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:  ?  

Date In:  2/10/83  

Date Completed:  6/23/83  

Deferrals To:  

- Ecological Effects Branch  
- Residue Chemistry Branch  
- Toxicology Branch  

ACTION CODE:  435  

EFB #: 207, 206, 210  

TAIS (level II)  

Days  

20  

5
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

\[
\text{C} = \text{C} - \text{H} - \text{C} = \text{H} - \text{C} - \text{C} - \text{O} - \text{C} = \text{H}_2 - \text{O} - \text{C} \text{H}_3
\]

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

Ectiban Pour-On and Ectiban Wipe-On:

\text{cis/trans ratio: Min 35% (+) cis and max 65% (+) trans}

Atraban EC:

\text{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

a. 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.

b. 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 m² (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.
3. 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 0 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.

<table>
<thead>
<tr>
<th></th>
<th>Exposure per Application* (mg/application)</th>
<th>Annual Exposure** (mg/yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>227</td>
<td>2270-11350</td>
</tr>
<tr>
<td>Respiratory</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* This is also hourly exposure.
** Assumes 10-50 applications/year.
### Table: Summary of Applicator Exposure Values to Permethrin in EC Formulations

<table>
<thead>
<tr>
<th></th>
<th>Exposure per Application <em>(mg/application)</em></th>
<th>Annual Exposure <strong>(mg/yr)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dermal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diluted</td>
<td>2 – 102</td>
<td>20 – 1020</td>
</tr>
<tr>
<td>Undiluted</td>
<td>1135 – 2040</td>
<td>11350 – 20400</td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td>0.0002 – 0.004</td>
<td>0.002 – 0.04</td>
</tr>
</tbody>
</table>

* This is also hourly exposure since 1 application takes 1 hr.
** Assuming a maximum of 10 applications/yr.
Reference

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
unintended ingestion if swallowed. Do not induce vomiting. Call a
Poison Control Center or a physician immediately. Vomiting should be
supervised by a physician or local medical authority because of the possible pulmonary damage via aspiration of the
solution.

For immediate emergency assistance call (202) 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
sorbent material. Do not treat area with water. Do not use in residential
areas. If chemical waste area and dispose of in accordance with state and
local regulations.

Notice to buyer: Use as directed. The chemical description on the label and
is reasonably fitted for the purposes stated on the label when used in accordance with
directives under normal conditions of use. This warranty does not
exclude, restrict, or modify the operation of the buyer.

Seller warrants that this product shall be conforming in all respects to
specifications and limitations set forth in the label and User shall assume
any risk of use by the user or other person.

For additional Precautionary Statements and Statement of Practical
Treatment, see inside panel.

Active ingredient:

Permethrin

Inactive ingredients:

2.2-dimethylcyclopropanecarboxylate

Non-systemic pour-on for cattle

U.S. Patent No. 3,924,160

EPA EM No.

Net Contents:

One (1) gallon (3.785 liters)

Batch No.

Expiration date: See inside panel.

Ectiban 
INSECTICIDE

Agricultural Chemicals Division
Wilmingston, Delaware 19997

© 1997

Caution of Reach of Children

Keep out of Reach of Children
DIRECTIONS FOR USE

READY TO USE — No dilution necessary.

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

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

SPECIAL NOTE: ECTIBAN POUR-ON is not effective in controlling cattle grubs.
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 (301) 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 polled 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 on floors of panel surfaces, soak up with sand, sawdust 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.

LICENSING AND USAGE: 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 "I-Fly"'s 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 there is no warranty or 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 remedy and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price.

Keep Out of Reach of Children

CAUTION

See Side Panel
For Additional Per-Autory Statements and Statements of Practical Treatment.

U.S. Patent No. 4,024,163
EPA Est. No.

Net Contents:
ONE U.S. PINT
(0.473 LITERS)

Batch No.

Agricultural Chemists, Inc.
Wilmington, Delaware 19897

Ectiban® Wipe-on
INJECTION

WIPE-ON FLY PROTECTANT FOR HORSES AND PONIES

ACTIVE INGREDIENTS:
Farnesihin
[3-Phenoxynapthyl] methyl (4-Chloro-2,6-dimethylphenoxy)carbinol* 1.0%
2,2-Dimethylcyclopropanecarboxylate* 0.6%
INERT INGREDIENTS 98.4%

Total 100.0%

*Chlorine Ratio: Min. 25% (v/v) and Max. 85% (v/v) Iprona
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, mosquitoes 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.
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-phenoxophenyl)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.
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 tbsp.s. 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.

<table>
<thead>
<tr>
<th>STORAGE AND DISPOSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not contaminate water, food or feed by storage or disposal.</td>
</tr>
<tr>
<td><strong>Pesticide Disposal</strong>: 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.</td>
</tr>
<tr>
<td><strong>Container Disposal</strong>: 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.</td>
</tr>
</tbody>
</table>

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