

773-59

08/26/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

8-26-13

Micah Reynolds
TSG Inc
1150 18th Street NW, Suite 1000
Washington, DC 20036

Subject: Amended Reregistration Label
Product Name: Atroban 11%EC
EPA Registration Number: 773-59

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 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 Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF and Alternate CSFs #1-4 dated 7-13-12

A copy of your label stamped "Accepted" is enclosed 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).

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If you have any questions about this letter, please contact either Erik Kraft at (703-308-9358) or via email at Kraft.Erik@epa.gov or Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov.

Sincerely yours,



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

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

(MASTER LABEL)

ATROBAN® 11%EC

(Alternate Brand Names: ATROBAN® 11% EC Insecticidal Spray)

Emulsifiable Concentrate Long-Lasting Insecticidal Spray For Livestock and their premises

ACTIVE INGREDIENT:

Permethrin: 3-(phenoxyphenyl)methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate* 11.0%

OTHER INGREDIENTS 89.0%
100.0%

*cis/trans ratio: Max. 55% (±) cis and min 45% (±) trans

Contains petroleum distillates.

This product contains 0.107 lbs (48.5 g) of permethrin per pint (473 mL)

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

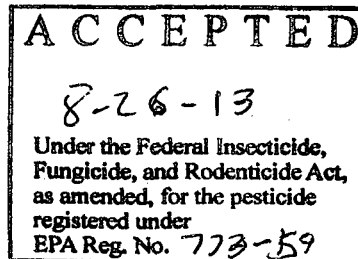
EPA Reg. No. 773-59
EPA Est. No. [6175-LA-1]

Net Contents: [One U.S. Quart (946 mL)]
[One U.S. Pint (473 mL)]

[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.)

[Pull here to open] [Press to reseal]



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

FIRST AID	
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 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.
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:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Loaders, applicators, and other handlers must wear: Long-sleeve shirt and long pants, shoes plus socks, and chemical-resistant gloves for all handlers, chemical-resistant apron for mixers/loaders, persons cleaning equipment, and persons exposed to the concentrate.

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.

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 actively visiting the treatment area.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. 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

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).

Mix ATROBAN® 11% EC Insecticidal Spray thoroughly according to the following table: Repeat applications as needed but not more often than once every two weeks. Spray lactating dairy animals only after milking is completed. Use as needed on horses not intended for human consumption.

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

LACTATING AND NON-LACTATING DAIRY CATTLE AND GOATS, BEEF CATTLE, HORSES, AND SHEEP

Target Species	Use	Dilute	Application Rate
Horn flies only	Sprayer	(For 32oz:) 1 qt to 100 gals water (6 tbsp/10 gals) (For 16oz:) 1 pt to 50 gals water (3 tbsp/5 gals)	1 qt of coarse spray per animal.
Horn flies, Face flies Stable flies, House flies, Horse flies, Black flies, Mosquitoes, Eye gnats, Mange mites, Scabies Mites, ticks, lice, Sheep keds	Sprayer	(For 32oz:) 1 qt to 50 gals water (6 tbsp/5 gals) (For 16oz:) 1 pt to 25 gals water (3 tbsp/2.5 gals)	1-2 qts of coarse spray per animal over whole body surface. For mange, scabies, ticks, and lice, thoroughly wet animal. Repeat application in 10-14 days for mites
Horn flies, Face flies Stable flies, Ear ticks	Low Pressure Sprayer	(For 32oz:) 1 qt to 5 gals water (6 tbsp/½ gal) (For 16oz:) 1 pt to 2.5 gals water (3 tbsp/qt)	1-2 oz spray per animal. Spot treat back, face, legs, and ears.
Horn flies, Face flies Stable flies	Back Rubber/ Self Oiler	(For 32oz:) 1 qt to 20 gals diesel oil (6 tbsp/2 gals) (For 16oz:) 1 pt to 10 gals diesel oil (3 tbsp/gal)	Keep rubbing device charged. Results improved by daily forced use.

POULTRY

Target Species	Use	Dilute	Application Rate
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Northern fowl mites Lice	Sprayer	(For 32oz.) 1 qt to 50 gals water (6 tbsp/5 gals)	1 gal of coarse spray per 100 birds, paying particu- lar attention to vent area.
		(For 16oz.) 1 pt to 25 gals water (3 tbsp/2.5 gals)	

SWINE

Target Species	Use	Dilute	Application Rate
Lice, mange	Sprayer	(For 32oz.) 1 qt to 50 gals water (6 tbsp/5 gals)	Thoroughly wet animals, including ears. For mange, repeat at 14 days.
		(For 16oz.) 1 pt to 25 gals water (3 tbsp/2.5 gals)	

For swine, allow 5 days between last treatment and slaughter.

PREMISES – in and around horse, beef, dairy, swine, sheep, and poultry premises, animal hospital pens and kennels, and *outside* meat processing premises. NOTE: This product is not recommended for use on vinyl or plastic surfaces.

Target Species	Use	Dilute	Application Rate
House flies, Stable flies, Little house flies (<i>Fannia</i> spp.) Aids in control of cockroaches, ants, spiders, mosquitoes crickets, Face flies.	Sprayer	(For 32oz.) 1 qt to 20 gals water (6 tbsp/2 gals)	Spray to point of runoff or 1 gal per 750-1,000 sq ft.
		(For 16oz.) 1 pt to 10 gals water (3 tbsp/gal)	
	Overhead space spray system	(For 32oz.) 1 qt to 20 gals diesel or mineral oil (6 tbsp/2 gals)	4 oz spray per 1,000 sq ft of air space.
		(For 16oz.) 1 pt to 10 gals	

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diesel or mineral
oil (3 tbsp/gal)

Do not apply dilutions for premise treatment directly on livestock or poultry. Ensure that animals' feed and water are not contaminated by spray drift. For space spraying, do not remain in treated areas and ventilate the areas before reoccupying. Animals should be removed from areas prior to treatment. Do not use in milk rooms. The use of any residual fly spray should be supplemented with proper manure management and general sanitation to reduce or eliminate fly breeding sites.

STORAGE AND DISPOSAL

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

STORAGE: Store in cool, dry place.

PESTICIDE DISPOSAL: Pesticides wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container 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. Then offer for recycling if available 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
- Made in the USA
- Merck Animal Health and/or Intervet Logo
- (For one quart container): Treats 400 550 lb Head of Cattle based on horn fly dosage
- (For one pint container): Treats 200 550 lb Head of Cattle based on horn fly dosage
- Pictures of Application Methods, Use Sites, and Target Pests
- Spray, Premises, Back Rubber icons