MEMORANDUM

Date: January 20, 1984

Subject: EPA File Symbol: 10445-7A
Calgon Thia bendazole Dispersion W

From: Deloris F. Graham 065
F4M/TSS

To: Henry Jacoby
Product Manager (21)

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

Active Ingredient:
2-(4-thi oxoy1) benzimidazole...........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. FIH/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.

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. LD50 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


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


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

**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.


**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
Proposed Label Copy for 9 gram size

CALGON THIABENDAZOLE DISPERSION W

To inhibit the growth of fungi in paint and stain, add CALGON THIABENDAZOLE DISPERSION W to paint in the amount indicated by the scale on the plunger of the syringe, mix thoroughly and then use the paint or stain as directed. Do not reuse the syringe. Rinse the syringe thoroughly with water and discard it.

Active ingredient: 2-(4-thiazolyl) benzimidazole ------- 50%

Inert ingredients: ---------------------------------- 50%

Net Weight: 9 grams

U.S. Patents 3,017,415 and 3,370,957

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P.O. Box 1346
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CAUTION!
Keep out of the reach of children.
Harmful if swallowed. Avoid contact with skin or eyes.
In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

EPA Est. No. 36213-Md-1 EPA Reg. No. 10445-

NOTE: Approximate size is 3-3/4" x 3-3/4"
Protect your house from damaging, unsightly mildew.
Fight Mildew with CALGON THIABENDAZOLE DISPERSION W,
an additive for all paints.
CAUTION! Keep out of the reach of children.
Harmful if swallowed.

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CALGON THIABENDAZOLE DISPERSION W is a highly effective, safe, non-metallic fungicide to inhibit mildew on paint, varnish and stain.
Calgon Thiabendazole Dispersion W has been used successfully in millions of gallons of paint for periods of up to five years in homes and industrial installations from the Eastern Shore to the Gulf Coast.
Use Calgon Thiabendazole Dispersion W indoors and outdoors, in both oil-based and water-based paint, where the ugly appearance and destruction by mildew may occur.

CALGON THIABENDAZOLE DISPERSION W can be added even to paints that are already resistant to mildew attack to provide the unique, extra protection your home deserves. Even in very hot, humid weather, CALGON THIABENDAZOLE DISPERSION W does not decompose. CALGON THIABENDAZOLE DISPERSION W does not cause yellowing or sulfide staining, nor does it alter brushing, flow, gloss, color or drying characteristics of paint.

To obtain maximum results, CALGON THIABENDAZOLE DISPERSION W must be completely mixed in the paint, varnish or stain. This can be done with a paint mixer of the type used with an electric hand drill.
Calgon Thiabendazole Dispersion W can also be mixed at your paint store.
After mixing, use the paint as directed.
CAUTION! Keep out of the reach of children
Harmful if swallowed

NOTICE: Buyer assumes all risks of use and handling which are at variance in any way with the directions hereon. There are no warranties which extend beyond the description on the label of the syringe.

EPA Est. No. 36213-Md-1
EPA Reg. No 10445-
END