signal word on label matches the Safety Data Sheet (SDS), if an SDS is required for state registration. Some states require toxicity data or other information to support label language. See Appendix A for additional guidance

FRONT OR OTHER PANEL

7. Precautionary Statements, First Aid, and other Hazard Statements

- 1. 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 State Requirements:

Washington requires that if a product is intended for commercial/agricultural use, the following GHS elements found on the SDS must appear on the label:

- a. Hazard Statements
- b. First Aid Statements
- c. PPE

8. Directions for Use and Product Information

- Directions for Use includes a description of intended uses, use rates, and specific use site locations. A statement such as "Treats xx sq. ft." where xx is based on container size, is acceptable for ready-touse products. If the label includes chemigation uses, the label must include directions for chemigation
- 2. Labels must contain clear and specific instructions for use that, if complied with, adequately protect the public and nontarget organisms
- 3. Some states may have additional data requirements and/or use restrictions. For example, Washington may request aquatic toxicity data to support use on aquatic sites. Maine would not allow for a 25(b) with aquatic uses because it would be a restricted use pesticide. Refer to state for specific restrictions
- 4. It is recommended to include label version ID or date code on the label
- 5. Product claims:

U.S. EPA 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 the U.S. 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"

U.S. EPA Condition 6: The label cannot include any false or misleading statements or claims, as described in 40 CFR 156.10(a)(5)(i)-(viii). Examples are available at https://www.epa.gov/minimum-risk-pesticides/conditions-minimum-risk-pesticides#tab-6:

- Statements concerning the composition of the product, such as "Chemical-free"
- 2. 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"
- 4. Use of certain statements that may imply review or acceptance of the minimum risk product by the U.S. 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"
- 5. Per LC21-1208 on EPA's Labeling Questions & Answers website, Claims such as "free of [active ingredient]" or "contains no [active ingredient]" may constitute misbranding and may need to be removed. Consumers can readily determine if a pesticide product contains an active ingredient (e.g., DEET) by reviewing the ingredients listed on the label. Because all ingredients must be listed, the absence of an ingredient in the ingredient statement would indicate it is not in the product. Misleading comparative claims about the safety of the product versus other products constitute misbranding under 40 CFR 156.10(a)(5)(iv) and (vii). These claims are therefore disallowable under FIFRA sections 2(q)(1)(A) and 12(a)(1)(E).

Additional State Requirements

- 1. When applicable¹, if the product contains ingredients that are not permitted for use on food/feed crops, the label must prohibit the use on food/feed crops
- 2. Non-toxic claims are not acceptable
- 3. All claims on the manufacturer's website and marketing must comply with U.S. EPA's six conditions and AAPCO 25b workgroup label guidance
- 4. No images of children are acceptable unless the product is intended for use on children or is a swimming pool/spa product
- 5. Safety claims are acceptable when accompanied by the qualifier, "When used as directed" and are not false or misleading. Human toxicity data may be required. Examples of safety claims include but not limited to, "safe for the environment," "safe around children and pets," or the term "safe" or other similar term used by itself
- 6. Natural claims are accepted if the product does not contain synthetic chemicals or those derived synthetically. Ingredients such as, but not limited to, sodium lauryl sulfate, isopropyl myristate, isopropyl alcohol, malic acid, potassium sorbate, citric acid, sodium benzoate, benzoic acid, and xanthan gum, are synthetic chemicals and therefore, are not considered natural
- 7. Some states may not accept the terms "Organic" or "Certified Organic" in reference to the product. NOTE: Washington allows WSDA's Organic Certificate logo after the product has been certified for compliance with the National Organic Standards.
 - a) The use of the USDA's Organic logo is not acceptable on any labeling
 - b) The use of the U.S. EPA's 3-leaf organic logo is not acceptable on 25(b) products, regardless of the organic status of the product. The use of the 3-leaf logo implies that EPA has reviewed and approved the organic status of the product per National Organic Program rules, which is a false or misleading claim when used on a 25(b) label. For more information, see PRN 2003-1 and Clarification of PR Notice 2003-1 at





¹ When applicable means that this statement is not required for products like topical insect repellents. Statement is applicable when the use site(s) deems it necessary.

https://www.epa.gov/pesticide-registration/prn-2003-1-labeling-pesticide-products-undernational-organic-program

- c) Individual ingredients may be listed as "grown organically" with supporting documentation
- d) The use of the term "organic" is acceptable when used with one of the following statements "For use in organic production," "For use in organic gardening," "For use on organic turf," or "OMRI listed"

9. FIFRA Exempt Statement

Preferred Statements

"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 FIFRA."

"This product qualifies for exemption from EPA registration under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)"

10. Storage and Disposal

11. Net Contents

- 1. Contents must be stated in product-appropriate units; e.g., use pounds or ounces for dry materials, use gallons, quarts, or fluid ounces for liquids.
- 2. Content information may also include other applicable units such as metric weight/volume, number of doses/treatments, etc.

12. Name and Address of Registrant or Manufacturer

U.S. EPA 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

- If the company whose name appears on the label is not the producer, the company name must be qualified by appropriate wording to show that the name is not that of the producer. Examples include: "Packed for [insert name]," "Distributed by [insert name]," "Sold by [insert name]"
- 2. The company's contact information must appear on the product label and provide the street address, including the city, state, and ZIP code, and telephone number

Optional Additional Contact Information to Include: email address

13. State Registration Number (if applicable)

Note: California requires a revised label to be submitted upon registration that includes the State Registration Number. The label submitted must be the marketplace label.

Washington recommends the addition of the WA Registration Number on the label.

Additional Information

25(b) products intended for use on Cannabis: (applicable to states with legal cannabis) States will accept labels with directions for use on Cannabis (marijuana and industrial hemp). States consider cannabis to be food crops; therefore, all ingredients must be allowed for use on food/feed crops

<u>WPS Statements:</u> 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**.

<u>Data requirements:</u> Efficacy data may be required to substantiate any claim that appears on the label or labeling. Labeling of products should include an advisory statement when data does not meet efficacy data expectations.

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).

25(b) products making fertilizer claims: Pesticides that are formulated in combination with fertilizers bear an ingredient statement the same as any other pesticide. The fertilizer composition is shown separately from the pesticide ingredient statement and may not detract from or obscure the required pesticide labeling statements. Each state has their own fertilizer registration, data, and labeling requirements. Contact the specific state agency responsible for registering fertilizers for more details.

25(b) products and biostimulants: Given the uncertain regulatory future of plant biostimulant products, State Lead Agencies may be hesitant to register a 25(b) product whose labeling states that

the product is or acts as a biostimulant (e.g., "biostimulant," "induces biostimulant effect," "promotes biostimulant activity," etc.). Please contact the State Lead Agency for data and labeling requirements, and to determine whether specific product claims are acceptable.

<u>All product claims</u>: Such as a claim that the product repels mosquitoes and ticks or eliminates bedbug infestation, should be substantiated in accordance with the <u>Federal Trade Commission's guidelines</u> for substantiating advertising.

OSHA references:

Applicable federal code re Hazard Communication Standard and its scope: https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1200

Response from OSHA re SDS/labeling requirements for minimum risk pesticides: https://www.osha.gov/laws-regs/standardinterpretations/2018-07-30-0

This list is to serve as guidance only. This document is a living document that may be updated at any time. For specific registration, requirements please contact the individual state regulatory agency responsible for pesticide registration.

Appendix A: Signal Word, PPE, Precautionary Statements

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 six acute toxicity studies performed with the product formulation.

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 states):

Signal Word, PPE and Precautionary Statement	Product Formulation (Composition)
CAUTION Eye protection and gloves	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
WARNING Eye protection and gloves	 Product contains greater than 5% cumulative total of all acids (acetic, citric and/or malic)
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	 Products containing cedarwood oil, citronella, and/or citronella oil of the Java type (Cymbopagon winterianus, 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 intended for topical application to human skin*

repeated skin contact may cause allergic reactions in some individuals"	
Not for topical application to human skin unless data is submitted and risk is acceptable	 Product contains greater than 1% citronella and/or citronella oil of the Ceylon type (Cymbopagon nardu, CAS No. 107-75-5)

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

Revision History

Date	Changes
12/16/21	• 5: Separated Signal Word & Globally Harmonized System into two different sections.
	 6: Added SDS to the header. Addition of background information related to 25(b) products and OSHA requirements. Provided additional guidance and SLA specific requirements
	7: Added State Specific Requirements
	8.4: Added recommended label version or date code for labels
	8.5.5: Added EPA's Q&A about comparative claims
	8, Additional State Requirements: clarification for "when applicable"
	• 11: Added details about Net Content requirements (points 1&2)
	13: Addition of and clarification for "when applicable" and reference specific to CA requirements, added WA recommendation.
	12: Clarification on optional contact information
	13: Clarification on CA requirements, added WA recommendation.
	 Additional Information (page 9): 25(b) with fertilizer claims and the use of biostimulants claims
	Added OSHA References (page 10)
	General formatting updates (alignment, numbering instead of bullet points, etc.)