

Memorandum

001835

Date: 12 April 1982

Subject: EPA Reg. No. 432-495 SBP-1382 INSECTICIDE CONCENTRATE 40% FORMULA I  
Caswell #83E

From: B. T. Backus  
IRB/TSS

To: Mr. Franklin Gee  
Product Manager 17

Registrant: Penick Corp.  
Pesticide Technology Dept.  
215 Watchung Ave.  
Orange, NJ 07050

**Active Ingredients:**

Resmethrin.....	40.00%
Related compounds.....	5.45%
Aromatic petroleum solvent.....	52.60%
Inert Ingredients:.....	1.95%

Background:

The registrant is proposing revisions in precautionary and statement of practical treatment labeling. One proposed revision is deletion of "Toxic to Birds." from the labels of products contain resmethrin.

Comments and Recommendations:

1. The proposed label does not have "Keep Out of Reach of Children." However, the last accepted label (dated Nov. 14, 1980) also does not have this statement, so presumably, since this is a formulating-use only product, the likelihood of contact with children is extremely remote (see CFR40 162.10(h)(1)(ii)).
2. With respect to deletion of the bird statement, this material should be referred to the Ecological Effects Branch for their review and comment.
3. The studies received 2-3-82 are acceptable. However, the oral LD50 study is borderline in that sexes of the animals dying at each dosage level, when they died, symptoms, and gross necropsies (if performed) were not reported.
4. IRB/TSS would have no objection, on the basis of hazards to humans and domestic animals, to the proposed labeling received 2-3-82 (note, however, that this label includes: "This product is toxic to fish and birds.").

Review:

The following studies were conducted at Leberco Laboratories, Inc. 123 Hawthorne St., Roselle Park, NJ 07204. Studies were conducted on the registered product. Studies were received at EPA 2-3-82, and are in Acc. 246865.

1. Acute Oral LD50 - Rat. Assay No. 08064; study dated Sept. 22, 1980.

Procedure: Groups of 5M, 5F rats received oral dosages of 4.0, 4.5, or 5.0 ml/kg of product, with subsequent 14-day observation.

<u>Results: Dosage Level (ml/kg)</u>	<u>Mortalities/Animals Dosed</u>
4.0	3/10
4.5	4/10
5.0	7/10

Oral LD50 = 4.6 ml/kg, with 95% confidence limits of 4.14-5.11 ml/kg. Since density of this product = 0.94 this represents 4.32 gm/kg with 95% confidence limits of 3.89-4.80 gm/kg. No symptoms reported.

Study Classification: Marginally acceptable - Core Minimum Data

Product Classification: Tox. Cat. III

2. Acute Dermal LD50 - Rabbit. Assay No. 08065; study dated April 21, 1981.

Procedure: 5M, 5F rabbits received 24-hr occluded dermal exposure to a dosage level of 5 ml/kg (=4.7 gm/kg), with subsequent 14-day observation. 3M, 2F had abraded skin.

Results: No mortalities. All subjects showed moderate (score of 2) erythema at 24 hours, which had disappeared by 2 weeks.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Acute Dermal LD50 - Rabbit. Assay No. 08065; study dated Sept. 8, 1980.

Procedure: 2M, 2F rabbits received 24-hr occluded dermal exposure to a dosage level of 5 ml/kg (= 4.7 gm/kg) with subsequent 14-day observation.

Results: 1M died on day 7. No other mortalities. No noticeable changes in internal organs of subject which died.

Study Classification: Core Supplementary Data (or Core Minimum Data, when combined with study above).

4. Primary Eye Irritation - Rabbit. Assay No. 08001; dated Sept. 1, 1980.

Procedure: 0.1 ml was applied to one eye of each of 9 rabbits. Three eyes were flushed with 20 mls water 30 seconds after instillation; other eyes remained unwashed.

Results: No irritation seen. All eyes scored zero at 24 hrs through 7 days.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. IV

5. Primary Dermal Irritation - Rabbit. Assay No. 14641; dated April 28, 1981.

Procedure: 0.5 mls was applied at each of 2 intact, 2 abraded skin sites on each of 6 rabbits, with 24-hr occluded dermal exposure.

Results: PDIS = 1.42 (calculated from data as presented); maximum score for erythema or edema = 1.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

*Byron T Backus 04/12/82*

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