UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

005270

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: January 20, 1984

Subject: EPA File Symbol: 10445-TA
Calgon Thiabendazole Dispersion W

From: Deloris F. Graham DFG 1/26/84
FAB/TSS
E 1/26/84

To: Henry Jacoby
Product Manager (21)

Applicant: Calgon Corporation
P.O. Box 1346
Pittsburgh, Pennsylvania 15230

Active Ingredient:
2-(4-thiazolyl) benzimidizole.....50%
Inert Ingredients.....50%

Background: Submitted acute oral, acute dermal, acute inhalation, eye irritation and primary dermal irritation studies. Studies conducted by Wells Laboratories, Inc. Data under accession number 251706. Method of support not indicated.

Recommendation:

1. FHB/TSS finds all studies, except acute dermal study, acceptable to support conditional registration of this product. In the acute dermal study, at least five animals per sex per dose must be used.
2. In the Acute Inhalation study chamber conditions (temperature, humidity, etc), must be submitted.
3. Based on data submitted, the appropriate signal word is CAUTION.
4. A dermal sensitization study was not submitted.

Label:

1. The statement "Keep out of the reach of children" must precede the signal word "CAUTION."

2. Additional labeling precaution may be necessary upon submission of acute dermal toxicity study.

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Review:

1. Acute Oral Toxicity Study: Wells Laboratories, Inc.; Lab. No. E-1612; April 12, 1972.

   Procedure: Reported method used is described in "Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics," published by the Association of Food and Drug Officials of the United States. This report indicates that for a given acute oral assay ten animals per dose, spaced at 0.1 log intervals are set up. Animals are observed for two weeks following treatment. Equal number of male and female animals used per dose. Four groups consisting of 10 animals (5/sex) each received one of the following doses: 11, 12, 13, 14 or 16 g/kg.

   Results: At 11 g/kg, 1/10 died; at 12 g/kg, 2/10 died; at 13 g/kg, 4/10 died; at 14 g/kg, 7/10 died; at 16 g/kg, 9/10 died. No toxic signs reported. Necropsy findings reported included pale and cloudy kidneys, pneumonia and petechiae throughout the alimentary tract. LD_{50} reported as 13.5 g/kg with 19/20 confidence limits between 12.6 and 14.6 g/kg.

   Study Classification: Core Guideline Data

   Toxicity Category: IV - CAUTION

2. Primary Skin Irritation Study: Wells Laboratories, Inc.; Lab. No. E-1615; March 14, 1972.
   Procedure: Six rabbits received 0.5 g of the test material at abraded and intact skin sites under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after treatment.

   Results: At 24 hours, 4/6 had slight erythema (scores of 1) and no edema. At 72 hours, erythema had cleared. Primary Irritation Index = 0.17.

   Study Classification: Core Guideline Data

   Toxicity Category: IV - CAUTION

3. Eye Irritation Study: Wells Laboratories, Inc.; Lab. No. E-1614; March 29, 1972.

   Procedure: Six rabbits received 0.1 g of the test material in one eye each. Observations made for 14 days.

   Results: No corneal opacity, iris irritation or conjunctive irritation present throughout 14-day observation period.

   Study Classification: Core Guideline Data

   Toxicity Category: IV - CAUTION

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4. Acute Dermal Toxicity Study: Wells Laboratories, Inc.; Lab. No. E-1613; April 14, 1972.

   Procedure: Range finding study using two rabbits per each of 6 groups. The following dose levels were used 10, 20, 25, 30, 40 and 50 ml/kg.

   Results: No mortalities. Mild transitory hyperemia and edema reported. Further testing was discontinued because excessive dosing without toxic response as stated in report.

   Study Classification: Core Supplementary Data. At least five animals per sex per dose must be used.

5. Acute Inhalation Toxicity Study: Wells Laboratories, Inc.; Lab. No. E-1616; April 18, 1972.

   Procedure: Four groups consisting of five male and five female rats each were exposed for one hour to one of the following concentrations 50, 200, 500 or 1,000 mg/l.

   Results: No deaths or toxic signs reported.

   Study Classification: Core Minimum Data. Chamber conditions, (temperature, humidity, etc.) must be submitted.

   Toxicity Category: IV - CAUTION

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Page_____ is not included in this copy.

Pages 4 through 5 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.