

109701
Shaughnessy No.

Date out of EFB MAR 3 1983

To: FDR Gee
Product Manager #17
Registration Division (TS-767)

From: E. Regelman, Head (acting)
Review Section 1
Environmental Fate Branch
Hazard Evaluation Division (TS-769c) 

Attached please find the EFB review of...

Reg./File No.: 10182-TE, 10182-TG, 59-ENR

Chemical: Permethrin

Type Product: Insecticide

Product Name: Ectiban Pour-On, Ectiban Wipe-On, Atroban (11%) EC

Company Name: ICI Americas (Ectiban), Cooper (Atroban)

Submission Purpose: Human Exposure Analyses

ZBB Code: ?

ACTION CODE: 435

Date In: 2/10/83

EFB # 207, 206, 210

Date Completed: 4 2 MAR 1983

TAIS (level II) Days

20 5

Deferrals To:

 Ecological Effects Branch

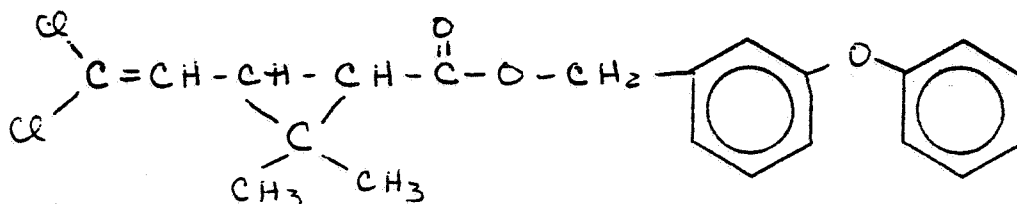
 Residue Chemistry Branch

 X Toxicology Branch

I. INTRODUCTION

This review is the fourth in a series of human exposure analyses requested by RD for the insecticide permethrin. Previous exposure analyses are dated 01/19/83, 01/26/83, and 02/02/83. The products reviewed for this assessment are Ectiban Pour-On, Ectiban Wipe-On, and Atraban EC. The labels are found in Attachment A.

II. Permethrin



(3-phenoxyphenyl)methyl(+)-cis,trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

Ectiban Pour-On and Ectiban Wipe-On:

cis/trans ratio: Min 35% (+) cis and max 65% (+) trans

Atraban EC:

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

III. Exposure Assessment

A. Ectiban Wipe-On and Ectiban Pour-On

Both of these products contain 1% permethrin. Each is applied undiluted to the animal. Ectiban Wipe-On is applied to horses or ponies using a sponge or cloth. About 2-4 oz of the Wipe-On is used per animal and treatment may be repeated after 3-7 days or as necessary. Up to 5 oz of the Pour-On product may be applied to cattle and treatment may be repeated every two weeks. No protective clothing such as gloves is recommended.

1. Assumptions

- Because of the similarities between the two products, they are considered together for determining the potential exposure. It is recognized that with the Wipe-On product greater exposure could result because of direct dermal exposure to the hands while product is being applied. It is believed that with the Pour-On product this dermal exposure is not expected but might occur if the farmer is looking for uniform treatment of animal.
- Since these are direct application methods and potentially are time consuming, it is not expected that a farmer would use this technique on more than a half dozen animals spending about 5-10 min per animal (Wipe-On).

- c. It is assumed that no protective clothing is worn. Further it is assumed that a short sleeved shirt and long pants are worn. The face, back of neck, the "V" of chest, the forearms, and the hands are unclothed. The total skin area exposed is 0.294 m^2 (Hayes, 1975).
- d. According to the labels treatment could occur as frequently as every 3 days during a 5 month long fly season. Minimally, treatment could occur every two weeks or less. Annual exposure to permethrin spanning this range of application intervals will be determined (that is, 10-50 applications per year).
- e. Dermal and respiratory absorption is assumed to be 100%.

2.1 Calculations - Dermal

The estimates which follow are prepared using the same procedure outlined for determining the dermal and respiratory exposures for permethrin products found in our review of 02/02/83 (Attachment B). Further, for purposes of calculation, it will be assumed that a constant amount of product is used per animal: 4 oz product.

Exposure per application

Since there are 0.01 lb ai/pt, then there are 0.0025 lb ai/4 oz of product which is 0.04 oz ai/0.03 gal.

$$\frac{0.04 \text{ oz}}{0.03 \text{ gal}} \times \frac{170 \text{ mg-gal}}{\text{oz - application}} = 227 \text{ mg/application}$$

Exposure per hour

Since the treatment of about 6 animals may take from 5-10 min/animal or about an hour, it will be assumed that hourly exposure is the same as the exposure per application.

Annual exposure

Since 10-50 treatments may occur, the annual exposure range is determined to be

$$2270 - 11350 \text{ mg/yr}$$

2.2 Calculations: Respiratory

Since these products are not sprayed on the animals, the potential for breathing respirable droplets containing permethrin is considered to be negligible.

B. Atroban EC

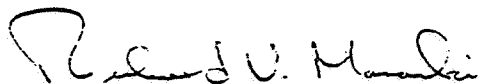
This product is similar to the products reviewed in our review of 02/02/83. The dilution and application rates and techniques do not differ significantly from those EC products reviewed earlier. It will be assumed, therefore, that the potential exposure to Atroban EC (11%) will fall in the range determined for the other EC products.

EFB takes note of the fact that Mineral Seal Oil is listed as an active ingredient on the label. Exposure to this ingredient is not considered in this review.

4.0 CONCLUSIONS

A summary of potential exposures is presented in the following two tables. Table O shows the exposures to the Wipe-On and Pour-On products. The second table was reproduced from the 02/02/83 review and summarizes exposures to EC products containing permethrin.

EFB defers to Tox Branch the determination of the risk assessment based on the exposure values found in the Tables.



Richard V. Moraski, Ph.D.
Chemist, Review Section No. 1
Environmental Fate Branch, HED

Table O. A Summary of Potential Exposure to Ectiban Wipe-On and Ectiban Pour-On.

	<u>Exposure per Application* (mg/application)</u>	<u>Annual Exposure** (mg/yr)</u>
Dermal	227	2270-11350
Respiratory	0	0

* This is also hourly exposure.

** Assumes 10-50 applications/year.

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Table. Summary of Applicator Exposure Values to Permethrin in EC Formulations

	<u>Exposure per Application *</u> <u>(mg/application)</u>	<u>Annual Exposure**</u> <u>(mg/yr)</u>
<u>Dermal</u>		
Diluted	2 - 102	20 - 1020
Undiluted	1135 - 2040	11350 - 20400
<u>Respiratory</u>	0.0002 - 0.004	0.002 - 0.04

* This is also hourly exposure since 1 application takes 1 hr.

** Assuming a maximum of 10 applications/yr.

Reference

Hayes, W.J., 1975. Toxicology of Pesticides, Williams and Wilkins Company, Baltimore, 580 pages

ATTACHMENT A

14052-TE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION AVOID CONTACT WITH EYES.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with plenty of water. Get medical attention if infection persists if SWALLOWED: Do not induce vomiting. Call a professional staff should be supervised by a physician or the expiration of the solvent.

For 24 hour emergency assistance call (302) 575-3000.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish. Use with care when applying to areas adjacent to any body of water. Keep out of lakes, streams, ponds, tidal marshes or estuaries. 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: Keep container sealed when not in use. Do not store near food or feed. Protect from freezing. In case of spill on floor or paved surfaces, soak up with sand, earth or synthetic absorbent, remove to chemical wastes area and dispose of in accordance with state and local regulations.

Do not re-use container. Dispose of container in sanitary landfill in accordance with state and local regulations.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or for unusual use conditions, or under conditions not reasonably foreseeable to Seller and Buyer and User assumes the risk of any such use. Seller disclaims all other warranties, expressed or implied, including any warranty of FITNESS OR MERCHANTABILITY. Seller shall be liable for consequential, special or indirect damages resulting from the use or handling of this product and Seller's sole liability and Buyer's and User's exclusive remedy shall be limited to the return of the purchase price.

Ectiban[®]

INSECTICIDE

NON-SYSTEMIC POUR-ON FOR CATTLE

ACTIVE INGREDIENT:

Permethrin:

trans-(2,2-dichloroethenyl)-
2,2-dimethylcyclopropenecarboxylate*

INERT INGREDIENTS 1.0%
..... 99.0%
Total 100.0%

*Cp 1220 ratio 1:1 35% (1:1) (35 and max 65% (1:1) (2:1)



Agricultural Chemicals Division
Wilmington, Delaware 19897

Keep Out
of Reach
of Children
CAUTION

See Side Panel
For additional
Precautionary
Statements and
Practical
Treatment.

U.S. Patent No.
4,024,183
EPA Est. No.

Net Contents:
ONE U.S. GALLON
(3.78 LITERS)

Batch No.

DIRECTIONS FOR USE

READY TO USE — No dilution necessary.

Apply To	Target Insects	Application Instructions
Lactating and Non-lactating Dairy Cattle and Beef Cattle and Calves	Horn Flies Face Flies Lice Aids in Control of: Horse Flies Stable Flies Mosquitoes Blackflies Ticks	Pour along back and down face using cup provided. Apply 1/2 fl. oz. per 100 lbs. body wt. of animal, up to a minimum of 5 fl. oz. for any one animal.

Repeat treatments as needed, but not more than once every 2 weeks. For lice control a double treatment at .4 day interval is recommended.

SPECIAL NOTE: ECTIBAN POUR-ON is not effective in controlling cattle grubs.

10182-16

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION AVOID CONTACT WITH EYES.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with plenty of water. Get medical attention if discomfort persists. IF SWALLOWED: Do not induce vomiting. Call a physician. Vomiting should be supervised by a physician or the professional staff because of the possible pulmonary damage via aspiration of the solvent.

For 24 hour emergency assistance call (302) 575-3000.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish. Use with care when applying to areas adjacent to any body of water. Keep out of lakes, streams, ponds, tidal marshes or estuaries. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label. Do not use on horses or ponies intended for slaughter.

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

STORAGE AND DISPOSAL: Keep container sealed when not in use. Do not store near food or feed. Protect from freezing.

In case of spill on floor or paved surfaces, sweep up with sand, earth or synthetic absorbent. Remove to chemical wastes area and dispose of in accordance with state and local regulations.

Do not reuse container. Dispose of container in sanitary landfill in accordance with state and local regulations.

INSTRUCTIONS TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller and buyer and user assumes the risk of any such use. Seller disclaims all other warranties, expressed or implied, including any warranty of FITNESS OR MERCHANTABILITY. Seller shall not be liable for consequential, special or indirect damages resulting from the use or handling of this product and Seller's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price.

Etibon Wipe-on INSECTICIDE

Keep Out of Reach of Children CAUTION

See Side Panel
For additional
Precautions and
Statements of
Practical
Treatment.

WIFE-ON FLY PROTECTANT FOR HORSES AND PONIES

ACTIVE INGREDIENT:

Permethrin
(1-Phenoxylphenyl methyl (±) etc,
2,2-dimethylcyclopropanecarboxylate*

..... 1.5%
..... 99.5%
INERT INGREDIENTS 100.0%
Total 100.0%
*Clasfione ratio: Min. 35% (±) etc and max. 65% (±) etc

U.S. Patent No.
4,024,183
EPA Est. No.
Net Contents:
ONE U. S. PINT
(0.473 LITERS)
Batch No.



HCH/Amend/LeSalle Inc.

Agricultural Chemicals Division
Wilmington, Delaware 19897

ECTIBAN WIPE-ON controls stable flies, horn flies, blackflies, eye gnats, and house flies on show, race, work or pleasure horses and ponies. Also aids in control of horse flies, mosquitos and ticks.

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. First brush horse's coat to remove excess dirt and dust. Dampen a small sponge or soft cloth with ECTIBAN WIPE-ON. Rub with growth of hair, paying special attention to legs, shoulders and face. For maximum protection apply 2-4 ozs. per animal. Repeat after 3-7 days or as necessary, this will vary according to season, climate and cleanliness of animal.

ECTIBAN WIPE-ON has demonstrated no irritancy to horses.

5-9-62

Label (Can) - Atroban EC (11%) x 1 pint

(Yellow Background)

(Front Panel)

Atroban® 11% EC

Long-lasting Insecticidal Spray for Livestock and Their Premises.

Active Ingredients

Permethrin	
(3-phenoxyphenyl)methyl(±)-cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate*.....	11.0%
Mineral Seal Oil	63.3%
Inert Ingredients	25.7%
	100.0%

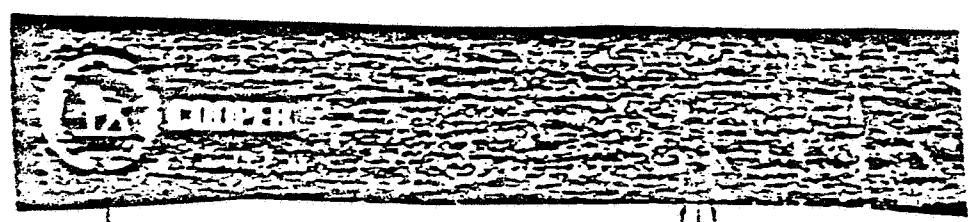
*cis/trans ratio: Max 55%(±)cis and min 45%(±)trans

This product contains 0.107 lbs. of permethrin per pint.

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

Net Contents: 1 Pint
(U.S. Measure)

EPA Est. 59-NC-1
EPA Reg. No.



(red circle)

(Black bar)

Label(Can) - Atroban EC (11%) x 1 pint

(Side Panel (s))

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

CAUTION

Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing.

STATEMENT OF PRACTICAL TREATMENT

If On Skin: Remove contaminated clothing and wash skin thoroughly with soap and water.

If In Eyes: Immediately flush eyes thoroughly for at least 5 minutes with water.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of waste.

**DIRECTIONS FOR USE
GENERAL CLASSIFICATION**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For all sprays intended for direct application to animals and building surfaces, add Atroban 11% EC to clean water as directed below, mix thoroughly, and apply as a coarse spray. Spray lactating dairy cows only after milking is completed. Repeat applications as needed but no more often than once every two weeks.

For Control of Horn Flies on Beef and Dairy Cattle and Horses:

Dilute at the rate of one pt. Atroban 11% EC to 50 gal. of water and apply directly to animals at the approximate rate of one qt. per animal.

For Control of Face Flies, Stable Flies, House Flies, Horse Flies and Lice on Beef and Dairy Cattle and Horses:

Dilute at the rate of one pt. Atroban 11% EC to 25 gal. of water and apply directly to animals at the approximate rate of two qts. per animal, giving particular attention to the face, legs, and underline.

For Control of Ticks and Psoroptic (Scabies) Mites on Beef and Dairy Cattle:

Dilute at the rate of one pt. Atroban 11% EC to 25 gal. of water and apply sufficient spray to thoroughly wet animals and ensure complete coverage. Repeat application in 10 to 14 days for mites.

For Control of Northern Fowl Mites and Lice on Poultry in Cages or Houses:

Dilute at the rate of one pt. Atroban 11% EC to 25 gal. of water and apply finished spray at the rate of one gal. per 100 birds. One application should eliminate an infestation.

For Control of Hog Lice on Swine:

Dilute at the rate of one pt. Atroban 11% EC to 25 gal. of water and apply spray directly to animals at the approximate rate of one pt. per animal. One application should eliminate an infestation.

Label(Can) - Atroban EC (11%) x 1 pint

(Side Panel(s), cont.)

For Control of Mange Mites on Swine:

Dilute at the rate of one pt. Atroban 11% EC to 12½ gals. of water and apply sufficient spray to thoroughly wet animals and ensure complete coverage. Repeat application in 14 days.

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.):

Dilute at the rate of one pt. Atroban 11% EC to 10 gals. of water. For small amounts of finished spray, mix 3 tbsps. in a gal. of water. Apply finished spray to surfaces where flies rest at the rate of one gal. per 750-1000 sq. ft., or to the point of runoff. Timing and frequency of applications should be based upon flies reaching nuisance levels but no more often than once every two 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 dilutions 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.

STORAGE AND DISPOSAL

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

→ Pesticide Disposal: Pesticide, spray mixture or rinse liquids that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

→ Container Disposal: Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

Wellcome Animal Health Division
Burroughs Wellcome Co.
Kansas City, MO 64108 U.S.A.

ATTACHMENT B