

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 1 6 2003

Patricia A. Sheehy Schering-Plough Animal Health Corp. 1095 Morris Avenue Union, New Jersey 07083

Subject:

Label Amendment per PR Notice 2001-1, First Aid Statement

Atroban 42.5% EC EPA Reg. No. 773-60

Your Submission Dated May 1, 2003

Dear Ms. Sheehy:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Replace "Harmful if swallowed." with "Harmful if swallowed or inhaled." in the Precautionary Statements.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

George T. LaRocca

Product Manager (3)

Insecticide Branch

Registration Division (7505C)



First Aid

with COMMENTS
In EPA Letter Dated
SEP \ 6 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

Treats 800
550 lb Head
of cattle
based on horn fly dosage

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ATROBAN 42.5%

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Corrosive. Causes skin burns and substantial but temporary eye injury. 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 (coverall worn over short sleeve shirt and short pants, socks, chemical resistant foot wear and gloves) when handling this concentrate. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and other aquatic organisms. 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. Apply this product only as specifies on this label

PHYSICAL OR CHEMICAL HAZARDS

Do not store near heat or open flame.

FIRST AID

If In Eyes • Hold eyes 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 clothing • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice. If Swallowed • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a 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 treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Control center at 1-303-595-4869 for emergency medical treatment information.

NOTE TO PHYSICIAN

Contains petroleum distillates. Vomiting may cause aspiration pneumonia.

STORAGE AND DISPOSAL

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

Storage: Store in cool dry place.

Pesticide Disposal: Pesticide wastes are toxic. 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 Wastes 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 incinerator or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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ATROBAN 42.5%

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

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DIRECTIONS FOR USE continued

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 (½ 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 2 weeks.

For Control of Horn flies, Face flies, Stable flies, House 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 qtx-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,

DIRECTIONS FOR USE continued

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.

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 control 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 control an infestation Do not treat swine 5 days prior to slaughter.

For Control of Mange mites on Swine: Dilute ATROBAN* 42.5% EC

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ATROBAN 42.5%

DIRECTIONS FOR USE continued

A 1:400 dilution gives a 0.108% permethrin concentration. Apply sufficient spray to thoroughly wet animals to ensure complete coveage (approximately 1 pint/animal). Repeat application in 14 days. <u>Do not treat swine 5 days prior to slaughter</u>.

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 dean 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 11/2 teaspoonfuls in a gallon of water. Apply finished spray are the state of the part spray, mix 172 teaspoontus in a gailori of water. Apply finished spray to surfaces where flies rest at the rate of one gallon per 750-1000 sq ft, but do not allow runoff to occur. 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

ATROBAN® 42.5% EC

Insecticidal Spray SEE BOOKLET FOR STATEMENT OF PRACTICAL TREATMENT AND DIRECTIONS FOR USE

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