



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) ~~TK~~ Metasol TK-100 Dispersion W.

From: Deloris F. Graham *DFG 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 LD₅₀ 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 LD₅₀ = 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. LD₅₀ 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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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.
 - ☒ 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.
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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.
