

PM

13

773-60

MVI 11/96 773-60 /NOTIF

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
248233

Application for Pesticide - Section I

1. Company/Product Number 773-60	2. EPA Product Manager George Larocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Atroban® 42.5% 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
DEC 6 1996

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 checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 16oz., 32oz., 128oz.	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 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: (312) 347-9709 (Include Area Code)
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	

2 7 4

Revised Label



ATROBAN® 42.5% EC

526012

EMULSIFIABLE CONCENTRATE

INSECTICIDAL SPRAY FOR LIVESTOCK
AND THEIR PREMISES



SPRAY PREMISE

Keep Out of Reach of Children
DANGER
See back panel for additional
precautionary statements.

Active Ingredient:

Permethrin (3-phenoxyphenyl methyl(a) cis, trans-3-(2,2-dichloroethyl)-2, 2-dimethylcyclopropane-carboxylate)	42.5%
Inert Ingredients:	57.5%

This product contains xylene.
cis/trans ratio: Max 55% (z) cis and min 45% (z) trans 100.0%

NET CONTENTS: 1 U.S. Pint (473 mL)

EPA Est. 6175-LA-1

EPA Reg. No. 59-204

Transferred to 773-60

This product contains 0.45lbs (204g) of permethrin per pint (473mL)

Mallinckrodt Veterinary, Inc.

Mundelein, IL 60060

1303449C R1096



PMS 341 GREEN

BLACK

BEST AVAILABLE COPY

LEAFLET LABEL (BACK OF BOTTLE)

Actual Size

Panel 4

Back - Panel 5

Front leaflet label

Revised Label

DIRECTIONS FOR USE continued

(approximately 1 gal/100 birds). One application should eliminate an infestation. Do not treat more often than once every two weeks and do not apply more than four treatments. For Control of Hog Lice on Swine: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:800 (¼ pint/25 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray to thoroughly wet animals to ensure complete coverage (approximately 1 pint/animal). One application should eliminate an infestation. Do not treat swine 5 days prior to slaughter. For Control of Mange Mites on Swine: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:400 (¼ pint/12½ gal). A 1:400 dilution gives a 0.108% permethrin concentration. Apply sufficient spray to thoroughly wet animals to ensure complete coverage (approximately 1 pint/animal). Repeat application in 14 days. Do not treat swine 5 days prior to slaughter. For use in and around Horse, Beef, Dairy, Swine, Sheep and Poultry Premises and Outside Meat Processing Premises for Control of House Flies, Stable Flies, and Little House Flies (*Fannia* spp.). NOTE: This product is not recommended for use on vinyl or plastic surfaces. Dilute Atroban® 42.5% EC with clean water at a ratio of 1:320 (¼ pint/10 gal). A 1:320 dilution gives a 0.128% permethrin concentration. For small amounts of finished spray mix 1½ teaspoons in a gallon of water. Apply finished spray to

DIRECTIONS FOR USE continued

surfaces where flies rest at the rate of one gallon per 750-1000 sq. ft. or to the point of run-off. Timing and frequency of application should be based upon flies reaching nuisance levels but not more often than once every two weeks. If, under conditions of heavy fly pressure, longer residual control is desired, it is permissible to double the above concentration for premise application. Do not apply dilution for premise treatment directly on livestock or poultry. Ensure that animals' feed and water are not contaminated by spray drift. Do not use in milk rooms.

glue area
PAT. 448802Z

ATROBAN® 42.5% EC

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

Corrosive. Causes burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Avoid breathing spray mist. Wear goggles or face shield and rubber gloves when handling this concentrate. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician immediately. DO NOT INDUCE VOMITING unless under medical attention.
If Inhaled: Remove victim to fresh air and apply respiration if indicated.
If On Skin: Remove contaminated clothing and wash skin with plenty of soap and water.

PULL HERE TO OPEN
PRESS TO RESEAL

1303450C R1096

Base Label (that leaflet attaches to)

ATROBAN® 42.5% 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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glue attaches here from back panel.

glue attaches here from Panel 7

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7
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BEST AVAILABLE COPY

ATROBAN® 42.5%
LEAFLET LABEL - INSIDE (BACK OF BOTTLE)

Actual Size

Panel 1

Panel 2

Panel 3

STATEMENT OF PRACTICAL TREATMENT continued

If In Eyes: Immediately flush eyes thoroughly for at least five minutes with plenty of water. Get medical attention.

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

ENVIRONMENTAL HAZARDS

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

PHYSICAL OR CHEMICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

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

Storage: Store in cool, dry place away from heat or open flame.

Pesticide Disposal: Pesticide wastes are acutely 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 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

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Dip Treatment General Instructions: Charge dip vats with recommended application concentration by using quantities of Atroban® 42.5% EC and clean water as directed below. Mix thoroughly before each use. Dip to thoroughly wet animals to insure complete coverage.

Spray Treatment General Instructions: For all sprays intended for direct application to animals and building surfaces, add Atroban® 42.5% EC to clean water as directed below, mix thoroughly and apply as a coarse spray. Spray lactating dairy cows only after milking is completed.

Recommended Applications

The use of Atroban® 42.5% EC requires no withdrawal period between last application and slaughter.

For Control of Horn Flies on Beef, Dairy Cattle (Lactating and Non-Lactating) and Horses: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:1600 (¼ pint/100 gal). A 1:1600 dilution gives a 0.027% permethrin concentration. Apply sufficient spray (approximately 1 qt/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every two weeks.

DIRECTIONS FOR USE continued

For Control of Horn Flies, Face Flies, Stable Flies, House Flies, Horse Flies, Mosquitoes and Lice on Beef, Dairy Cattle (Lactating and Non-Lactating) Sheep, Goats and Horses: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:800 (1 pint/100 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray (approximately 2 qts/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every two weeks.

For Control of Ticks (Including the genera *Boophilus* spp., *Amblyomma*, *Dermacentor* and *Rhipicephalus*), Chorloptic Mites, and Psoroptic (Scabies) Mites on Beef, Dairy Cattle (Lactating and Non-Lactating) Sheep, Goats and Horses: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:800 (1 pint/100 gal). A 1:800 dilution gives a 0.054% concentration. Apply sufficient spray (approximately 2 qts/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every 10 to 14 days.

For Control of Northern Fowl Mites and Lice on Poultry in Cages or Houses: Dilute Atroban® 42.5% EC with clean water at a ratio of 1:800 (¼ pint/25 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray

glue area

Revised Label

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