

FEB 16 2000

Mr. Joseph C. Pavelchak
Schering- Plough Animal Health
1095 Morris Avenue
Union, NJ 07083-1982

Dear Mr. Pavelchak:

Subject: Amendment - label revisions
Atroban 42.5% EC
EPA Registration No. 773-60
Your submission dated November 18, 1999

The product referred to above will be acceptable for registration under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below:

a. Add "This pesticide is toxic to fish and other aquatic organisms" to the beginning of the Environmental Hazards paragraph.

b. Change the word "eliminate" to "control" throughout the labeling.

c. Under premise treatment replace "xxx to the point of runoff" to "but do not allow runoff to occur".

d. Change the Statement of Practical Treatment to First Aid and revise these statements as follows: "IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. 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 IN EYES: Hold eye open ands rinse gently with water 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center for treatment advice. 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 advice."

Also, add the following statement near the first aid statements: "Have the product container or label with you when calling a poison control center or doctor or going for treatment."

EPA recommends that these statements be boxed or bulleted to present the information in a clear, easy-to-read fashion.

e. Identify protective clothing under Precautionary Statements i.e., "Coveralls worn over long-sleeved shirt and long pants, socks, and chemical resistant footwear."

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 16 2000

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

773-60

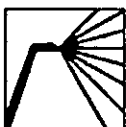
0061-5054-01



ATROBAN[®] 42.5% EC

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(±) cis, trans-3-(2,2-dichloroethenyl)-2, 2-dimethylcyclopropanecarboxylate*..... 42.5%

INERT INGREDIENTS: 57.5%

This product contains xylene. 100.0%


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

Contains petroleum distillates.

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

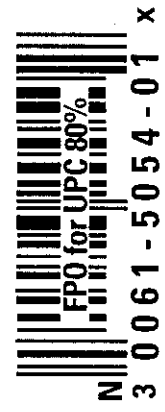
EPA Reg. No. 773-60 EPA Est. No. 6175-LA-1

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

 Schering-Plough Animal Health

Schering-Plough Animal Health Corp., 1095 Morris Avenue, Union, NJ 07083.

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ATROBAN® 42.5% EC

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

NOTICE OF WARRANTY

SCHERING-PLOUGH ANIMAL HEALTH CORP. 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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STATEMENT OF PRACTICAL TREATMENT continued

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

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 insecticidal spray and clean water as directed below. Mix thoroughly before each use. Dip to thoroughly wet animals to ensure complete coverage.

Spray Treatment General Instructions: For all sprays intended for direct application to animals and building surfaces, add ATROBAN® 42.5% EC insecticidal spray 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 insecticidal spray 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 insecticidal spray with clean water at a ratio of 1:1600 (1/4 pint/100 gal). A 1:1600 dilution gives a 0.027% permethrin concentration. Apply

DIRECTIONS FOR USE continued

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 2 weeks.

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 insecticidal spray 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 2 weeks.

For Control of Ticks (including the genera *Boophilus* spp., *Amblyomma*, *Dermacentor*, and *Rhipicephalus*), Chorioptic mites, and Psoroptic (Scabies) mites on Beef, Dairy Cattle (Lactating and Non-Lactating), Sheep, Goats, and Horses: Dilute ATROBAN® 42.5% EC insecticidal spray 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.

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DIRECTIONS FOR USE continued

For Control of Northern fowl mites and Lice on Poultry in Cages or Houses: Dilute ATROBAN® 42.5% EC insecticidal spray with clean water at a ratio of 1:800 (1/4 pint/25 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray (approximately 1 gal/100 birds). One application should eliminate an infestation. Do not treat more often than once every 2 weeks and do not apply more than four treatments.

For Control of Hog lice on Swine: Dilute ATROBAN® 42.5% EC insecticidal spray with clean water at a ratio of 1:800 (1/4 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 insecticidal spray with clean water at a ratio of 1:400 (1/4 pint/12 1/2 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.

DIRECTIONS FOR USE continued

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 insecticidal spray with clean water at a ratio of 1:320 (1/4 pint/10 gal). A 1:320 dilution gives a 0.128% permethrin concentration. For small amounts of finished spray, mix 1 1/2 teaspoonfuls in a gallon of water. Apply finished spray to 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 2 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.

ATROBAN® 42.5% EC

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

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

STATEMENT OF PRACTICAL TREATMENT

If On Skin: Wash with plenty of soap and water. Get medical attention. **If In Eyes:** Flush eyes with plenty of water. Call a physician if irritation persists. **If Swallowed:** Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol. **If Inhaled:** Remove victim to fresh air and apply respiration if indicated. Get medical attention.

20722312 Rev. 4/99

EC (Fly & Fannia) Pet. 448822

PULL HERE TO OPEN
PRESS TO RESEAL

FRONT COVER BLEED AREA

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