

773-72

08/27/2013

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

8-27-13

Intervet, Inc.
c/o
Micah T. Reynolds
Technology Sciences Group, Inc.
1150 18th Street, Suite 1000
Washington DC, 20036

Subject: Amended Reregistration Label
Product Name: Atroban Delice Plus Insecticide
EPA Registration Number: 773-72
EPA Decision Number: 413184, 411155

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 and PBO REDs, 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 be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statement of Formulation (CSF) listed below. Any CSFs other than those listed below are superseded.

- Basic CSF dated >> 05/07/12
- Alternate CSF #1 dated >> 05/07/12
- Alternate CSF #2 dated >> 05/07/12
- Alternate CSF #3 dated >> 05/07/12
- Alternate CSF #4 dated >> 05/07/12

A copy of your label 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 Gene Benbow at 703-347-0235 or benbow.gene@epa.gov.

Sincerely,



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

*Enclosures: Acute Toxicity Review, dated 09/27/10
Product Chemistry Review, dated 08/03/12
Stamped Accepted Label, dated*

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

(MASTER LABEL)

ATROBAN® DELICE PLUS INSECTICIDE

(Alternate Brand Names: SYNERGIZED DELICE®, SYNERGIZED DELICE®
Insecticide)

Pour-On Insecticide For Cattle, Sheep, and their premises

ACTIVE INGREDIENT:

Permethrin: 3-(phenoxyphenyl)methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate*.....1.0%

Piperonyl Butoxide**.....1.0%

OTHER INGREDIENTS***98.0%
100.0%

*cis/trans ratio: Min. 35% (±) cis and max 65% (±) trans

** (butylcarbityl)(6-propylpiperonyl) ether and related compounds

***Contains petroleum distillates.

CAUTION KEEP OUT OF REACH OF CHILDREN

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

[Manufactured [by][for]:]

Intervet, Inc. (d/b/a Merck Animal Health)
556 Morris Avenue
Summit, NJ 07901

EPA Reg. No. 773-72

EPA Est. No. [6175-LA-1]

Net Contents: [One U.S. Gallon (3.785 L)]

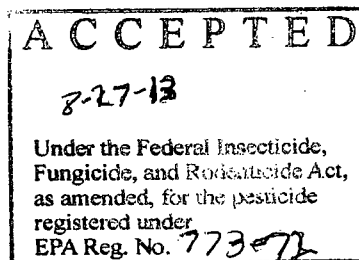
[UPC Code]

[Copyright XXXX]

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[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	Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
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 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.
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 is absorbed through skin. Avoid contact with skin, eyes, and clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling.

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 or Viton).

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.

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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.

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.

PHYSICAL AND 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. READY TO USE – No dilution necessary.

USE RESTRICTIONS

Except when applying to livestock:

- Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.
- Only protected handlers may be in the area during application.
- Do not enter or allow or allow others to enter treated area until sprays have dried.
- Do not enter or allow other to enter treated area until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.

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 treated animals before milking.

Not for use in outdoor residential misting systems (indoor or outdoor). Not for use in metered release systems.

Apply To: Lactating and Non-Lactating Dairy Cattle, Beef Cattle, and Calves

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

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

Application Instructions

Dosage: Apply ½ fl oz (15 cc) per 100 lbs body wt of animal up to a maximum of 5 fl oz for any one animal. **Pour On:** Pour correct dose along back and down face. **Ready To Use Sprayer:** Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears. **Back Rubber Use:** Mix 1 pint per gallon #2 diesel or mineral oil. Keep rubbing device charged. Results improved by daily forced use.

Apply To: Sheep

Target Insects: Sheep keds, Lice

Application Instructions

Pour along back. Apply ¼ fl oz (7.5 cc) per 50 lbs body weight of animal, up to a maximum of 3 fl oz for any one animal. For optimum control, all animals in the flock should be treated after shearing.

Apply To: Premises – In and around Horse, Beef, Dairy, Swine, Sheep and Poultry Premises, Animal Hospital Pens and Kennels and outside Meat Processing Premises.

Target Insects: House flies, Stable flies, Face flies, Gnats, Mosquitoes, Black flies, Fleas, Little House flies (*Fannia* spp.). Aids in control of cockroaches, ants, spiders, crickets.

Application Instructions

For use as a ready-to-use spot spray 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. One gallon will treat approximately 7,300 square feet.

For cattle and 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.

Special Note: [SYNERGIZED DELICE Insecticide] [This product] is not effective in controlling cattle grubs. [SYNERGIZED DELICE Insecticide] [This product] is an oil-base, ready-to-use product, that may leave an oily appearance on the hair coat of some animals. [SYNERGIZED DELICE Insecticide] [This product] 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: Store in cool, dry place.

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 accord with the statements made on this label.]

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Optional Marketing claims, pictograms, and product information

(May be presented on the container or supplemental labeling)

- Insecticidal Spray
- Insecticidal Pour-On
- Made in the USA
- Merck Animal Health and/or Intervet Logo
- Treats 46 550 lb [Head of] Cattle
- Pictures of Application Methods, Use Sites, and Target Pests
- Pour-On, Spray, Mist, Premises, Back Rubber icons