

PM 13

773-59

12/6/96

MVI 11/96 773-59 / NOTIF

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Approval expires 05-31-98

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060.

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United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number  
248233

Application for Pesticide - Section I

1. Company/Product Number 773-59	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Atroban® 11% EC	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Mallinckrodt Veterinary, Inc. 421 E. Hawley St. Mundelein, IL 60060 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION  
12/6/96

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
Notification of Revision to Advisory Statements per PR Notice 95-2. This notification is consistent with the provisions of PR notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 16 oz and larger sizes		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Eileen T. Valenta	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 847-970-7109
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Eileen T. Valenta</i>	3. Title Regulatory Affairs Specialist	
4. Typed Name Eileen T. Valenta	5. Date 11-13-96	

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Revised Label (pint)

NOTIFICATION

- PMS 341 GREEN
- PMS 186 RED
- PMS 577 SILVER
- PMS 292 BLUE
- BLACK

BEST AVAILABLE COPY

ATROBAN 11% EC (pint)  
LEAFLET LABEL (BACK OF BOTTLE)  
PRINTED AT ACTUAL SIZE

**DIRECTIONS FOR USE continued**

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	1 pt to 10 gals water (3 tbs/gal)	Spray to point of runoff or 1 gal per 750-1000 sq ft.
	Overhead space spray system	1 pt to 10 gal diesel or mineral oil (3 tbs/gal)	4 oz. spray per 1000 cu. ft. of air space

Do not apply dilutions for premise treatment directly on livestock or poultry. Ensure that feed and water are not contaminated by spray drift. For space spraying, do not remain in treated areas and ventilate the area before reoccupying. Animals should be removed from area 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.

**ATROBAN® 11% EC**

**PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS**  
**CAUTION**

Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist.

**STATEMENT OF PRACTICAL TREATMENT**

**If Swallowed:** Call a physician immediately. DO NOT INDUCE VOMITING unless under medical attention.  
**If On Skin:** Remove contaminated clothing and wash skin thoroughly with soap and water.  
**If In Eyes:** Immediately flush eyes with plenty of water. Get medical attention if irritation persists.

1303446B R1096

PULL HERE TO OPEN  
PRESS TO RESEAL

PAT 446892

Revised Label (pint)

BEST AVAILABLE COPY

**ATROBAN® 11% EC**

**SEE BOOKLET FOR STATEMENT OF PRACTICAL TREATMENT AND DIRECTIONS FOR USE**

**NOTICE OF WARRANTY**

MALLINCKRODT VETERINARY, INC. 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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ATROBAN 11% EC (pint)  
LEAFLET LABEL - INSIDE (BACK OF BOTTLE)  
PRINTED AT ACTUAL SIZE

**STATEMENT OF PRACTICAL TREATMENT continued**

If inhaled: Remove victim to fresh air. Apply artificial respiration if needed.

Note to Physician: This product contains petroleum distillates. Vomiting may cause aspiration pneumonia.

**ENVIRONMENTAL HAZARDS**

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

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

**DIRECTIONS FOR USE  
GENERAL CLASSIFICATION**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Mix ATROBAN® 11% EC 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.

Target Species	Use	Dilute	Application Rate
<b>LACTATING AND NON-LACTATING DAIRY CATTLE AND GOATS, BEEF CATTLE, HORSES AND SHEEP</b>			
Horn Flies Only	Sprayer	1 pt to 50 gals water (3 tbspt/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	1 pt to 25 gals water (3 tbspt/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.

**DIRECTIONS FOR USE continued**

Target Species	Use	Dilute	Application Rate
<b>LACTATING AND NON-LACTATING DAIRY CATTLE AND GOATS, BEEF CATTLE, HORSES AND SHEEP</b>			
Horn Flies, Face Flies, Stable Flies, Ear Ticks	Low Pressure Sprayer	1 pt to 2-1/2 gals water (3 tbspt/pt)	1-2 qt spray per animal. Spot front back, face, legs and ears.
Horn Flies, Face Flies, Stable Flies	Back-rubbers Self Oiler	1 pt to 10 gal (water) oil (3 tbspt/gal)	Keep rubbing device charged. Results improved by daily forced use.

**POULTRY**

Northern Fowl Mites, Lice	Sprayer	1 pt to 25 gals water (3 tbspt/2.5 gal)	1 gal of coarse spray per 100 birds paying particular attention to vent area.
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**SWINE**

Lice, Mange		1 pt to 25 gals water (3 tbspt/2.5 gals)	Thoroughly wet animals, including ears. For mange, repeat at 14 days.
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For swine allow 5 days between last treatment and slaughter.

Revised Label (pint)

**BEST AVAILABLE COPY**