



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 19, 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: Permethrin S Synergized Formula
EPA Registration Number: 11556-178
Application Date: 3/24/2021
Decision Number: 572613

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.

Sincerely,

A handwritten signature in dark ink that reads "Marianne A. Walters". The signature is written in a cursive, flowing style.

Marianne A. Walters, Team Leader
Risk Management and Implementation Branch 3
Pesticide Re-evaluation Division
Office of Pesticide Programs

Enclosure

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

Permethrin S Synergized Formula

Ready-To-Use Pour-On & Spray Insecticide Treats Up To 25 Cows per Gallon

Kills Flies, Lice and Ticks
On Beef and Lactating Dairy Cattle and Kids on Sheep

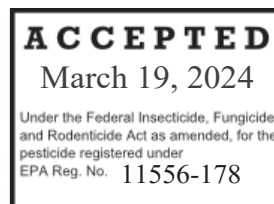
ACTIVE INGREDIENTS:	<u>% by Weight</u>
Permethrin (CAS # 52645-53-1)	1.00%
Piperonyl Butoxide (CAS # 51-03-6) *	1.00%
OTHER INGREDIENTS**:	98.00%
	Total 100.00%

*(butylcarbityl)(6-propylpiperonyl) ether and related compounds

**Contains petroleum distillate

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



EPA Reg. No. 11556-178

EPA Est. No. TBD

KEEP OUT OF REACH OF CHILDREN CAUTION

See [location on package] for [Precautionary Statements] [and] [First Aid] [and] [Storage and Disposal] [and] [Directions for use]

FIRST AID	
If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 eye. • 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. [For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), you may call 1-800-428-4441, twenty-four (24) hours per day, seven (7) days per week.] .] [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.]]	
Note to Physician: Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

Net Contents: 1 U.S. Gallon

Manufactured For:
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Contains petroleum distillate. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

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

Mixers, loaders, applicators (except for hand-held foggers or fog/mist generator use indoor spaces), and other handlers must wear the following:

- Long sleeved shirt;
- Long pants;
- Shoes and socks;
- Chemical-resistant gloves made of barrier laminate, nitrile rubber, neoprene rubber or Viton; and
- Chemical-resistant apron for mixers/loaders, persons cleaning equipment, and persons exposed to the concentrate and for handlers performing animal dip applications.

In addition to the above PPE, applicators using hand-held foggers or fog/mist generators in indoor spaces must wear:

- Coveralls over long-sleeved shirt and long pants;
- Chemical-resistant gloves made of barrier laminate, nitrile rubber, neoprene rubber, and viton;
- Chemical-resistant footwear and socks;
- Chemical-resistant headgear, if overhead exposure; and
- 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 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/PPB 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 HAZARD

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high-water mark. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash-waters or rinsate.

This product may contaminate water through run-off. This product has a potential for run-off for several months or more after application. Poorly draining soils and soils with shallow water tables are prone to produce run-off that contains this product. Applying this product in calm weather when rain is not predicted for the next 24 hours will help insure that wind or rain does not blow or wash pesticide off the treatment area. See Directions For Use for additional precautions and requirements.

This product 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.

PHYSICAL AND CHEMICAL HAZARDS: Do not use or store near heat or open flame.

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.

For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

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

- 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.
- Except when applying to livestock, do not enter or allow others to enter treated area until sprays have dried.
- Except when applying to livestock, do not apply this product in a way that will contact workers or other persons, either directly or through drift.
- Only protected handlers may be in the area during application.
- Do not breathe dusts, vapors or spray mist.
- Application is prohibited directly into sewers or drains, or to any area like a 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.
- 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 application. Wash teats of animals before milking.
- Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces, or wash them before use.
- All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:
- Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (e.g., soil);
- Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure;
- Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch;
- Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level;
- Applications to vertical surfaces directly above pervious surfaces, such as soil, or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters.
- Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches, and structural surfaces (such as windows, doors, and eaves) are limited to spot and crack-and-crevice application only. Spot treatments must not exceed two square feet in size (for example, 2ft. by 1 ft or 4 ft. by 0.5 ft.).
- Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours).
- Do not spray 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.
- 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.

APPLY TO	TARGET PESTS	APPLICATION INSTRUCTIONS
Beef Cattle, Lactating and Non-Lactating Dairy Cattle And Calves	Horn Flies, Face Flies and Lice Aids in control of Horse Flies, Stable Flies, House Flies, Mosquitoes, Black Flies and Ticks	<p>Dosage: Apply ½ fl. oz. (15 ml.) per 100 lbs. body wt. of animal up to a maximum of 5 fl. oz. for any one animal. For Pour-On and Ready-To-Use Spray applications, repeat treatment as needed, but do not exceed 5 fl. oz. during any 14 day interval. For optimum insecticidal effectiveness against lice, a second treatment at 14 day intervals is recommended.</p> <p>Pour-On: Pour correct dose along back and down face.</p> <p>Ready-To-Use Spray: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears.</p> <p>Back Rubber Use: Mix one pt. per gal. of mineral oil. Keep rubbing device charged. Results are improved by daily forced use.</p>
Sheep	Sheep Keds, Lice, Horn Flies and Face Flies. Aids in the insecticidal control of Horse Flies, Stable Flies, Mosquitoes, Black Flies and Ticks	<p>Dosage: Apply ¼ fl. oz. (7.5 ml.) per 50 lbs. body wt. of animal, up to a maximum of 3 fl. oz. for any one animal. For optimum control, all animals in the flock should be treated after shearing. For optimum insecticidal effectiveness against lice, a second treatment at 14 day intervals is recommended.</p> <p>Pour-On: For Keds, pour along back line over neck, shoulders and rump. Pour along back line down face for lice, flies and ticks.</p> <p>Ready-To-Use Spray: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck face, back, legs and ears.</p>
Premises- In and around Horse, Beef, Dairy, Swine, Sheep and Poultry premises. Animal Hospital Pens and Kennels "outside" Meat Processing Premises.	House Flies, Stable Flies, Face Flies, Gnats, Mosquitoes, Black Flies, Fleas and Little House Flies. Aids in control of Cockroaches, Ants, Spiders, Crickets.	<p>Ready-To-Use Spot Spray or Premise Spray: Use undiluted in a mist sprayer.</p> <p>Apply directly to surface to leave a residual insecticidal coating, paying particular attention to areas where insects crawl or alight. One gallon will treat approximately 7,300 square feet.</p>

NOTE: This is an oil-based, ready-to-use product that may leave an oily appearance on the hair coat of some animals. This product should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry (preferably locked) place in an area that is inaccessible to children and animals. Protect from freezing. Store upright at room temperature. Avoid exposure to extreme temperatures.

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 pour or dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options. 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 for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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 LIMITATIONS OF DAMAGES:

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.