7-7-79
707-156

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: July 5, 1979

150

SUBJECT: EPA File Symbol: 707-RLA-(156)
DITHANE M-45 FLOWABLE AGRICULTURAL FUNGICIDE Caswell 913A

FROM: B.T. Backus
IRB/TSS

TO: H. Jacoby
Product Manager 21

Applicant: Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105

Active Ingredient:
Coordination product of zinc ion and manganese ethylene bisdithiocarbamate.....35.0%
in which the ingredients are:
Manganese.....7.0%
Zinc.....0.9%
Ethylene bisdithiocarbamate ion.....27.1%
Inert Ingredients:.....65.0%

Background:

A wettable powder formulation containing 62% active ingredient has been previously registered (EPA Reg. No. 707-78); this application is for a liquid product with the same use patterns as the previously registered powder.

The proposed label for DITHANE M-45 FLOWABLE AGRICULTURAL FUNGICIDE is similar to that of EPA Reg. No. 707-78, slight differences are due to the change in percentage active ingredient, conversion of dosages from pounds per acre to quarts per acre, and changes in label format.

The applicant has submitted Acute Oral LD50, Acute Dermal LD50, Skin and Eye Irritation studies on this liquid formulation, and has indicated that an Inhalation LC50 study is forthcoming.

Recommendations:

1. The submitted Oral LD50, Dermal LD50, Skin and Eye Irritation studies are acceptable and adequate for registration purposes. The applicant has indicated an Inhalation LC50 study is underway and will be submitted when completed. Use directions for the previously registered wettable dust formulation (EPA Reg. No. 707-78) include mixing with water and spraying, so inhalation exposure to this active ingredient does not represent an additiona hazard. Also, applicant's proposed label includes a statement to avoid breathing spray mist which would minimize this route of exposure.

2. IRB/TSS has no objection, on the basis of incremental risk hazards to man and the environment, to the conditional registration of this application for the proposed uses.

3. No labeling revisions are necessary from the proposed labeling received 6-5-79.

4. The applicant should submit a list of references to fish and wildlife data for the active ingredient as supporting data.

Review:

Studies were conducted by the Toxicology Department, Rohm and Haas Co, Spring Home, PA 19477. The material tested is identified as Mancozeb Flowable, with 36% active ingredient (label declaration on proposed product is 35%); studies received June 5, 1979, and are in EPA Acc. No. 238564.

1. Acute Oral LD50 (rat)

   Procedure: 10 fasted male rats, mean wt 210 gms, were dosed by gavage with 5 gms/kg of test substance, and observed 14 days.

   Results: No deaths. 3/10 showed brown stained ano-genital area during first day, all recovered within 24 hours. Final mean wt 334 gms. Necropsies were unremarkable.

   Data Classification: Core Minimum Data (only males used, no individual body weight data; we can accept these data because of the high dosage level and mild symptomology).

   Product Classification: Tox. Cat. IV: CAUTION

2. Acute Dermal LD50 (rabbit)

   Procedure: 6 New Zealand White male rabbits, presumably with unabraded skin, were dermally exposed to 5 gm/kg of the test substance for 24 hrs., with a subsequent 14-day observation period.

   Results: No mortalities. One animal had weight loss, scant tray droppings 2-7 days after exposure, mean initial wt was 2.4 kg, mean final wt 2.8 kg. Necropsies were unremarkable.

   Data Classification: Core Minimum Data (only males used, no individual body weight data; we can accept this study because of the high dosage level and mild symptomology).

   Product Classification: Tox. Cat. III:CAUTION

3. Skin Irritation (rabbit)

Procedure: 0.5 ml of the test substance was applied to 2 sites (one abraded, one intact) on each of 6 rabbits with 24-hr exposure.

Results: Most scores at 24 and 72 hours for erythema and edema were zeros; the remaining were all "1" with a Primary Irritation Score = 0.4 .

Data Classification: Core Guideline Data

Product Classification:Tox. Cat. IV:CAUTION

4. Eye Irritation (rabbit)

Procedure: 0.1 ml was instilled into the conjunctival sac of one eye of each of 9 rabbits; 3 rabbits had eye washed 20-30 seconds afterwards.

Results: No corneal opacity. 5/6 unwashed, 1/3 washed eyes showed conjunctival irritation at 4 hrs. All scores zero at 24 hours and subsequently.

Data Classification: Core Guideline Data

Product Classification: Tox. Cat. III:CAUTION

Byron T Backus July 5, 1979

Byron T. Backus
IRB/TSS