BF-129
TXR-3117

003117

Memorandum

Date: 21 July 1983

Subject: EPA Reg. No. 432-664 FOLIAFUME INSECTICIDE WITH ROTENONE/PYRETHRINS
Caswell #725, 715
In 06-27-83; Record No. 98167

From: B. T. Backus
IRB/TSS

To: Mr. Tim Gardner
Product Manager 17

Registrant: Penick Corporation
Pesticides Technical Support Group
1050 Wall Street West
Lyndhurst, NJ 07071

Active Ingredients:

Rotenone	1.1%
Other Cube Extractives	2.2%
Pyrethrins	0.3%
Petroleum Distillate	3.2%
Aromatic Petroleum Solvent	84.7%
Inert Ingredients:	8.0%

Background:

The registrant has sent in a series of acute toxicity studies (oral LD_{50}, dermal LD_{50}, primary eye and dermal irritation) on this formulation, along with proposed revisions in precautionary labeling.

Comments and Recommendations:

1. The toxicity studies received 4-20-83 are acceptable.

2. The product is in toxicity category II by the oral exposure route, toxicity category III by the dermal LD_{50} potential, is borderline for toxicity categories I and II by the eye exposure potential, and is in category II by dermal irritation potential.

3. We can accept WARNING as the signal word.

4. IRB/TSS recommends revisions in the proposed labeling as indicated below.

Labeling:

1. The Hazards to Humans and Domestic Animals statement should be revised to something like the following"

1 of 5

WARNING: May be fatal if swallowed. Harmful if absorbed through skin. Causes skin irritation. May cause substantial but temporary eye injury. Wear safety glasses. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

2. Because of the considerable irritation potential, the If swallowed statement of practical treatment should be something like:

If Swallowed: Call a physician or Poison Control Center. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. Do not induce vomiting. This product contains aromatic petroleum solvent. Aspiration may be a hazard.

Review:

The following studies were conducted on the formulated product. Studies were conducted at M B Research Laboratories, Inc. Steinsburg and Wentz Rds, P.O. Box 178, Spinnerstown, PA 18968. They were received at EPA 4-20-83, and are in Acc. 250015.

1. Acute Oral LD_{50} - Rat. Project No. MB 82-6509A; dated 3-16-83.

Procedure: Groups of 5M, 5F Wistar albino rats received dosage levels of 0.15, 0.23, 0.47, 0.68, or 5 gm/kg, with subsequent 14-day observation.

Results:

Dosage Level (g/kg)	Mortalities/Animals Dosed M	F
0.15	0/5	0/5
0.23	0/5	4/5
0.47	2/5	5/5
0.68	2/5	5/5
5.0	5/5	5/5

Symptoms: lethargy, diarrhea, dyspnea, piloerection, chromodacryorrhea, ataxia, coma. Deaths occurred by day 2, with most deaths on day of dosage. A frequent necropsy finding in rats which died was hemorrhagic or congested lungs.

Oral LD_{50} (M) = 0.64 (0.42-0.97) g/kg
Oral LD_{50} (F) = 0.21 (0.15-0.29) g/kg
combined oral LD_{50} = 0.34 (0.24-0.49) g/kg

Study Classification: Core Minimum Data (some mortalities cannibalized)

003117

Product Classification: Tox. Cat. II

2. Acute Dermal LD_{50} - Rabbit. Project No. MB 82-6509B; dated 3-02-83.

Procedure: 5M, 5F albino rabbits received a 24-hr occluded dermal exposure to a dosage level of 2 g/kg, with subsequent 14-day observation.

Results: No mortalities. Diarrhea in 6 subjects on day of dosage; all showed considerable dermal irritation which was still present in most at 14 days.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Primary Eye Irritation - Rabbit. Project No. MB 82-6509D; dated 3-02-83.

Procedure: 0.1 ml was applied to one eye of each of 6 rabbits, with no subsequent wash.

Results: Corneal opacity observed in 4/6 rabbits; in 3 of these rabbits it appeared after no corneal involvement was seen at the 24-hr reading. One rabbit still showed corneal opacity on day 21; eyes of 2 rabbits were completely cleared on that day, 2 others showed minimal conjunctival redness only, while one showed minimal redness, minimal swelling.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. II

4. Primary Dermal Irritation - Rabbit. Project No. MB 82-6509C; dated 3-02-83.

Procedure: 0.5 ml was applied to one intact site on each of 6 rabbits, with 4-hr occluded exposure, readings at 4.5,24,48,72 hrs and on days 7 and 14.

Results: Severe erythema/eschar at 72 hrs, slight edema at all sites. Most sites still showed considerable irritation at 7 days, but had healed by 14 days.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. II

Byron T Backus 07-21-83

Byron T. Backus
IRB/TSS

3

Rotenone/Pyrethrins toxicology review

Page _____ is not included in this copy.

Pages 4 through 5 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

X A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
