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

005454

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Date: May 31, 1983

Subject: EPA Registration Number: 10445-32 • EPA Registration Number: 10445-32
TK-50 Dispersion) ~~EX~~ Metasol TK-100 Dispersion

From: Deloris F. Graham ~~EJS~~ 6/17/83
FHB/TSS CS 6/17/83

To: Henry Jacoby
Product Manager (21)

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

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

Background: Submitted Acute Oral, Eye Irritation and Primary Skin Irritation Studies. Data under Accession Number 249800. Studies conducted by Wells Laboratories, Inc. Cite-All Method of Support. ~~Studies~~ Studies conducted on EPA Registration number 10445-32.

Recommendation:

(1) FHB/TSS finds these data unacceptable to support conditional registration of this product.

a. In the previously mentioned studies, method of procedure including doses used, and LD_{50} with 95% confidence limits for Acute Oral Study must be submitted.

b. Acute Dermal and Acute Inhalation Studies were not submitted and these studies must be submitted.

Label:

(1) Labeling comments reserved until acceptable data are submitted.

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Review:

(1) Acute Oral Toxicity Study: Wells Laboratories, Inc.; Lab. # E-6618; March 28, 1973.

Procedure: Reference method described in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics."

Results: Oral LD_{50} = 8.6 ml/kg; 19/20. Confidence limits = 7.81 to 9.46 ml/kg. Necropsy findings indicated hemorrhages in the lungs and heart, fluids in the chest cavity and petachiae throughout the alimentary tract.

Study Classification: Core Supplementary Data. LD_{50} for males and females must be used. Individual symptomatology and necropsy reports for each animal must be submitted.

(2) Eye Irritation Study: Wells Laboratories, Inc.; Lab # E-6617; March 12, 1973.

Procedure: Referenced method described in the Hazardous Substances Labeling Act Regulations, Part 191, Chapter 1, Title 21, Code of Federal Regulations, paragraph 191.12. Dose: 0.1 gm in one eye of each of six rabbits.

Results: No irritation.

Study Classification: Core Supplementary Data. Nine animals (six with treated unwashed eyes and three with treated washed eyes) must be used. Method of procedure must be submitted.

(3) Primary Skin Irritation Study: Wells Laboratories; Lab. # E-6616; February 27, 1973.

Procedure: Referenced method described in the U.S. Department of Agriculture, Insecticide, Fungicide and Rodenticide Act, Section 362.3 of the regulations (7 CFR Part 362), paragraph (c).

Results: No irritation. Primary Skin Irritation Index = 0.0.

Study Classification: Core Supplementary Data. Method of procedure including dosage used must be submitted.

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THIABENDAZOLE 060101

Page_____ is not included in this copy.

Pages 3 through 4 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.