

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 8, 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 WS

EPA Registration Number: 11556-172

Application Date: 3/24/2021 Decision Number: 572588

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

Page 2 of 2 EPA Reg. No. 11556-172 Decision No. 572588

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,

Jackyn Pyrie

Jaclyn Pyne, Team Leader

Risk Management and Implementation Branch 3

Pesticide Re-Evaluation Division

Office of Pesticide Programs

Enclosure

Date: 08/02/2023 Supersedes: 08/31/2010

Page 1 of 8

PERMECTRINTM WS

A WATER BASE, SYNERGIZED, CONCENTRATE INSECTICIDE WITH UP TO 30 DAYS RESIDUAL EFFECTS ON INANIMATE SURFACES

FOR AGRICULTURAL USE ONLY, NOT FOR HOUSEHOLD USE

- Broad Spectrum Synergized Insecticide/Acaracide
- Quick Knockdown
- For Control of Insect Pests on Livestock, Poultry and Farm Premises
- For Control of Insect Pest on Horses
- For Control of Ticks Including Deer Ticks (Carrier of Lyme Disease)
- Water Based, Pleasant Citrus Scent

ACTIVE INGREDIENTS:	% by Weight
Permethrin (CAS # 52645-53-1)	8.50%
Piperonyl Butoxide* (CAS # 51-03-6)	4.25%
*(butyl carbityl)(6-propylpiperonyl) ether and related	compounds
OTHER INGREDIENTS:	<u>87.25%</u>
TOTAI	100.00%

PERMETHRIN	GROUP	3A	INSECTICIDE

[Note to reviewer: box will be in the upper right corner of front panel.]

Contains 80.4 g. Permethrin and 40.2 g. Piperonyl Butoxide per quart.

EPA Reg. No. 11556-172

EPA Est. No. TBD

KEEP OUT OF THE REACH OF CHILDREN CAUTION

SEE SIDE/BACK PANEL FOR
DDITIONAL PRECAUTIONARY STATEMENT

ACCEPTED

02/08/2024

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 44550 470

11556-172

ADDITIONAL PRECAUTIONARY STATEMENTS				
	FIRST AID			
If Swallowed	Swallowed • Call a poison control center or doctor immediately for treatment advice.			
	• Have person sip a glass of water if able to swallow.			
	• Do not induce vomiting unless told to do so by a poison control center or doctor.			
	 Do not give anything by mouth to an unconscious person 			
If in Eyes	If in Eyes • 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.			
If on Skin or	on Skin or • Take off contaminated clothing.			
Clothing	• Rinse skin immediately with plenty of water for 15-20 minutes.			
	Call a poison control center or doctor for treatment advice.			
If Inhaled	If Inhaled • Move person to fresh air.			
	• If person is not breathing, call 911 or an ambulance, then give artificial respiration,			
	preferably by mouth-to-mouth, if possible.			
	Call a poison control center or doctor for further treatment advice.			

Date: 08/02/2023 Supersedes: 08/31/2010

Page 2 of 8

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 1-800-322-8177 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.]

Net Contents: 1.0 U.S. Quart

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. When applying indoors as a space spray or fog, wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.

ENVIRONMENTAL HAZARDS: This pesticide is highly toxic to fish. Do not apply directly to water, or to areas where surface water is present or intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

GENERAL INSTRUCTIONS

INDICATIONS: For use on Horses, Beef and Dairy Cattle, Swine, Sheep, Goats, Poultry, and their premises to kill Flies, Fleas, Lice, Imported Fire Ants, Mites, and Ticks including Deer Ticks (carrier of Lyme Disease). Aids in control of Cockroaches, Mosquitoes, Spiders and Crickets.

BUYER GUIDE: The following statements are made as a general guide to quantity of pesticide required for various applications. See Chart on inside of back panel for complete directions on dilution and use.

Premise Use as a Spray or Fog: Mix 1 qt. in 25 gal. of water to make a ready-to-use spray.

Livestock Use: Mix 1 qt. in 100 gal. of water to treat up to 400 animals.

Poultry Use: Mix 1 qt. in 50 gal. of water to treat up to 5,000 birds.

Horse Use: Mix 1.5 fl. oz. (45 ml) in 2 gal. of water for ready-to-use spray.

CONVERSION EQUIVALENTS: 1 fl. o= 30 ml = 2 tablespoons = 6 teaspoons

Date: 08/02/2023 Supersedes: 08/31/2010

Page 3 of 8

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, Permectrin WS contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to Permectrin WS. 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

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:

Date: 08/02/2023 Supersedes: 08/31/2010

Page 4 of 8

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.

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. 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.

SHAKE WELL BEFORE USE.

Add the required amount of concentrate to water and mix thoroughly. Do not hold dilutions for more than 24 hours.

Mix **PERMETRIN**TM **WS** and apply the use-diluted material to animals and pest breeding or resting surfaces at the rates shown on the accompanying chart. These dilutions and rates will provide most efficient pest control under conditions of heavy pressure when good contact is achieved. Timing and frequency of application should be based on pest populations reaching nuisance levels, but accompanying manure removal and sanitation practices should precede sprays.

Reason to Issue: EPA updates. Date: 08/02/2023 Supersedes: 08/31/2010

Page 5 of 8

Do not spray feed, food or water. Retreat as needed, but not more often than once every two weeks. Wash udders thoroughly before milking. Do not use on sick or debilitated animals.

PESTS ON LIVESTOCK: Beef Cattle, Lactating and Non-Lactating Dairy Cattle, Sheep, Goats and Swine Note: For swine, allow 5 days between last treatment and slaughter

Note. For swine, anow 3 days between last treatment and staughter		
PESTS	DILUTIONS FOR USE	APPLICATION INSTRUCTIONS
Horn Flies, Face Flies, Stable Flies,	Mix 1 part concentrate in 400 parts	High Pressure Spray:
House Flies, Lesser House Flies,	water (1 qt. in 100 gal. or 10 ml. in 1	Spray to thoroughly wet entire animal
Horse Flies, Deer Flies, Black Flies,	gal.). For severe infestations or for	(1-2 qts. per animal). For lice and
Mosquitoes, Eye Gnats, Blow Flies,	longer residual control, mix 1 part	mites, a second treatment is
Psoroptic (scabies) Mites, Lice, Ticks	concentrate in 132 parts water [1 qt. in	recommended in 14 days.
including Deer Ticks (carrier of Lyme	33 gal. or 4 fl. oz. (120 ml.) in 1 gal.].	
Disease), and Sheep Keds		
Horn Flies, Face Flies, Ear Ticks and	Mix 7 fl. oz. (210 ml.) in 1 gal. water.	Low Pressure Spray:
Lice		For flies and lice, apply 4-5 fl. oz.
		(120-150 ml.) along midline from face
		to tailhead. For ear ticks, spray
		directly onto each ear (1/2 fl. oz per
		ear).
Horn Flies, Face Flies, Stable Flies,	Mix 1 part concentrate in 48 parts	Pour-On:
House Flies, Lesser House Flies,	water (1 qt. in $12\frac{1}{2}$ gal. or 4 oz. in $1\frac{1}{2}$	Apply up to 4 oz. of dilution down
Horse Flies, Deer Flies, Black Flies,	gal. or 80 ml. in 1 gal.)	midline of back. Repeat application
Mosquitoes, Eye Gnats, Blow Flies,		in 14 days if necessary.
Psoroptic (scabies) Mites, Lice, Ticks		
including Deer Ticks (carrier of Lyme		
Disease), and Sheep Keds		

PESTS ON POULTRY

PESTS	DILUTIONS FOR USE	APPLICATION INSTRUCTIONS
Chicken Mite, Northern Fowl Mite,	Mix 1 part concentrate in 200 parts	High Pressure Spray:
Chiggers, Lice and Bed Bugs	water (1qt. in 50 gal. or 19 ml. in 1	Spray 1 gal. of coarse spray per 100
	gal.) For severe infestation or for	birds paying particular attention to
	longer residual control, mix 1 part	vent area.
	concentrate in 100 parts water (1 qt. in	
	25 gal. or 38 ml. in 1 gal.).	

<u>PESTS ON FARM PREMISES:</u> Barns, Loafing Sheds, Milking Parlors, Feed Lots, Stables, Paddocks, Poultry and Livestock Housing, Animal Hospitals and Outside Meat Processing Premises.

PESTS	DILUTIONS FOR USE	APPLICATION INSTRUCTIONS
House Flies, Stable Flies, Lesser	Mix 1 part concentrate in 100 parts	SURFACE SPRAY:
House Flies, other Manure Breeding	water (1 qt. in 25 gals. or 38 ml. in 1	Spray all surfaces thoroughly with
Flies, Bed Bugs, Chicken Mites, Fleas,	gal.). For severe infestation or for	diluted emulsion using 1 gal. per 750-
Mealworms, Lice, Mites, Ticks	longer residual control, mix 1 part	1000 square feet, but do not let runoff
including Deer Ticks (carrier of Lyme	concentrate in 33 parts water (1 qt. in	occur
Disease). Aids in control of	8-1/3 gal. or 115 ml. in 1 gal.). The	
Cockroaches, Ants, Spiders,	use of the higher concentration is	
Mosquitoes, Crickets an8d Face Flies.	recommended on painted wood	
	surfaces.	

Reason to Issue: EPA updates. Date: 08/02/2023 Supersedes: 08/31/2010

Page 6 of 8

In mist blower or power fogger (nonthermal) mix 1 part concentrate in 20 parts water (1 qt. in 5 gal. or 189 ml. in 1 gal.)

In mist blower or power fogger (nonthermal) mix 1 part concentrate in 20 parts water (1 qt. in 5 gal. or 189 ml. in 1 gal.)

INDOOR SPACE SPRAY:
Apply as fog or fine mist until area is filled with mist, using 2 fl. oz. (60 ml.) per 1000 cubic ft. (Can be used in Milk Rooms).

OUTDOOR SPACE SPRAY:
Fill area with mist. Apply while air is still.

DO NOT APPLY DILUTIONS FOR **PREMISE TREATMENT** DIRECTLY TO LIVESTOCK OR POULTRY. ENSURE THAT FEED AND WATER ARE NOT CONTAMINATED BY SPRAY DRIFT. FOR **SPACE SPRAYING** DO NOT REMAIN IN TREATED AREAS AND VENTILATE THE AREA BEFORE REOCCUPYING. REMOVE ANIMALS PRIOR TO TREATMENT. THE USE OF ANY RESIDUAL FLY SPRAY SHOULD BE SUPPLEMENTED WITH PROPER MANURE MANAGEMENT AND GENERAL SANITATION TO ELIMINATE FLY BREEDING SITES.

Fleas and Ticks on other outdoor Farm Premises	Mix 3 fl. oz. (90 ml.) concentrate in 8 gal. water or 11 ml. in 1 gal. water	OUTDOOR PREMISE SPRAY: Use enough finished spray to penetrate foliage, usually 50-100 gal. per acre. To prevent infestation of buildings, treat a band of vegetation 6-10 feet adjacent to the structure.
Imported Fire Ants	Mix 14 fl. oz. (420 ml.) in 1 gal. water.	SPRINKLER CAN: Gently sprinkle one gal. over the surface of each mound. Thoroughly wet mound and surrounding area to a 4 ft. diameter. For best results, apply in cool weather 65-85° (early morning or late evening). Pressurized sprayers may disturb ants and cause migration, reducing product effectiveness.

PESTS ON HORSES:

LESTS ON HORSES.			
PESTS	DILUTIONS FOR USE	APPLICATION DIRECTIONS	
Horse Flies, Deer Flies, Stable Flies,	Mix 1.5 fl. oz. (45 ml.) concentrate in	SPRAY OR SPONGE ON:	
House Flies, Horn Flies, Face Flies,	2 gal. water or 23 ml. in 1 gal. water.	Thoroughly wet animal to skin with	
Black Flies, Mosquitoes, Eye Gnats,		spray or sponge.	
Mange Mites, Lice and Ticks.			
	Mix 7 fl. oz. (210 ml.) concentrate in 3	LOW PRESSURE SPRAY OR	
	qts. water or 70 ml. in 1 qt. water.	WIPE ON:	
		Spray or wipe on 1-2 fl. oz. per	
		animal. Pay particular attention to treat	
		back, face, legs, and ears.	

PESTS ON EQUINE PREMISES: Barns, Stables, Paddocks, and Animal Hospitals.

PESTS	DILUTIONS FOR USE	APPLICATION DIRECTIONS
House Flies, Stable Flies, Lesser	Mix 1 part concentrate in 100 parts	SURFACE SPRAY:
House Flies, other Manure Breeding	water (1 qt. in 25 gals. or 38 ml. in 1	Spray all surfaces thoroughly with
Flies, Bed Bugs, Chicken Mites, Fleas,	gal.). For severe infestation or for	diluted emulsion using 1 gal. per 750-
Mealworms, Lice, Mites, Ticks	longer residual control, mix 1 part	1000 square feet, but do not let runoff

Reason to Issue: EPA updates. Date: 08/02/2023 Supersedes: 08/31/2010

Supersedes: 08/31/2 Page 7 of 8

including Deer Ticks (carrier of Lyme Disease). Aids in control of Cockroaches, Ants, Spiders, Mosquitoes, Crickets and Face Flies.

concentrate in 33 parts water (1 qt. in 8-1/3 gal. or 115 ml. in 1 gal.).

In mist blower or power fogger (non-thermal), mix 1 part concentrate in 20 parts water (1 qt. in 5 gal. or 189 ml. in 1 gal.).

occur.

INDOOR SPACE SPRAY:

Apply as fog or fine mist until area is filled with mist, using 2 fl. oz. (60ml.) per 1000 cubic ft.

OUTDOOR SPACE SPRAY:

Fill area with mist. Apply while the air is still.

DO NOT APPLY DILUTIONS FOR **PREMISE TREATMENT** DIRECTLY TO HORSES. ENSURE THAT FEED AND WATER ARE NOT CONTAMINATED BY SPRAY DRIFT. FOR **SPACE SPRAYING** DO NOT REMAIN IN TREATED AREAS AND VENTILATE THE AREA BEFORE REOCCUPYING. REMOVE ANIMALS PRIOR TO TREATMENT. THE USE OF ANY RESIDUAL FLY SPRAY SHOULD BE SUPPLEMENTED WITH PROPER MANURE MANAGEMENT AND GENERAL SANITATION TO ELIMINATE FLY BREEDING SITES.

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. 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 ¼ 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.

Date: 08/02/2023 Supersedes: 08/31/2010

Page 8 of 8

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.