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United States Environmental Protection Agency

February 9, 1999

Mr. Joseph C. Pavelchak Schering-Plough Animal Health Corporation 1095 Morris Avenue PO Box 3182 Union, New Jersey 07083-1982

Subject:

Label Amendment to Split Label to 2 and 10 lb label and submission of CSFs

Ectiban® D Insecticide EPA Reg. No. 773-63

Your Letter Dated November 23, 1998

Dear Mr. Pavelchak

The label 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. A stamped copy of the label is enclosed for your records. Please submit two (2) copies of your final printed labeling before you release the product for shipment.

1) Since your product contains the statement "1 oz of this dust equals approximately 2½ level tablespoonfuls" please add the following statement to your Precautionary Statements.

"Food Utensils such as teaspoons and measuring cups should not be used for food purposes after use with insecticide"

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United States Environmental Protection Agency

need to be revised, but we do not have in your file an acute toxicological profile for this product. Please submit a completed data matrix which references the toxicological studies (with MRID numbers) used in the determination of your product's acute toxicological status. We understand that your product has been with a number of companies and are sympathetic, but the need for this information so that we may provide you with the safest and most practical label is essential. If the acute toxicity data was bridged from another product please identify that product. Since we do not have your toxicology information in your file, we are basing your Precautionary Statements on a Tox category III product. Please change your "Statement of Practical Treatment to the following:

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give these anything by mouth and do not induce vomiting.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention

Please change your "Hazards to Humans and Domestic Animals" statement to read the following:

> Harmful if swallowed, inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

3) Your basic and alternate formulations have been found acceptable, however you forgot to date them. Please submit new (dated) copies of your CSFs with your final

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printed labels for our records.

4) For future submissions, please fill out the standard "Application for Pesticide" form (form 8570-1). This helps us process your request as quickly and efficiently as possible.

If you have any further questions regarding this action, please contact Tracy Keigwin of my team at (703) 305-6605.

Sincerely,

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

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Avoid contact with skin and eyes. Avoid breathing dust. STATEMENT OF PRACTICAL TREATMENT In case of skin or eye contact, immediately flush eves with plenty of water.

If inhaled: Move to fresh air.

If Swallowed: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by month to an unconscious person.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Use with care when applying to areas adjacent to any body of water. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

PHYSICAL OR CHEMICAL HAZARDS Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

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

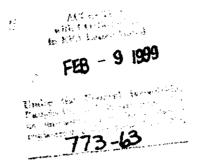
Storage: Store in cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty the container by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of empty container in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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.



Ectiban® D Insecticide

Poultry and Livestock Dust

Active ingredient

Permethrin (3-phenoxyphenyl) methyl

(±) cis. trans-3-(2.2-dichloroethenyl)

-2,2-dimethylcyclo-propanecarboxylate*.....0.25%

100 00%

*cis/trans ratio: Min. 35% (±) cis and max 65% (±) trans

Contains Ectiban insecticide for control of horn flies, faceflies, lice (dairy, beef and swine) and mites (poultry).

KEEP OUT OF REACH OF CHILDREN **CAUTION**

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 2 Pounds (908 g)

EPA Reg. No. 773-63 EPA Est. No. 67517-MO-1



Schering-Plough Animal Health Corporation Union, NJ 07083

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Ready-to-Use in dust bags or hand dusting equipment. Follow specific use instructions on

dust dispensing equipment to be used.					
Apply to	Target	1 Application			
,	Insects	Instructions			
Lactating	Horn flies	DUST BAGS: Suitable for all			
and Non-	Face flies	refill bags. Place contents of			
Lactating	Lice	package in dust bag and refill			
Dairy Cattle		as needed. Results improved			
and		by daily forced use.			
Beef Cattle		DUST READY TO USE			
	}	BAG: Installation of cattle			
		dust bag. Suspend the dust			
		bags by inserting rope, chain			
]	or wire through the grommets			
		at the top of the bag and			
		attaching to an overhead			
		structure, or by hooking the			
		grommets into hooks fixed to			
		a stationary overhead 2x4 at			
		the heights recommended for			
		louse and horn fly or face fly			
		control. Rope, chain or wire			
	1	can also be tied or attached to			
	}	two posts or other fixed points			
		with the dust bag hanging in			
		the center. After the bags are			
	l	in place, pull the rip cord to allow the insecticide to release			
		from the sifter bottom.			
		DIRECT APPLICATION:			
		Apply up to 2 oz. per animal.			
		For lice, a second treatment at			
		14 days is recommended and			
		dust should be rubbed well			
		into coat.			
		into coat.			
Swine	Lice	Apply up to 1 oz. * per animal			
	2.00	paying particular attention to			
		the cars. A second treatment at			
		14 days is recommended. Do			
ł	l	not ship animals for slaughter			
ļ	i	within 5 days of last treatment.			
Poultry	Mites	Apply at a rate of 1 lb/100			
•		birds. Ensure thorough			
		treatment of vent areas.			

*1 oz of this dust equals approximately 2 1/4 level tablespoonsful.

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Avoid contact with skin and eyes. Avoid breathing dust. STATEMENT OF PRACTICAL TREATMENT In case of skin or eye contact, immediately flush eyes with plenty of water.

If inhaled: Move to fresh air.

If Swallowed: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by month to an unconscious person.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Use with care when applying to areas adjacent to any body of water. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

PHYSICAL OR CHEMICAL HAZARDS 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.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

NOTICE OF WARRANTY

Schering-Plough Animal Health Corp. makes no warranty of merchaniability, 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 seatements made on this label.

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Ectiban® D Insecticide

Poultry and Livestock Dust

Active ingredient

Permethrin (3-phenoxyphenyl) methyl (±) cis, trans-3-(2,2-dichloroethenyl) -2,2-dimethylcyclo-propanecarboxylate*.....0.25% Inert Ingredients 99.75% 100.00%

*cis/trans ratio: Min. 35% (1) cis and max 65% (1) trans

Contains Ectiban insecticide for control of horn thes, facethes, face (dairy, beef and swine) and mites (poultry).

KEEP OUT OF REACH OF CHILDREN **CAUTION**

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 10 Pounds (4.54 kg) EPA Reg. No. 773-63 EPA Est. No. 67517-MO-1



Schering-Plough Animal Health Corporation Union, NJ 07083

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Ready-to-Use in dust bags or hand dusting equipment. Follow specific use instructions on dust dispensing aguinment to be used

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Apply to	Target	Application			
	Insects	Instructions			
Lactating	Horn flies	DUST BAGS: Suitable for all			
and Non-	Face flies	refill bags. Place contents of			
Lactating	Lice	package in dust bag and refill			
Dairy Cattle		as needed. Results improved			
and		by daily forced use.			
Beef Cattle		DUST READY TO USE			
		BAG: Installation of cattle			
		dust bag. Suspend the dust			
		bags by inserting rope, chain			
		or wire through the grommets			
		at the top of the bag and			
		attaching to an overhead			
		structure, or by hooking the			
		grommets into hooks fixed to			
		a stationary overhead 2x4 at			
		the heights recommended for			
		louse and horn fly or face fly control. Rope, chain or wire			
	1	can also be tied or attached to			
		two posts or other fixed points			
		with the dust bag hanging in			
	!	the center. After the bugs are			
		in place, pull the rip cord to			
		allow the insecticide to release			
	Í	from the sifter bottom.			
		DIRECT APPLICATION:			
	}	Apply up to 2 oz.* per animal.			
		For lice, a second treatment at			
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Swine	Lice	Apply up to 1 oz.* per animal paying particular attention to			
		the care. A second treatment at			
		14 days is recommended. Do			
		not ship animals for slaughter			
		within 5 days of last treatment.			
		within 3 days of last freatment.			
Poultry	Mites	Apply at a rate of 1 lb /100			
r outry	1471(03	birds. Ensure thorough			
	ĺ	treatment of vent areas.			
		1			

*1 oz of this dust equals approximately 2 1/2 level tablespoonsful.