



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 19, 2023

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 CDS Pour-On Insecticide
EPA Registration Number: 11556-170
Application Date: 9/9/2022
Decision Number: 572600

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.

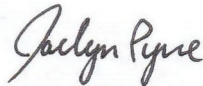
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or 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

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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 black ink that reads "Jaclyn Pyne". The signature is written in a cursive style with a large initial "J".

Jaclyn Pyne
Team Leader
Risk Management & Implementation Branch III
Pesticide Re-evaluation Division
Office of Pesticide Programs

Enclosure

Reason to Issue: add pictograms/pictures, updated phone numbers, address and minor revisions.

Date: 08/02/2023

Supersedes: 03/24/2021

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

Permethrin™ CDS Pour-on Insecticide

SYNERGIZED FORMULA

{Alternate Brand Name: Buzz Off Insecticide}

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

{{Selected optional marketing claims bulleted here from page 7}}

{{Selected pictograms from page 7}}

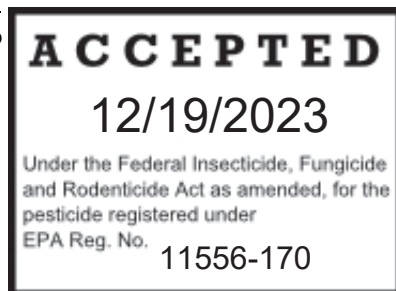
ACTIVE INGREDIENTS:

% by Weight

Permethrin (CAS No. 52645-53-1).....	7.4%
Piperonyl Butoxide Technical (CAS No. 51-03-6).....	7.4%
OTHER INGREDIENTS: *	85.2%
TOTAL.....	100.0%

* Contains petroleum distillates

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

EPA Reg. No. 11556-170

EPA Est. No. TBD

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional Precautionary Statements [Directions for Use] [Storage and Disposal] [and] [First Aid].

FIRST AID	
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> • 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	
<p>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</p>	

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: [16 oz (0.47 Liters)] [32 oz] [64 oz] [2.5 gal (9.5 Liters)]

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

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)

Mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus 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.
- 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/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.
- 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 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

For both indoor and outdoor use.

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

RESISTANCE-MANAGEMENT RECOMMENDATIONS

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



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:

1. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (e.g., soil);
2. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure;
3. 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;
4. 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;
5. 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. 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.

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.

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, Face Flies. Aids in control of Horse Flies, Stable Flies, House Flies,	Dosage: For moderate fly control apply 1.5 mL per 100 lbs. body wt. of animal, up to a maximum of 15 mL per animal. For lice and severe horn fly control apply 2.0 mL per 100 lbs. body wt. of animal, up to a maximum of 20 mL per animal.

Mosquitoes, Black Flies and Ticks. Controls Horn Flies up to 6 weeks after application.	<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 64 mL (2.1 oz.) per gallon of mineral oil. Keep rubbing device charged. Results improved by daily forced use.</p>
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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 Lice	Pour-on: Pour along the back. Apply 1 mL per 50 lb. body weight of animal, up to 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.

APPLY TO: HORSES AND FOALS

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

APPLY TO: HORSE, BEEF, DAIRY, SWINE, SHEEP AND POULTRY PREMISES, ANIMAL HOSPITAL PENS AND KENNELS AND “OUTSIDE” MEAT PROCESSING PREMISES

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

Special Note: [Permethrin CDS Pour-on][ABN] is not effective in controlling cattle grubs.

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

[Permethrin CDS Pour-on][ABN] 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: 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. Do not pour or dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options. 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 $\frac{1}{4}$ 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 claims appearing on any location:]}

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

{[Optional marketing pictograms and pictures appearing on any location:]}



Beef



*Dairy Cattle
(Including Lactating)*



Sheep



Horses