

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 8, 2025

Pete Stevenson Senior Regulatory Advisor tsg consulting for Intervet Inc D/B/A Merck Animal Health 1150 18th Street NW, Suite 475 Washington, DC 20036

Subject: Label Amendment - Registration Review Mitigation for Permethrin

Product Name: Atroban 11% EC EPA Registration Number: 773-59 Application Date: 30 March 2021

Decision Number: 597093

Dear Pete Stevenson:

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 and must be used at your next label printing. You must

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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 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 Kent Fothergill via email at fothergill.kent@epa.gov.

Sincerely,

Dana L. Friedman, Chief

Risk Management and Implementation Branch 1

Pesticide Re-Evaluation Division

Dana & Friedman

Office of Pesticide Programs

U.S. Environmental Protection Agency

ENCLOSURE: Stamped label

ACCEPTED

Jul 08, 2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 773-59



(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)-2,2dimethylcyclopropanecarboxylate*......11.0% OTHER INGREDIENTS 89.0% 100.0%

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]:] EPA Reg. No. 773-59 Intervet, Inc. (d/b/a Merck Animal Health) EPA Est. No. [6175-LA-1]

126 E. Lincoln Avenue

Rahway, NJ 07065 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]

^{*}cis/trans ratio: Max. 55% (±) cis and min 45% (±) trans Contains petroleum distillates.

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. For both indoor and outdoor use.

For resistance management, ATROBAN® 11% EC, contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to ATROBAN® 11% EC and other Group 3A insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly. Appropriate resistance-management strategies should be followed.

To delay insecticide/acaricide resistance, take the following steps:

Rotate the use of ATROBAN® 11% EC or other Group 3A insecticides with different groups that control the same pests.

Adopt an integrated pest management program for insecticide use that includes inspection of animals and/or premises, uses historical information related to pesticide use, record keeping, and which considers cultural, biological and other chemical control practices.

Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.

Contact your local extension specialist for any additional pesticide resistancemanagement and/or IPM recommendations for the specific site and pest problems in your area.

For further information or to report suspected resistance contact Intervet, Inc. (d/b/a Merck Animal Health) at merck-animal-health.com.

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).

Do not allow to enter indoor or outdoor drains (*No permita la entrada a desagues internos o externos*).

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.

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

Target Species Horn flies only	Use Sprayer	Dilute (For 32oz:) 1 qt to 100 gals water (6 tbsp/10 gals)	Application Rate 1 qt of coarse spray per animal.
		(For 16oz:) 1 pt to 50 gals water (3 tbsp/5 gals)	
Horn flies, Face flies Stable flies, House flies, Horse flies, Black flies, Mosquitoes, Eye gnats,	Sprayer	(For 32oz:) 1 qt to 50 gals water (6 tbsp/5 gals)	1-2 qts of coarse spray per animal over whole body surface. For mange, scabies, ticks, and lice,
		ATPORA	NO 11% FC: FDA Rea No 773-50

Mange mites, Scabies Mites, ticks, lice, Sheep keds		(For 16oz:) 1 pt to 25 gals water (3 tbsp/2.5 gals)	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)	1-2 oz spray per animal. Spot treat back, face, legs, and ears.
		(For 16oz:) 1 pt to 2.5 gals water (3 tbsp/qt)	
Horn flies, Face flies Stable flies	Back Rubber/ Self Oiler	(For 32oz:) 1 qt to 20 gals diesel oil (6 tbsp/2 gals)	Keep rubbing device charged. Results improved by daily forced use.
		(For 16oz:) 1 pt to 10 gals diesel oil (3 tbsp/gal)	
POULTRY			
Target Species Northern fowl mites Lice	Use Sprayer	Dilute (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)	Application Rate 1 gal of coarse spray per 100 birds, paying particular attention to vent area.
OVACIANTE		(c 130p/210 gene)	
SWINE	II.	Dilata	Auglion4les Dete
Target Species Lice, mange	Use Sprayer	Dilute (For 32oz:) 1 qt to 50 gals water (6 tbsp/5 gals)	Application Rate Thoroughly wet animals, including ears. For mange, repeat at 14 days.
		(For 16oz:)	10.44W FO FDA D N 370.50

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 House flies, Stable flies, Little house flies (Fannia spp.) Aids in control of cockroaches, ants, spiders, mosquitoes crickets, Face flies.	Use Sprayer	Dilute (For 32oz:) 1 qt to 20 gals water (6 tbsp/2 gals) (For 16oz:) 1 pt to 10 gals water (3 tbsp/gal)	Application Rate Spray to point of runoff or 1 gal per 750-1,000 sq ft.
	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 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. All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: 1) Application to pervious surfaces such as soil, lawn, turf, and other vegetation; 2) Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (e.g. soil, mulch, or lawn); 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; and 5) Applications to vertical surfaces directly above pervious surface (such as soil, lawn, turf, mulch or other

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

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, 2 ft. by 1 ft. or 4 ft. by 0.5 ft.).

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. Treat surfaces to ensure thorough coverage but avoid runoff.

Do not allow the product to enter any drain during or after application. 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.

For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.

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.

SPRAY DRIFT ADVISORIES <u>Handheld Technology Applications</u>: Take precautions to minimize spray drift.

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. Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options.

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

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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