



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 19, 2023

J. Todd Frank
Senior Regulatory Affairs Consultant
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Subject: Registration Review Label Mitigation for Permethrin
Product Name: Permethrin Fly and Louse Dust
EPA Registration Number: 11556-168
Application Date: 11/4/2022
Decision Number: 572602

Dear J. Todd Frank:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

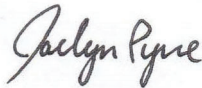
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently

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approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Carolyn Smith by phone at (202) 566-2273, or via email at smith.carolyn@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jaclyn Pyne". The signature is written in a cursive style with a large initial "J".

Jaclyn Pyne
Team Leader
Risk Management & Implementation Branch III
Pesticide Re-evaluation Division
Office of Pesticide Programs

Enclosure

Reason to Issue: Add pictograms and minor revisions. Date: 08/02/2023

Supersedes: 02/06/2014

NOTE TO REVIEWER: Braces “{ }” indicate note to reviewer. Brackets “[]” indicate optional language.

PERMECTRIN™ FLY & LOUSE DUST

Ready-To-Use Dust Insecticide

For Control of Horn Flies and Lice on Beef & Dairy Cattle, as an aid in reducing Face Fly populations on Beef & Dairy Cattle

Control of Lice on Swine

For control of Northern Fowl Mites on Poultry

[Contains:]

[Contains refillable dispenser bag]

[Two 12.5 lbs. bags of dust]

[Use in dust bags or shaker can]

{[Optional marketing claims bulleted appearing from page 5]}

{[Selected pictograms from page 5]}

PERMETHRIN	GROUP	3A	INSECTICIDE
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{Box will be in the upper right corner of front panel.}

ACTIVE INGREDIENT:	<u>% by Weight</u>
Permethrin (CAS # 52645-53-1).....	0.25%
OTHER INGREDIENTS:.....	99.75%
TOTAL	100.00%

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EPA Est. No. TBD

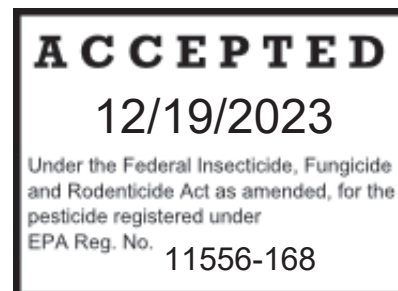
Net Contents: [12.5 pounds] [2 pounds] [Two 12.5 pounds]

[Lot No.:]

[See [back] [side] panel for additional Precautionary Statements [and] [First Aid]]

Manufactured For:
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140 [U.S.A.]

KEEP OUT OF REACH OF CHILDREN



CAUTION

FIRST AID

If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. [You may also contact 1-800-428-4441 for emergency medical treatment information.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441] [or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.]	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

Personal Protective Equipment (PPE)

Loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves, butyl rubber, neoprene, or polyvinyl chloride (PVC), and
- Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters.

Application with aerial or motorized ground equipment is prohibited.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintain PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched (except as required by directions for use) or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS:

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, or to area where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.

Under some conditions, it may also have a potential for transport into surface water in runoff (primarily absorbed to suspended soil particles), for several months or more after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, and areas overlying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlying tile drainage systems that drain to surface waters.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

DIRECTIONS FOR USE

For both indoor and outdoor use.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Avoid contamination of feed and foodstuffs. Read the entire label prior to use.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Permethrin Fly & Louse Dust contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to Permethrin Fly & Louse Dust. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same sites. Appropriate resistance-management strategies should be followed.

Contact your local extension specialist advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific pest problems in your area.

Application is prohibited directly into sewer or drains, or to any area like gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur.

Do not allow to enter indoor or outdoor drains.

No permita la entrada a desagües internos o externos.



When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination of the product. Remove or cover milking utensils before application.

Wash teats of animals before milking.
Use of handheld power duster equipment is prohibited.

BEEF & DAIRY CATTLE

Horn Flies, Lice, Face Flies: Place contents of this package in any commercially available dust bag, suspend bags in areas frequently by cattle or in gateways or lanes through which the animals pass daily for water, feed or minerals. Bags may also be suspended in loafing sheds or in front of protected mineral feeders.

For lactating dairy cows, bags may be suspended in the exit through which cows leave the milking barn. In all cases, the bags should be adjusted so that the bottom of the bag will hang four to six inches below the topline of the cattle. For reduction of face flies, the bags must be located so the animals will be forced to use them daily and hung at the height to ensure that the faces of the cattle will be dusted.

Horn Flies, Lice: Direct Application: Apply 2.0 ounces of dust per animal by shaker can over the head, neck shoulders, back and tailhead. Repeat as necessary.

POULTRY

Northern Fowl Mites: Direct Application: Apply not more than 1lb/100 birds, directing dust to thoroughly cover vent area.

SWINE

Lice on Swine: Direct Application: Apply not more than 1 ounce* (3 level tablespoons) per head as a uniform coat to the head, shoulders and back by use of a shaker can. Repeat as necessary, but not more often than once every ten days.

In severe infestations, both individual animals and the bedding may be treated as directed above.

Do not ship animals for slaughter within 5 days of last treatment.

*Note: 1 ounce of this material equals approximately three level tablespoonfuls.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open as needed. Keep container sealed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options. Do not reuse or refill this container. Completely empty container into application equipment. Then dispose of empty container in a landfill or by incineration. Do not burn unless allowed by state and local ordinances.

CONDITIONS OF SALE:

The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. To the extent permitted by applicable law, Elanco offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of Elanco and are, therefore, the responsibility of the buyer.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Elanco US Inc warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Elanco is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

{{Optional marketing claims appearing on any location:}}

1. For Control of [Horn Flies] [and] [Lice] on [Beef] [&] [and][Dairy] Cattle, as an aid in reducing Face Fly populations on [Beef] [&][and] [Dairy] Cattle
2. For Control of [Horn Flies] [and] [&] [Lice] on [Beef] [and] [Dairy] Cattle
3. As an aid in reducing Face Fly population on [Beef] [and] [&] [Dairy] Cattle
4. For Control of Lice on Swine
5. For Control of Northern Fowl Mites on Poultry

{{Optional marketing pictograms appearing on any location:}}

