003222

Memorandum

Date: 8 September 1983

Subject: EPA Reg. No. 432-686 SBP-1382/ALLETHRIN/PIPERONYL BUTOXIDE INSECTICIDE
Caswell #83E, 25, 670
In 08-09-83; record no. 102544

From: B. T. Backus
IRB/TSS

To: Mr. Tim Gardner
Product Manager 17

Registrant: Penick Corp.
Pesticides Technical Support Group
1050 Wall St. West
Lyndhurst, NJ 07071

Active Ingredients:

Resmethrin	0.20%
Allethrin	0.60%
Piperonyl Butoxide, Technical	1.20%
Petroleum Distillate	8.63%
Inert Ingredients:	89.37%

Background:

Acute oral LD_{50}, dermal LD_{50}, inhalation LC_{50}, primary eye and dermal irritation studies have been submitted with proposed labeling.

Comments and Recommendations:

1. The acute oral LD_{50}, dermal LD_{50}, inhalation LC_{50}, primary eye and dermal irritation studies received 6-01-83 are acceptable.

2. IRB/TSS would have no objection, on the basis of hazards to humans and domestic animals, to the labeling as proposed by the registrant with the revisions as indicated below.

Labeling:

1. In addition to the material proposed, the Hazards to Humans and Domestic Animals statement should include the following:

> Harmful if swallowed or absorbed through skin. May cause eye or skin irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

Review:

The following studies were conducted on the registered product formulation without propellant. Studies were conducted at M B Research Laboratories, Inc. Steinsburg & Wentz Rds, P.O. Box 178, Spinnerstown, PA 18968. Studies

were received 6-01-83 and are in Acc. 250403.

1. Acute Oral LD_{50} - Rat. Project No. MB 83-6534A; dated 3-14-83.

Procedure: Groups of 5M, 5F rats were orally dosed at 2.5, 3.5, 5.0 and 7.1 g/kg, with subsequent 14-day observation.

Results:

Dosage Level (g/kg)	Mortalities/Animals Dosed M	F
2.5	1/5	0/5
3.5	3/5	1/5
5.0	4/5	3/5
7.1	5/5	5/5

Oral LD_{50}'s with 95% confidence limits:
(M) = 3.3 (2.5-4.4) g/kg
(F) = 4.3 (3.5-5.3) g/kg
combined = 3.8 (3.1-4.7) g/kg

Symptoms: coma, tremors, dyspnea, ataxia, prostration, flaccid muscle tone, lethargy, diarrhea, chromorhinorrhea, emaciation. Some animals which died showed lung, peritoneal cavity, urinary tract and gastrointestinal abnormalities. Post-sacrifice necropsies of survivors showed some with kidney and gastrointestinal abnormalities.

Study Classification: Core Minimum Data (partial cannibalization of some mortalities)

Product Classification: Tox. Cat. III

2. Acute Dermal LD_{50} - Rabbit. Project No. MB 83-6534B; dated 3-02-83.

Procedure: 2 g/kg was applied to 5M, 5F rabbits with 24-hr occluded dermal exposure and subsequent 14-day observation.

Results: No mortalities. Diarrhea and ptosis noted on day zero. Local skin reactions present and especially severe on day 7. Dermal LD_{50} > 2 g/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Primary Dermal Irritation - Rabbit. Project No. MB 83-6534C; dated 3-02-83.

Procedure: 0.5 ml was applied to one intact site on each of 6 rabbits, with 4-hr occluded exposure.

Results: PDIS (average of readings at 5, 24 and 72 hrs) = 3.1; with some scabbing on day 7. Some effects (including moderate edema) still present in some animals on day 14.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

4. Primary Eye Irritation - Rabbit. Project No. MB 83-6534D, dated 3-02-83.

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

Results: No corneal involvement. Conjunctival irritation in 6/6 eyes, with clearing in 5/6 by day 7. One eye had minimal redness only on day 7.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

The following study was conducted at Temple University, School of Dentistry, 3223 North Broad St., Philadelphia, PA. Received 6-01-83; in Acc. 250403.

5. Acute Inhalation LC_{50} - Rat. Project No. MB 83-6670; dated 03-21-83.

Procedure: 5M, 5F SD rats were exposed for 4 hrs to a calculated nominal concentration of 74.9 mg/L of product. Analytical measurements of concentrations of actives suggest an actual higher value (5.75 mg/L actives ÷ 0.0667 = 86.2 mg/L product. 99.9% by weight of particles were smaller than 10 um; 62.9% were smaller than 5.8 um. Rats were observed for 14 days following exposure.

Results: No mortalities or symptoms. However, all animals had lost weight 2 days after exposure. All males and 3/5 females had gained weight at termination. Inhalation LC_{50} > 5 mg/L (4-hr exposure).

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

Byron T Backus 09/08/83

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