Wisconsin Guide for Minimum Risk Pesticides (FIFRA Section 25(b) Exempt)

Different states may have different requirements for registering minimum risk pesticide product labels. Adherence to one state's requirements or acceptance of a minimum risk pesticide label in one state does not guarantee that product will be accepted in another state with different requirements. Please check with each state on their requirements for minimum risk pesticide prior to distributing in that state.

All minimum risk pesticide labels must comply with the EPA's Conditions for Minimum Risk Pesticides, as listed below.

Condition 1: Active Ingredients

Active ingredients are the ingredients that kill, repel, or mitigate the pests identified on the product label. If an ingredient does not perform one of these functions, then it is an inert ingredient (or impurity) and should not be identified as an active ingredient on the label. To be considered minimum risk, the product's <u>active ingredients must be only those listed in 40 CFR 152.25(f)(1)</u>.

Condition 2: Inert Ingredients

Inert ingredients are defined as all ingredients (other than impurities) that are not active ingredients. The only inert ingredients that may be used in the product are those that EPA has classified as:

Inert Ingredients Approved for Use in Minimum Risk Pesticide Products (As described in <u>40 CFR</u> <u>152.25(f)(2)(iv)</u>

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); and
- edible fats and oils 40 CFR 180.950 (c).

EPA has finalized a rule that <u>clarifies the list of inert ingredients qualifying for the minimum risk</u> <u>exemption</u>. Review the rule to ensure which inert ingredients are eligible for the minimum risk exemption.

Minimum risk pesticide producers may use eligible inert ingredients in whatever amounts they believe will result in an effective product when combined with the <u>listed active ingredients</u> (referred to as minimum risk active ingredients).

Condition 3: Ingredients Listed on Label

All of the ingredients in an exempted product (both active and inert) must be listed on the label:

- All active ingredients must be listed by label display name* and percentage (by weight).
- All inert ingredients must be listed by label display name*.

*Pursuant to the final rule published on <u>December 28, 2015</u>, the compliance date for the requirement to label ingredients with a label display name is February 26, 2019.

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 or rodents carrying specific diseases.

Claims Regarding Control of Microorganisms

The label cannot bear claims to control or reduce microorganisms, such as bacteria or viruses, that pose a threat to human health. For example, minimum risk products may not claim to:

- "Sterilize"
- "Disinfect."
- "Sanitize."
- "Kill germs."

This includes, for example:

- hospital sterilants and disinfectants;
- swimming pool water disinfectants;
- human drinking water disinfectants;
- purifiers; and
- surface sanitizers.

Restrictions on Making Claims on Labels about Minimum Risk Active Ingredients

- Minimum risk products may not claim to control any microorganism (such as viruses, bacteria, spores, algae, etc.) that could lead to infection or disease in humans. This also means the products cannot make claims, such as to:
 - "prevent infection;"
 - "stop the spread of germs and disease;"
 - o "germ-free;" or
 - o "kill influenza."

- Use of pesticide products at hospitals, nursing homes, medical or health care facilities or similar environments would typically be considered to imply control or mitigation of microorganisms that may pose a threat to human health. In addition to the other limitations, claims at these types of sites would need to be qualified with language indicating that the product does not kill or control microorganisms of public health concern or of human health significance.
- Since the term "biohazard cleanup" implies disinfection, "biohazard cleanup" cannot be used as a claim on a minimum risk product.
- Descriptions such as "trauma," "post-mortem," or "crime scene cleanup" have similar implications and therefore also cannot be used as a claim on a minimum risk product.
- Since "mold remediation" or "mold control" implies sterilization and disinfection, neither "mold remediation" nor "mold control" can be used as a claim on a minimum risk product.

Symbols and Terms that are Prohibited

Symbols implying safety or non-toxicity such as a medical seal of approval (caduceus) cannot be used as a claim on a minimum risk product. Terms such as the following imply safety, and therefore cannot be used as a claim on a minimum risk product:

- "clinically proven;"
- "scientifically proven;" or
- "certified germ killer."

Allowable Microorganism Claims

Some types of claims regarding microorganisms can meet the conditions of the minimum risk exemption. An example would be an antimicrobial pesticide product that bears a claim to control microorganisms of economic or aesthetic significance, and the presence of the microorganism would not normally lead to infection or disease in humans.

With the appropriate qualifications, minimum risk pesticide labels may claim to control:

- The growth of algae:
 - Acceptable use sites could include fish tanks or ornamental ponds.
 - Application sites that could have public health implications such as pools, spas, or farm animal drinking sites are unlikely to be acceptable.
- Odor-causing bacteria:
 - Minimum risk products may claim to "kill odor-causing bacteria," or to "neutralize and remove odors."
- Bacteria that cause spoilage, deterioration, or fouling of materials. Possible use sites could include, for example:
 - cooling towers;
 - o jet fuel;
 - o paints;
 - treatments for textile and paper products, and a variety of surfaces.

- Mold stain:
 - Minimum risk products may claim to clean or remove mold stain.
 - Acceptable use sites could include decks, patios, or structures.
- Microorganisms infectious only to animals and not used on human pathogens.
 - Products with claims against specific animal pathogens or pathogen groups identified in this publication do not meet the conditions for minimum risk.
 - This publication includes a listing of animal diseases (and the associated organisms) that are considered to affect humans.
- A claim to clean non-food-contact surfaces or to kill odor-causing bacteria on non-food-contact surfaces is acceptable.
- A claim to clean food contact surfaces, such as countertops and sinks, or to kill odor-causing bacteria on food contact surfaces is also acceptable.
 - For these minimum risk products each ingredient in the minimum risk product must have the appropriate tolerance or tolerance exemption.

Condition 5: Company name and 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*.

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]."

The company's contact information must appear on the product label and provide the following information:

- Street address.
- City, State, and ZIP code.
- Telephone number.

*Pursuant to the final rule published on <u>December 28, 2015</u>, the compliance date for the requirement to provide company contact information on the label is February 26, 2019.

**Wisconsin does not consider mailing addresses, such as PO Boxes, acceptable in place of a physical street address. A street address is specifically required per 40 CFR 152.25(f)(3)(iii)(B).

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).

Examples of Label Statements that can be False or Misleading

- Statements concerning the composition of the product.
- Claims such as "free of [active ingredient]" or "contains no [active ingredient]" constitutes misbranding and will need to be removed.
 - EPA is concerned that users might understand these types of statements to be safety claims. This could give users the impression that products without a certain active ingredient are safe or safer than products with the active ingredient, which may be false or misleading. Safety claims are considered false or misleading statements that constitute misbranding under 40 CFR 156.10(a)(5)(ix) and (x).
 - Example: "Chemical-free"
 - Minimum risk pesticide products are composed of chemicals that are listed on the product label.
 - The use of the term "chemical-free" may be an attempt to convey that the product does not pose risk. However, the use of such a claim is not based on facts and may be considered false or misleading.
 - Consumers could misunderstand such a claim to be a safety claim.
- Statements about the effectiveness of the product as a pesticide or device.
 - Examples:
 - "Kills all insects"
 - "Kills many insects"
 - "Repels all insects"
 - These label claims may imply a misleading range of effectiveness.
 - However, "Kills many insects as listed below" or "Kills the following insects" may be acceptable.
- Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the federal government.
 - Example: "Recommended by EPA as safe and exempt."
 - This type of statement leads the consumer to believe that the federal government has made such a determination for a particular product.
 - Because EPA does not review exempted products, this type of statement is misleading.
- The use of certain statements that are required to be on the label of a registered pesticide product 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.
 - "EPA registration number" or "EPA establishment number"
 - Consumers could mistakenly assume, based on these statements, that EPA or another federal agency has reviewed or accepted the product.

Website and Advertising Materials

- The producer's website and other advertising materials cannot include any false or misleading statements.
 - Similar to the other examples, an EPA-issued company number on the Web page of a company offering minimum risk products for sale, with no EPA-registered products offered for sale, could cause a consumer to believe that the products offered for sale are recommended or endorsed by EPA.
- Many websites offer testimonials and endorsements from satisfied customers.
 - As an example of a potentially problematic endorsement, the picture of a health professional (white coat and stethoscope) next to an endorsement could cause a consumer to believe that the product is endorsed by the medical establishment.
 - Such claims should be accompanied by name, affiliation, and credentials of the expert making the endorsement, so consumers have the ability to judge the relevance of the claim.

Wisconsin encourages registrants to review the: <u>Association of</u> <u>American Pesticide Control Officials (AAPCO) FIFRA 25(b) Workgroup:</u> Product Label Guide

The association of American Pesticide Control Officials Workgroup has created a product label guide in order to give consistency to 25(b) label regulations across the country. Minimum risk pesticide labels that comply with the <u>Product Label Guide</u> will likely be accepted in many states. The following are specific elements the state of Wisconsin has adopted and requires:

- "Keep Out of Reach of Children" is to be prominently displayed on the front panel
- A signal word (e.g. Caution, Warning, Danger) must be prominently displayed on the front panel when certain active ingredients and uses of the product are present
 - See Appendix A of the <u>Product Label Guide</u> for more information on signal words
- 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-to-use products. If the label includes chemigation uses, the label must include directions for chemigation.
 - Labels must contain clear and specific instructions for use that, if complied with, adequately protect the public and non-target organisms.
- Storage and Disposal instructions for the product must be included on the label

- The label cannot include any false or misleading statements or claims, including but not limited to:
 - Statements concerning the composition of the product, such as "Chemical-free" or "Non-Toxic"
 - 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 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"
- 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 are not limited to, "safe for the environment," "safe around children and pets, or the term "safe" or other similar term used by itself.
- "Organic" or "Certified Organic" in reference to the product itself is not acceptable. The use of the USDA's Organic logo or the U.S. EPA's 3-leaf organic logo is not acceptable on any labeling.
 - Individual ingredients may be listed as "grown organically". Other acceptable uses of the term "organic" would be; "For use in organic production," "For use in organic gardening," or "For use on organic turf"
 - 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"
- "Natural" claims are accepted if the product does not contain synthetic chemicals or those derived synthetically in active ingredients. 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.
- Efficacy data or additional documentation 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.





Products labeled for use to Public Waters: The Wisconsin Department of Natural Resources <u>requires a permit for pesticide applications to public waters</u>. This includes minimum risk pesticides. Any product labeled for use in public waters must contain a labeling statement about consulting with appropriate state or local water authorities before application.