TOX

849A

001237

DATE: March 24, 1981

SUBJECT: Thiabendazole Concentrate
EPA File Symbol: 43410-U

FROM: Sherkell A. Sterling
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

Applicant: Agri-Chem, Inc.
P.O. Box 17477
Orlando, FL 32860

Active Ingredient:
2-(4-thiazolyl) benzimidazole.....3%
Inert Ingredients.....97%

Background: An acute oral study was submitted in response to two previous reviews (see Sterling November 6, 1980; December 29, 1980). Acute Dermal, Eye and Skin Irritation studies were previously submitted and reviewed; data for these studies were found adequate for conditional registration purposes.

The Acute Oral study was conducted by Tox Monitor Laboratories, Inc. of Oak Park, Illinois. The method of support is "alternate."

Recommendations:

1. The Acute Oral study is considered adequate and acceptable for conditional registraton purposes.

2. Data are sufficient in this instance to show that the Acute Dermal toxicity is no worse than Toxicity Category III in males. Due to the high dosage rate tested in males, females are expected to be no worse than Toxicity Category III.

3. An Acute Inhalation study was not submitted, as stated in previous reviews (see Sterling November 6, 1980; December 29, 1980).

4. The Eye and Skin Irritation studies were found to be adequate and acceptable in previous reviews (see Sterling December 29, 1980).

5. FHB/TSS has no objection to the conditional registration of this product provided that adequate Acute Inhalation data are submitted.

6. The appropriate signal word is "CAUTION."

103

Labeling Recommendations:

1. Under the "Environmental Hazards" section, the statement "Keep out of lakes, streams or ponds" should be revised to the following:

   "Do not apply directly to lakes, streams or ponds."

2. Please note the following revisions under the "Storage and Disposal" heading:

   Pesticide Disposal: Pesticide spray mixture or rinsate 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.

Review:

1. Acute Oral Toxicity; Tox Monitor Report # TM 80-209; February 5, 1981; Acc. No. 244546.

Procedure: Four groups of 4M, 4F Sprague - Dawley rats each received a dosage of Thiabendazole Concentrate at a level of 2.5, 5.0, 10.0 or 20.0 ml/kg. Test substance was administered by an oral feeding tube. Animals were observed for 14 days post-treatment. All animals were subjected to necropsies.

Results: During the study, the following were observed: sluggishness, ruffled fur, poor condition, poor coordination. All survivors gained weight over the 14 day period. Deaths were: none at 2.5 and 5.0 ml/kg; 2/4M and 3/4F at 10 ml/kg ~~ml/kg~~ 4/4M and 4/4F at 20 ml/kg. LD_{50} for M was 9.80 ml/kg (9.78g/kg) with a 95% confidence range of 6.70 - 10.41 ml/kg. LD_{50} for F was 8.41 ml/kg (8.39 g/kg) with a 95% confidence range of 5.95 - 10.17 ml/kg. Necropsies revealed: lungs - dark red, suggestions of pulmonary congestion; stomach - filled with material similar to test substance; small intestine - small amount mucous.

Study Classification: Core Minimum Data.

Toxicity Category: IV - CAUTION

2

THIABENDAZOLE 060101

Page 3 is not included in this copy.

Pages _____ through _____ are not included.

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 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.