

DATE: March 23, 1981

SUBJECT: Fungicide T
EPA File Symbol: 43410-E

Fungicide 4T
EPA File Symbol: 43410-T

From: Sherell 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.....98.5%
Inert Ingredients.....1.5%

Background: An Acute Oral, Acute Inhalation and Primary Skin Irritation studies were submitted on Fungicide T/Fungicide 4T (these formulations are identical). The studies were conducted by Tox Monitor Laboratories, Inc. of Oak Park, Illinois.

The Acute Dermal and Eye Irritation studies were previously submitted and found acceptable (see Sterling, 9/15/80).

The method of support is "Alternate."

Recommendations:

1. The Acute Oral and Primary Dermal Irritation Studies are adequate and acceptable for conditional registration purposes. Please note, however, that in the future additional information must be submitted on testing procedures.
2. The Acute Inhalation study was found to be inadequate to support conditional registration. The toxicity of a product is determined using the actual atmospheric concentration, and not the nominal concentration. It does not appear that an actual concentration was determined since no mention of this was made in the test method description. The registrant should note that if the concentration was the maximum obtainable concentration, a statement to this effect must be submitted for

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consideration. Also, note that if an atmospheric concentration of 20 mg/l is not obtainable, data on at least 5 animals per sex showing that the LC50 is greater than 5 mg/l (atmospheric conc.) with a 4 hour exposure would be acceptable.

3. Thus far Acute Oral, Acute Dermal, Eye and Skin Irritation studies have been found acceptable for conditional registration purposes.
4. FHB/TSS does not recommend for conditional registration until adequate Acute Inhalation information is submitted.

Labeling Recommendations:

1. For both the unit packaging label and the master label, the "Hazards to Humans and Domestic Animals" Statement must read as follows:

"Harmful if swallowed. Avoid contact with skin, eyes or clothing."

Also, the "First Aid" Statement must be modified as follows:

"If in eyes: Flush with water for 15 minutes.
Get medical attention if irritation persists."

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person."

2. For the master label, the "Storage and Disposal" section must be modified in the areas indicated as follows:

"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."

Also, under the "Container" section:

"Dispose of bags according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act."

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3. The "Environmental Hazards" section should change the statement "Keep out of lakes, streams or ponds" to:

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

Review:

1. Acute Oral Toxicity; Tox Monitor Report # TM 80-534; January 16, 1980; Acc. No. 244531

Procedure: Groups of 4M, 4F Sprague - Dawley rats received a dosage of 10.0, 5.0, 2.5 or 1.25 g/kg of Fungicide T as a 50% suspension in distilled water. Animals were observed for 14 days. All animals were subjected to necropsies.

Results: Deaths were: at 10 g/kg, 3/4 M and 4/4 F; at 5 g/kg, 4/4 M and 3/4 F; at 2.5 g/kg, 0/4 M and 1/4 F; at 1.25 g/kg, no deaths. Observation included ruffled fur, arched back, sluggish, poor condition, prostrate; all survivors gained weight. Necropsies revealed: lungs - dark pink throughout; stomach - filled with grey material (like test substance). LD50 for M is 3.97 g/kg with a 95% confidence range of 2.92 - 5.40 g/kg. The LD50 for F is 3.54 g/kg with a 95% confidence range of 2.14 - 5.85 g/kg.

Study Classification: Core Minimum Data. Procedure must be described in further detail.

Toxicity Category: III - CAUTION

2. Inhalation Toxicity; Tox Monitor #TM-80-534; February 4, 1981, Acc. No. 244532

Procedure: 5M, 5F Sprague - Dawley rats were exposed to 20 mg/l of Fungicide T for one hour. The test chamber was made of Plexiglas with a volume of 355.5 l³ with separate cages. Animals were observed for 14 days. All animals were subjected to necropsies. Nominal concentration was 26 mg/l.

Results: All animals survived the test and 14 day observation period. Ruffled fur observed. Autopsy revealed: Lungs - dark pink with pulmonary adhesions (1/5 M) and focal dark red spots (1/5 F).

Study Classification: Core Supplementary Data. Atmospheric concentration data must be submitted. Further details on the testing method must be submitted.

3. Primary Skin Irritation; Tox Monitor #TM 80-534; January 16, 1981; Acc. No. 244530

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Procedure: 6 albino rabbits each received 0.5 ml of Fungicide T at each of 2 sites (1 intact and 1 abraded). Animals were observed at 24, 72 hrs.

Results: At 24 hours, 1/6 abraded sites exhibited very slight erythema. The PII is 0.40.

Study Classification: Core Minimum Data. Only 2 sites tested.

Toxicity Category: IV - CAUTION

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