



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 23, 2024

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: Permectrin II  
EPA Registration Number: 11556-166  
Application Date: 11/4/2022  
Decision Number: 572618

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.

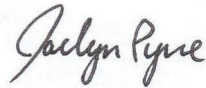
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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

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](mailto:smith.carolyn@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Jaclyn Pyne". The signature is written in a cursive, flowing style.

Jaclyn Pyne, Team Leader  
Risk Management and Implementation Branch 3  
Pesticide Re-Evaluation Division  
Office of Pesticide Programs

Enclosure

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

PERMECTRIN™ II

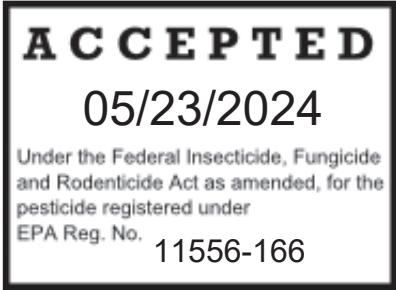
An Emulsifiable Animal and Premises Spray with  
30-Day Residual Effects

{[Optional marketing pictos appearing from page 7]}

PERMETHRIN	GROUP	3A	INSECTICIDE
------------	-------	----	-------------

{Box will be in the upper right corner of front panel.}

ACTIVE INGREDIENT:	% by Weight
Permethrin (CAS # 52645-53-1).....	10.0%
OTHER INGREDIENTS: *.....	90.0%
TOTAL .....	100.0%
*Contains petroleum distillates	
Contains 0.75 lb. permethrin per gallon	



KEEP OUT OF REACH OF CHILDREN

WARNING

See [back panel] [inside booklet] for [first aid statement] [and] [additional precautionary statements]

DO NOT USE ON CATS {This statement will be on the front panel}

FIRST AID	
If on Skin or Clothing:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If in Eyes:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If Inhaled:	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth, if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>

<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give any liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
<b>HOT LINE NUMBER</b>	
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.]	
<b>NOTE TO PHYSICIAN</b>	
Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

EPA Reg. No. 11556-166      EPA Est. No. TBD

Net Contents: 8 fl.oz. (237 ml) or 1.0 [U.S.] Quart (946 mL)

[Lot No.:]

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

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**WARNING:** Causes skin irritation. Do not get on skin, or on clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Causes moderate eye irritation. Avoid contact with eyes. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear Coveralls worn over long sleeved shirt and long pants, socks, chemical resistant footwear, and chemical resistant gloves made of barrier laminate, nitrile rubber, neoprene, rubber, viton.

### **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Some materials that are chemical-resistant to this product are made of barrier laminate, nitrile rubber, neoprene rubber, and viton.

All mixers, loaders, applicators and other handlers must wear:

- Coveralls over a short-sleeved shirt and short pants
- Chemical resistant footwear plus socks
- Chemical-resistant gloves made of barrier laminate, nitrile rubber, neo-prene rubber or Viton, and
- Chemical resistant apron for mixer/loaders, persons cleaning equipment, and persons exposed to the concentrate and for handlers performing animal dip application
- Chemical resistant headgear, if overhead exposure for applicators using ULV cold foggers or fog/mist generators in indoor spaces
- Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters.

## USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining 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 product is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid runoff to water bodies or drainage systems.

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 foraging the treatment area.

## PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For both indoor and outdoor use.

Directions for use in commercial animal premise automatic misting systems.

- Not for use in outdoor residential misting systems (indoor or outdoor).
- Do not use mister when food, feed, or water is present.
- Do not use mister when animals or people are present.
- When using this product, installers and service technicians must comply with the license, certification, or registration requirements of the state(s), tribe(s), or local authority(ies) where they are installed.
- When applying via a remote activation device, do not apply when people and pets are present. If possible, when applying via automatic timer, set the timing for application when people and pets are unlikely to be present.
- Direct nozzles to spray towards the target area and away from areas where people are typically present.
- Do not use in an evaporative cooling system.
- Do not use in misters located within 3 feet of air vents, air conditioner units, or windows.
- If used in a system with a reservoir tank for the end use dilution, the system reservoir tank must be locked. Securely attach the end use pesticide label and a dilution statement to the system reservoir tank in a

weather protected area or plastic sleeve. The dilution statement must be phrased as follows: this container holds \_\_\_ parts Permethrin II to \_\_\_ parts water.

- If used in a direct injection system, the pesticide container must be locked. Securely attach the end use label to the pesticide container in a weather protected area or plastic sleeve.
- This product must only be used in systems that have been calibrated to apply no more than the maximum application rate of per the application instructions.

#### RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Permethrin II contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to Permethrin II. 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.

Do not allow to enter indoor or outdoor drains.  
No permita la entrada a desagües internos o externos.



#### USE RESTRICTIONS:

Application of product on pet dogs must only be done indoors.

Do not apply the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur.

Do not allow the product to enter any drain during or after application.

Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment.

Do not apply or irrigate to the point of runoff.

When used in dairy barns or facilities close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before applications. Wash teats of animals before milking.

**DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats.** Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.



#### READ ENTIRE LABEL BEFORE EACH USE:

Use only on dogs and their premises, horses, beef and dairy cattle, swine, sheep and poultry and their premises. Kills flies, fleas, lice, mites and ticks including deer ticks (carrier of Lyme disease).

Do not spray feed, food or water. Do not repeat treatment for 2 weeks.  
Wash udders thoroughly before milking.

Not for use in outdoor residential misting systems (indoor or outdoor).  
Do not use this product on dogs under 12 weeks old.

### ENTRY RESTRICTIONS:

For space spray use do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.

For surface spray use except when applying to livestock, do not enter or allow others to enter treated area until sprays have dried.

Mix Permethrin II and apply the use-diluted material to animals and pest breeding or resting surfaces at the rates shown on the application instructions charts. These dilutions and rates will provide most efficient pest control under conditions of heavy pressure when good contact is achieved. Timing and frequency of applications should be based on pest populations reaching nuisance levels but accompanying manure removal and sanitation practices should precede sprays. Consult a veterinarian before using product on debilitated, aged, medicated, pregnant or nursing animals.

Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours).

Rainfall within 24 hours after application may cause unintended runoff of pesticide application.

Treat surfaces to ensure thorough coverage but avoid runoff

To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants.

### APPLICATION INSTRUCTIONS

APPLY TO: FARM PREMISES (BARNS, DAIRIES, LOAFING SHEDS, MILKING PARLORS, FEEDLOTS, STABLES, PADDOCKS, POULTRY AND LIVESTOCK HOUSING)

Target Pests	Application Instructions
House Flies, Stable Flies, Lesser House Flies and other manure breeding Flies, Fleas, Lice, Mites, Ticks, including Deer	Spray Application: Mix 1 qt. in 25 gal.; 8 fl.oz. in 6.25 gal.; 1-1/3 fl. oz. (40 ml.) in 1 gal. of water. Spray all surfaces to run-off with diluted emulsion using 1 gal. per 750 sq. feet.  Mist Blower: Use undiluted in mist blower. Mist at 4 fl. oz. per 1000 sq. feet.

Ticks (carrier of Lyme disease).	Power Fogger: Mix 1 qt. in 25 gal.; 1-1/3 fl. oz. (40 ml.) in 1 gal. of water. Fog at 4 oz. per 1000 sq. feet.
----------------------------------	--

Premises Use as a Spray or Fog: 8 fl. oz. makes 6.25 gal., 1 qt. makes 25 gal. of ready-to-use spray when mixed with water or oil.

APPLY TO: LARGE ANIMALS (DAIRY OR BEEF CATTLE AND HORSES)

Target Pests	Application Instructions
Face Flies, Horn Flies, Horse Flies	Backrubber: Animals self-apply. Mix 1qt. in 20 gal.; 8 fl. oz. in 5 gal.: 1.6 fl. oz. (48 ml.) in 1 gal. of any backrubber oil approved for use on livestock. Recharge backrubber oiler as needed.

Face Flies, Horn Flies, Horse Flies, Stable Flies, Mosquitoes, Lice, Mites, Ticks, including Deer Ticks (carrier of Lyme disease)	<p>High Pressure Sprayers: Mix 1 qt. in 200 gal. or 8 fl. oz. in 50 gal. of water. Spray to thoroughly cover entire animal. Apply from ½ to 1 gal. of spray per animal. For lice or mites, a second treatment is recommended 14-21 days later.</p> <p>Hand, Garden or Low Pressure Sprayer: Mix 8 fl. oz. in 3 gal.; 2.5 fl. oz. (75 ml.) in 1 gal. or 2/3 fl. oz. (20 ml.) in 1 qt. of water. Spray each animal with up to 8 fl. oz. of mixed spray. For lice or mites, a second treatment is recommended 14- 21 days later.</p>
Ear Ticks, Face Flies, Horn Flies	Spot Application: Mix 2 fl. oz. (60 ml.) in 1 gal. of mineral oil or non-irritating organic oil or water. Apply ½ oz. per ear or 2-4 fl. oz. on face or 12-16 fl. oz. along the backline.

**APPLY TO: SWINE, SHEEP, POULTRY AND DOGS ONLY (DO NOT SHIP SWINE FOR SLAUGHTER WITHIN 5 DAYS OF LAST TREATMENT)**

Target Pests	Application Instructions
Mange Mites	Mix 1 qt. in 100 gal.; 8 fl. oz. in 25 gal.; 1 fl. oz. (30 ml.) in 3 gal. of water. Spray or dip animals. Retreat after 14 days spraying walls and floor and replace bedding to kill late hatching, developing stages. Do not reapply product for 2 weeks.
Blow Flies, Mosquitoes, Hog Lice, Fleas, Ticks, including Deer Ticks (carrier of Lyme disease)	Mix 1 qt. in 100 gal.; 8 fl. oz. in 25 gal.; 1 fl. oz. (30 ml.) in 3 gal. of water. Spray, paint or dip to apply 1 pt. per dog, pig or sheep, especially around ears. Do not reapply for 2 weeks.
Poultry Mites	Mix 1 qt. in 50 gal.; 8 fl. oz. in 12.5 gal.; 2 fl. oz. (60 ml.) in 3 gal. of water. Spray ½ fl. oz. per bird or 1 gal. per 100 birds, directed towards vent area. Spray cages.

1 fl. oz. is equivalent to 2 tablespoons or 30 ml.

**Large Animal Use:** Mix 8 fl. oz. in 5 gal. or 1 qt. in 20 gal. of oil for backrubbers and oilers; mix 2 fl. oz. in 1 gal. of oil or water for spot application; mix 8 fl. oz. in 50 gal. or 1 qt. in 200 gal. of water as a spray for beef or dairy cattle and horses.

**Swine, Sheep, Poultry and Dog Use:** Mix 8 fl. oz. in 25 gal. or 1 qt. in 100 gal. of water as a spray, paint or dip for swine, sheep and dogs; mix 8 fl. oz. in 12.5 gal. or 1 qt. in 50 gal. of water and spray ½ fl. oz. per bird or 1 gal. per 100 birds for poultry.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Keep container sealed when not in use. Protect from freezing. In case of spill on floor or paved surfaces, soak up with sand, earth or synthetic absorbent. Remove to chemical waste area and dispose of in accordance with state and local regulations.

**Pesticide Disposal:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available.

**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 Pictograms appearing on any location:}}

