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WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 10, 2003

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

Subject:

Label Amendment - Updating First Aid Statement in Accordance with PR Notice

2001-1,

ATROBAN DELICE Plus Insecticide

EPA Reg. No. 773-72

Your Submission 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 listed below. Please submit three (3) 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 the "If Swallowed" first aid to include "Do not give **any** liquid to the person."
- 2. The pesticide disposal statement appears more restrictive than necessary. Either justify this statement or revise to that appearing on earlier accepted labeling i.e., "Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

Based upon the acute toxicity profile for this product you may delete the "If in eyes and If inhaled first aid statements. If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely, 2500 nota Wyander for George T. LaRocca

Product Manager (13)

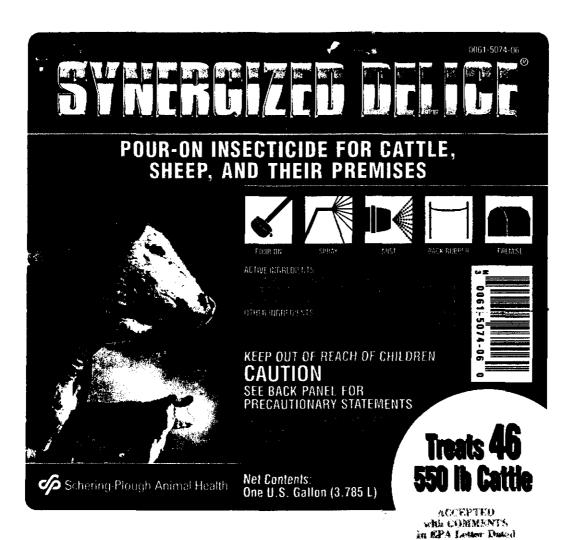
Insecticide Branch

Registration Division (7505C)

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Alternate Brandnames: SYNERGIZED DELICE® POUR-ON



ADD: UNDER OTHER INGREDIENTS***

"****Contains Petroleum Distillates"

OTHER FRONT PANEL STATEMENTS

"Kills Flies and Lice"

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773-78

"Synergized DeLice (stylized) is a registered trademark of Schering-Plough Animal Health Corp."

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Alternate Brandnames: SYNERGIZED DELICE® POUR-ON

ATROBAN DELIGETINSECULCIDE POUR (ON USE Calloid

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful I absorbed through skin. Avoid contact with skin, eyes and clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling.

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	 Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lense 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 Rinse skin immediately with plenty of water for 15-20 minutes Call a poison control center or doctor for treatment advice 		
If swallowed	 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	 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

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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Alternate Brandnames: SYNERGIZED DELICE® POUR-ON

POUR-ON INSECTICIDE FOR CATTLE, SHEEP, AND THEIR PREMISES

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-Coulaing Dairy Came, Beet Cathe and Calves	LICE, Horn flies Face flies Aids in Control of Horse flies. Stable flies, House flies, Mosquitoes and Black flies	Dusage: Apply the feor (15 cc) per 100 lbs body wtiol animal in, the almaximum of 5 flor for any one anima; Pour On: Pour correct those afor a back and down face. Ready To Use Sprayer: Use undiffused in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears Back Rubber Use. Mix it pint per gallon #2 dieset or imneration. Kixportibing device charged Results improved by daily forced use.
Sheep	Sheep keds, LICE	Pour along back Apply 1/4 ft oz (7.5 cc) per 50 lbs body wt of animal up to a maximum of 3 ft oz for any one animal. For optimum control lab animals in the flock should be treated after shearing.
Premises—In and around Horse, Beef, Dairy, Swine, Sheep and Poultry premises. Animal Hospital Pens and Kennels and "outside" Meat Processing Premises	House flies, Stable flies Face flies, Gnats, Mosquitoes, Black flies, Fleas, Little House flies (Fanna spp), Aids in control of cockroaches, ants, spiders, crickets	For use as a ready-to-use spot spray or premise spray, use undifined in a mist sprayer. Apply directly to surface to leave a residual insecticidal coating, paying particular attention to areas where insects cravif or anoth One gallon will treat approximately 7.300 square teet.

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

Special Note: SYNERGIZED DELICE Insectocide is not effective in controlling cattle grups. SYNERGIZED DELICE Insectocide is an oil-base, ready-to-use product that may leave an oily appearance on the hau coat of some animals. SYNERGIZED DELICE Insectocide should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices.

TREATMENTS AND THE USE OF OTHER PEST CONTROL PRINCIPLES.

NOTICE OF WARRANTY

SCHERING-PLOUGH ANIMAL HEALTH CORP, MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE EXPRESSED OR IMPLED CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORDANCE WITH THE STATEMENTS MADE ON THIS LABEL.

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