

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 30 2013

Mr. Micah T. Reynolds
Intervet, Inc.
556 Morris Avenue
Summit, New Jersey 07901

Subject: Amended Reregistration Label
Product Name: Synergized 5% Permethrin Pour-On
EPA Registration Number: 773-84
EPA Decision Number(s): 413187

Dear Mr. Reynolds:

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 RED(s), and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

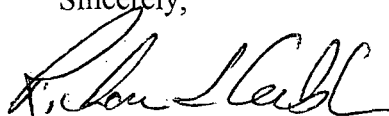
Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated [May 7, 2012]

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. 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 constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Dani Daniel at (703)305-5409 or via e-mail at daniel.dani@epa.gov

Sincerely,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

*Enclosures: Label stamped "Accepted," dated
Acute Toxicity Review, dated (September 23, 2010)
Product Chemistry Review, dated August 32, 2012)*

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(MASTER LABEL)

SYNERGIZED 5% PERMETHRIN POUR-ON

(Alternate Brand Names: ULTRA BOSS[®], ULTRA BOSS[®] Pour-On Insecticide)

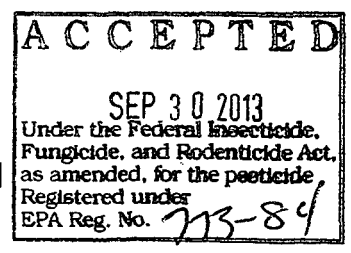
Pour-On Insecticide For Cattle, Sheep, Goats and Horses

Take Control of Flies and Lice
[Season-Long Lice Control[†] with One Application]
[[†]Season long lice control from January – April]
[May be used with Automatic Dosing System]

ACTIVE INGREDIENT:

Permethrin: 3-(phenoxyphenyl)methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate*	5.0%
Piperonyl Butoxide**	5.0%
INERT INGREDIENTS***	90.0%
	100.0%

*cis/trans ratio: Min. 35% (±) cis and max 65% (±) trans
**(butylcarbityl)(6-propylpiperonyl) ether and related compounds
***Contains petroleum distillates.



**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [back] [other] [side] [panel] for [additional] precautionary statements

(Note to reviewer: the following reference statement for small container sizes):
See additional precautionary statements and directions for use inside booklet

[Manufactured [by]][for]:
Intervet, Inc. (d/b/a Merck Animal Health)
556 Morris Avenue
Summit, NJ 07901

EPA Reg. No. 773-84
EPA Est. No. [6175-LA-1]

Net Contents: [One U.S. Gallon (3.785 L)]
[One U.S. Quart (0.946 L)]
[4 fl. oz (120mL)]

[UPC Code] [Copyright XXXX] [All rights reserved.] [Rev. XXX]

[Lot/Batch No.] (Note to reviewer: the lot or batch number may also be stamped directly on the product container.)

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

FIRST AID	
IF ON SKIN OR CLOTHING	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	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. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.	
Note to Physician: Contains petroleum distillates. Vomiting may cause aspiration pneumonia.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: **CAUTION:** Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wear long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves (Barrier laminate, Nitrile rubber, Neoprene rubber, Viton, selection category E). Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All handlers must wear: Long-sleeve shirt, long pants, shoes plus socks, and chemical-resistant gloves (barrier laminate, nitrile rubber, neoprene rubber, Viton, selection category E).

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

User 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. User 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.

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

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.

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 actively visiting the treatment area.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READY TO USE** – No dilution necessary.

USE RESTRICTIONS

Only protected handlers may be in the area during applications.
Not for use in outdoor residential misting systems.

Apply To: Lactating and Non-Lactating Dairy Cattle, Beef Cattle, Calves, Horses (Not intended for human consumption)

Target Species: Lice, Horn flies, face flies. Aids in control of Horse flies, Stable flies, Mosquitoes, Black flies, and Ticks

Dosage: Apply 3 mL per 100 lbs body weight of animal up to a maximum of 30 mL for any one animal. Pour along back and down face.

Back Rubber Use: Mix 100 mL per gallon of #2 diesel oil or mineral oil. Keep rubbing device charged. Results improved by forced daily use.

Apply To: Lactating and Non-Lactating Dairy Goats

Dosage: Apply 1.5 mL per 50 lbs body weight of animal up to a maximum of 18 mL for any one animal. Pour along back and down face.

Apply To: Sheep

Target Species: Sheep keds, Lice

Dosage: Pour along back. Apply 1.5 mL per 50 lbs of body weight of animal, up to a maximum of 18 mL for any one animal.

For cattle, horses, sheep, and goats, repeat treatment as needed but not more than once every two weeks. For horses, do not stable horse for 6 hours after application and refrain from washing down area of application. For optimum lice control, two treatments at 14-day intervals are recommended.

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

Special Note: [SYNERGIZED 5% Permethrin Pour-On] [This product] is not effective against cattle grubs.

STORAGE AND DISPOSAL

(Note to reviewer: This product is non-dilutable.)

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: 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 (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

[Optional Warranty Statement

NOTICE OF WARRANTY

To the extent consistent with applicable law, Intervet, Inc./Merck Animal Health makes no warranty of merchantability, fitness for any particular purpose or otherwise expressed or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accordance with the statements on this label.]

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

Optional Marketing claims, pictograms, and product information

(May be presented on the container or supplemental labeling)

- Take Control of Flies and Lice
- May be used with Automatic Dosing System
- Squeeze 'N' Measure Bottle
- U.S. Patent No. 5,750,514
- Made in the USA
- Merck Animal Health and/or Intervet Logo
- (For one gallon container): Treats 229 550 lb [Head of] Cattle
- (For one quart container): Treats 57 550 lb [Head of] Cattle
- Pictures of Application Methods, Use Sites, and Target Pests
- Squeeze 'N' Measure™ bottle icon
- Automatic Dosing system icon
- Back Rubber Icon