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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 31 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 and PR Notice 2001-6, Storage & Disposal
Ectiban Pour-On Insecticide
EPA Reg. No. 773-66
Your Letter Dated: October 25, 2002

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 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. Due to the presence of petroleum distillate revise in the formulation revise the If Swallowed first aid in accordance with Section III G of the PR Notice 2001-1.
2. Based on the acute toxicity profile for this product revise the section under Precautionary Hazards to read:

"Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling."

We note that we have not received a response to letter of April 19, 2000 regarding efficacy studies on file for this product. Please respond. If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,

A handwritten signature in cursive that reads "BeWanda Alexander for".

George T. LaRocca

Product Manager (13)

Insecticide Branch

Registration Division (7505C)

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ATROBAN® DELICE POUR-ON US 1 Gallon

Alternate Brandnames: ATROBAN® DELICE POUR-ON Insecticide
EXPAR Pour-On

0061-5052-03

ATROBAN® DELICE

POUR-ON INSECTICIDE



**NON-SYSTEMIC POUR-ON INSECTICIDE FOR BEEF, LACTATING AND NON-LACTATING DAIRY CATTLE
CONTROLS LICE AND FLIES ON CATTLE
CONTROLS KEDS AND LICE ON SHEEP**

Active Ingredient:
Permethrin: 3-(phenoxyphenyl)methyl (+)-cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate* 1.0%
Other Ingredients** 99.0%
*cis:trans ratio: Min 95% cis and max 05% trans
**Contains petroleum distillates. 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 773-66 EPA Est. No. 6175-LA-1
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**Treats 46
550lb Cattle**

 Schering-Plough Animal Health **Net Contents:
One U.S. Gallon (3.785 L)**

ACCEPTED
with COMMENTS
by EPA Louis Rossi

JAN 31 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
773-66

OTHER FRONT PANEL STATEMENTS

"Kills Flies and Lice"

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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Avoid contact with eyes.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Call a poison control center or doctor for treatment advice • Do not induce vomiting unless told to do so by a poison control center or doctor • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • 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.

Alternate Brandnames: ATROBAN[®] DELICE[®] POUR-ON Insecticide
EXPAR Pour-On

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ATROBAN[®] DELICE POUR-ON US 1 Gallon

Alternate Brandnames: ATROBAN[®] DELICE POUR-ON Insecticide
EXPAR Pour-On



DIRECTIONS FOR USE

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

READY TO USE - No dilution necessary.

Apply To	Target Insects	Application Instructions
Lactating and Non-Lactating Dairy Cattle and Beef Cattle and Calves	LICE Horn flies, Face flies and Aids in Control of Horse flies, Stable flies, Mosquitoes, Black flies, and Ticks.	Pour along back and down face. Apply 1/2 fl oz (15 cc) per 100 lbs body wt of animal, up to a maximum of 5 fl oz for any one animal.
Sheep	Sheep Keds LICE	Pour along back. Apply 1/4 fl oz (7.5 cc) per 50 lb body wt of animal, up to a maximum of 3 fl oz for any one animal.

For cattle and sheep, repeat treatment as needed, but not more than once every 2 weeks. For optimum lice control, two treatments at 14-day intervals are recommended.

Special Note: Atroban DELICE Pour-On Insecticide is not effective in controlling cattle grubs.

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 ACCORDANCE WITH THE STATEMENTS ON THIS LABEL.

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