

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 30, 2017

Todd Frank Regulatory Affairs Consultant Bayer U.S Research & Development P.O. Box 390 Shawnee Mission, KS 66201-0390

Subject: Amended Reregistration Label

Product Name: Permectrin CDS Pour-on Insecticide

EPA Registration Number: 11556-170 Decision Number: 410201, 413322

Dear Mr. Frank:

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

NOTE: This product is **not** yet being reregistered under section 4(g) of FIFRA.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

• Basic CSF, dated 03/12/2014

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.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label

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constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions about this letter, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Sincerely,

Gene Benbow, Acting Product Manager 4

Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

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Office of Pesticide Programs

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Permectrin® CDS Pour-on Insecticide SYNERGIZED FORMULA

(Alternate Brand Name: Buzz Off Insecticide)

Concentrated Insecticide for Beef, Lactating Dairy Cattle, Sheep and Horses

- Can be applied topically to livestock and their premises.
- Controls lice, horn and face flies, and aids in the control of ticks on beef and lactating dairy cattle.
- Controls lice, horn, stable, deer and face flies, eye gnats and ticks on horses.
- Controls sheep keds, lice and biting midges on sheep.

Active Ingredients:

Permethrin (CAS No. 52645-53-1)	• • • • • • • • • • • • • • • • • • • •	7.4%
Piperonyl Butoxide Technical (CAS No. 51-03-6)		
Other Ingredients:*		
J	Total	

* Contains petroleum distillates EPA Reg. No. 11556-170

EPA Est. No. XXXX-XX-XX

Keep Out of Reach of Children

CAUTION

See back panel for additional precautionary statements and Directions for Use

FIRST AID	
If 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 swallowed	Immediately call a poison control center or doctor.
	• Do not induce vomiting unless told to 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.
HOTLINE 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.

NOTE TO PHYSICIAN

Contains petroleum distillate – vomiting may cause aspiration pneumonia.

Net Contents: 16 oz. / 32 oz. / 64 oz. / 2.5 gal.

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

ACCEPTED

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

11556-170

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling.

Personal Protective Equipment (PPE)

Chemical-resistant gloves

Mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical resistant gloves for all handlers except for applicators using motorized ground equipment, pilots, and flaggers,
- Chemical-resistant apron for mixers/loaders, persons cleaning equipment, and persons exposed to the concentrate and for handlers performing animal dip applications.

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.

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.

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ENVIRONMENT AL HAZARDS: This pesticide 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 run off 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.

KEEP CONTAINER SEALED WHEN NOT IN USE.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING

IMPORTANT: Use only with an accurate measuring container or applicator.

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:

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(1) Treatment to soil or vegetation around structures;

- (2) Applications to lawns, turfs, and other vegetation;
- (3) Applications to building foundations, up to a maximum height of 3 feet.

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.

EXCEPT FOR BACK RUBBER / READY TO USE – No dilution necessary.

APPLY TO: LACTATING AND NON-LACTATING DAIRY CATTLE, BEEF CATTLE AND CALVES

Target Pests	Application Instructions
Lice, Horn Flies,	Dosage: For moderate fly control apply 1.5 mL per 100 lbs. body wt. of animal, up
Face Flies. Aids in	to a maximum of 15 mL per animal.
control of Horse	
Flies, Stable Flies,	For lice and severe horn fly control apply 2.0 mL per 100 lbs. body wt. of animal,
House Flies,	up to a maximum of 20 mL per animal.
Mosquitoes, Black	
Flies and Ticks.	Pour-on: Pour correct dose along back and down face.
Controls Horn	
Flies up to 6 weeks	Ready-to-use Spray: Use undiluted in a mist sprayer to apply correct dose. Apply
after application.	directly to neck, face, back, legs and ears.
	Back Rubber Use: Mix 64 mL (2.1 oz.) per gallon of mineral oil. Keep rubbing
	device charged. Results improved by daily forced use.

Repeat treatment as needed, but not more than once every two weeks. For optimum lice control, two treatments at a 14-day interval are recommended.

APPLY TO: SHEEP AND LAMBS

Target Pests	Application Instructions
Sheep Keds and	Pour-on: Pour along the back. Apply 1 mL per 50 lb. body weight of animal, up to
Lice	maximum of 12 mL for any one animal. For optimum control, all animals in the
	flock should be treated after shearing.
Biting Midges	Ready-to-use Spray: Use undiluted in a mist sprayer to apply 4 mL of product per
	animal to the ventral (underside) of sheep.

Repeat treatment as needed, but not more than once every two weeks. For optimum lice control, two treatments at a 14-day interval are recommended.

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APPLY TO: HORSES AND FOALS

Target Pests	Application Instructions
Stable Flies, Deer	Pour-on: Do not use this application method on foals. After riding or exercise,
Flies, Horn Flies,	pour 8 mL to 16 mL per animal along back and down the face of MATURE horses,
Face Flies, House	being careful to avoid the eyes. Repeat treatment as needed, but not more than once
Flies, Eye Gnats,	every two weeks.
Lice and Ticks.	
Aids in control of	Wipe-on: Apply 8 mL to 16 mL. Dampen an applicator mitt, cloth or toweling
Horse Flies,	(Turkish). Rub over hair with special attention to the legs, shoulders, neck and
Mosquitoes and	facial areas where flies tend to congregate. Avoid the eyes. Repeat treatment as
Black Flies.	needed, but not more than once every two weeks.
	Ready-to-use Spray: Use after riding or exercising. Apply 8 mL to 16 mL
	undiluted in a mist sprayer per animal. Apply directly to ticks. Repeat treatment as
	needed, but not more than once every two weeks.

APPLY TO: HORSE, BEEF, DAIRY, SWINE, SHEEP AND POULTY PREMISES, ANIMAL HOSPITAL PENS AND KENNELS AND "OUTSIDE" MEAT PROCESSING PREMISES

Target Pests	Application Instructions
House Flies, Stable	Ready-to-use Spot or Premise Spray: Use undiluted in a mist sprayer. Apply
Flies, Face Flies,	directly to surface to leave a residual insecticidal coating, paying particular attention
Gnats, Mosquitoes,	to areas where insects crawl or alight. 500 mL will treat approximately 7,200
Black Flies, Fleas,	square feet.
Little house Flies	
(Fannia spp.).	
Aids in control of	
Cockroaches,	
Ants, Spiders and	
Crickets.	

Special Note: Permectrin CDS Pour-on is not effective in controlling cattle grubs.

Permectrin CDS Pour-on is an oil-base, ready-to-use product that may leave an oily appearance on the hair coat of some animals.

Permectrin CDS Pour-on should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices.

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STORAGE AND DISPOSAL

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

STORAGE: Keep container sealed when not in use. Do not store near food or feed.

PESTICIDE DISPOSAL: Waste 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 (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, 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 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.