

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 12, 2017

J. Todd Frank Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201

Subject: PRIA Label Amendment – Revise Precautionary Language Product Name: PERMECTRIN II EPA Registration Number: 11556-166 Application Date: June 2, 2017 Decision Number: 530249

Dear Mr. Frank:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

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 18 months from the date of this letter. After 18 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.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions about this letter, please contact Maggie Rudick by phone at 703-347-0257, or via email at <u>rudick.maggie@epa.gov</u>.

Sincerely,

For TOT

Michael Wagman, Acting Product Manager 4 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

Update Label with EPA required mitigation language.

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PERMECTRINTM II

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

ACTIVE INGREDIENT Permethrin (CAS # 52645-53-1).....10.0% **OTHER INGREDIENTS***<u>90.0%</u> Total 100.0%

*Contains petroleum distillates Contains 0.75 lb. permethrin per gallon

Keep Out of Reach of Children WARNING

See back panel for additional precautionary statements

	FIRST AID		
If on skin or	Take of 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 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 inhaled	• Move person to fresh air.		
	• If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably		
	mouth-to-mouth, if possible.		
	Call a poison control center or doctor for further treatment advice.		
If swallowed	Call a poison control center or doctor immediately for treatment advice.		
	• 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		
HOT LINE NUMBER			
	ct container or label with you when calling a poison control center or doctor, or going for treatment. You ct 1-800-322-8177 for emergency medical treatment information.		
2	NOTE TO PHYSICIAN		
Contains petrol	eum distillate – vomiting may cause aspiration pneumonia.		

EPA Reg. No. 11556-166

EPA Est. No. Net Contents: 8 oz. (237 ml) or 1.0 U.S. Quart (946 ml)

Manufactured For: Bayer HealthCare, LLC Animal Health Division PO Box 390 Shawnee Mission, KS 66201 USA



and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

11556-166

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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 (barrier laminate, nitrile rubber, neoprene, rubber, viton, selection category F*).

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, butyl rubber greater or equal to 14 mils, and nitrile rubber greater or equal to 14 mils.

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, neoprene rubber, or viton
- 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

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.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should 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 clam 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.

Permectrin II b

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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.

USE RESTRICTIONS

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 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 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 Permectrin 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.

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,	Spray Application: Mix 1 qt. in 25 gal.; 8 oz. in 6.25 gal.; 1-1/3 oz. (40 ml.) in 1 gal. of			
Lesser House Flies and other	water ^a . Spray all surfaces to run-off with diluted emulsion using 1 gal. per 750 sq. feet.			
manure breeding Flies,				

Fleas, Lice, Mites, Ticks,	Mist Blower: Use undiluted in mist blower. Mist at 4 oz. per 1000 sq. feet.
including Deer Ticks (carrier	
of Lyme disease).	Power Fogger: Mix 1 qt. in 25 gal.; 1-1/3 oz. (40 ml.) in 1 gal. of water ^a . Fog at 4 oz. per
	1000 sq. feet.

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

Target Pests	Application Instructions
Face Flies, Horn Flies, Horse	Backrubber: Animals self-apply. Mix 1qt. in 20 gal.; 8 oz. in 5 gal.: 1.6 oz. (48 ml.) in 1
Flies	gal. of any backrubber oil approved for use on livestock. Recharge backrubber oiler as
	needed.
Face Flies, Horn Flies, Horse	High Pressure Sprayers: Mix 1 qt. in 200 gal. or 8 oz. in 50 gal. of water. Spray to
Flies, Stable Flies,	thoroughly cover entire animal. Apply from 1/2 to 1 gal. of spray per animal. For lice or
Mosquitoes, Lice, Mites,	mites, a second treatment is recommended 14-21 days later.
Ticks, including Deer Ticks	Hand, Garden or Low Pressure Sprayer: Mix 8 oz. in 3 gal.; 2.5 oz. (75 ml.) in 1 gal. or
(carrier of Lyme disease)	2/3 oz. (20 ml.) in 1 qt. of water. Spray each animal with up to 8 oz. of mixed spray. For
	lice or mites, a second treatment is recommended 14-21 days later.
Ear Ticks, Face Flies, Horn	Spot Application: Mix 2 oz. (60 ml.) in 1 gal. of mineral oil or non-irritating organic oil
Flies	or water. Apply ½ oz. per ear or 2-4 oz. on face or 12-16 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 oz. in 25 gal.; 1 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	Mix 1 qt. in 100 gal.; 8 oz. in 25 gal.; 1 oz. (30 ml.) in 3 gal. of water. Spray, paint or dip
Lice, Fleas, Ticks, including	to apply 1 pt. per dog, pig or sheep, especially around ears. Do not reapply for 2 weeks.
Deer Ticks (carrier of Lyme	
disease)	
Poultry Mites	Mix 1 qt. in 50 gal.; 8 oz. in 12.5 gal.; 2oz. (60 ml.) in 3 gal. of water. Spray ½ oz. per
	bird or 1 gal. per 100 birds, directed towards vent area. Spray cages.

^a1 oz. is equivalent to 2 tablespoons or 30 ml.

IMPORTANT: Read Entire Label Before Each Use: Use 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). 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.

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

Large Animal Use: Mix 8 oz. in 5 gal. or 1 qt. in 20 gal. of oil for backrubbers and oilers; mix 2 oz. in 1 gal. of oil or water for spot application; mix 8 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 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 oz. in 12. 5 gal. or 1 qt. in 50 gal. of water and spray ½ oz. per bird or 1 gal. per 100 birds for poultry.

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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: 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 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, Bayer 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 that extraordinary or unusual environmental conditions are beyond the control of Bayer and are, therefore, the responsibility of the buyer.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Healthcare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer 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.