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

005453

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Date: May 27, 1983

Subject: EPA Registration Number: 10445-31
TK-100 Liquid Concentrate

From: Deloris F. Graham DFG. 6/17/83
PHB/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, as the
hypophosphite salt . . . . . .20%
Inert Ingredient . . . . . .80%

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Primary Skin Irritation studies. Data under Accession Number 249806. Cite-All Method of Support.

Recommendation:

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

a. In the Acute Oral, Acute Dermal and Acute Inhalation and Primary Skin Studies, method of procedure, dosage, individual symptomatology and necropsy reports, $LC_{50}$ and 95% confidence limits must be submitted.

b. In the Eye Irritation Study, nine animals (six with treated unwashed eyes and three with treated washed eyes) must be used. Method of procedure 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. # D-4293; September 10, 1970.

Procedure must be submitted. Exact doses used could not be determined. However, it was stated that the $LD_{50}$ was 5300 mg/kg, with 19/20 confidence limits between 5100 and 5510 mg/kg.

Study Classification: Core Supplementary Data. Procedure methods must be submitted. Doses must be given. Individual symptomatology and necropsy report for each animal must be submitted also.

(2) Acute Dermal Toxicity Study: Wells Laboratories, Inc.; Lab # D-4296; September 10, 1970.

Procedure: Four young adult rabbits weighing between 2.5 kilograms per each of three groups received one of the following doses: 5000; 10,000; or 20,000 mg/kg. Test material was applied to abraded skin under occlusive wrap for 24-hour exposure. Observations were made for two weeks after treatment.

Results: No mortalities. Mild to moderate hyperemia and slight edema and moderate sloughing. Hair regrowth showed no aberrations.

Study Classification: Core Supplementary Data. Five male and five females per dose must be used. Individual symptomatology and necropsy reports for each animal must be submitted. $LD_{50}$ and 95% confidence limits for males and females individually must be submitted.

(3) Primary Skin Irritation Study: Wells Laboratories; Lab. # F-369; October 15, 1983.

Procedure: See U.S. Department of Agriculture, Federal Insecticide, Fungicide and Rodenticide Act, Section 362.3 of the regulations (7 CFR Part 363), paragraph (c).

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

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

(4) Eye Irritation Study: Wells Laboratories; Lab. # F-370; October 19, 1973.

Procedure: See U.S. Department of Agriculture, Federal Insecticide, Fungicide and Rodenticide Act, Section of 363.116 regulations (7 CFR part 363) paragraph (d). Dose: 0.1 ml in one eye of each of six rabbits.

Results: No irritation.

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

(5) Acute Inhalation Toxicity Study: Wells Laboratories; Lab. # P-371; October 26, 1973.

Procedure: See U.S.D.A. Regulation 362.8, Title 7, Chapter III, part 362, Code of Federal Regulations. Ten rats inhaled 2 mg/liter for one hour.

Results: All animals (5M and 5F per dose) survived at the following doses: 2 4 and 6 ml/liter. No sign of toxicity observed and no gross findings at necropsy.

Study Classification: Core Supplementary Data. Actual concentrations in mg/l must be used. $LC_{50}$ and 95% confidence limits for males and females must be submitted.

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Page 4 is not included in this copy.

Pages _____ through _____ 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.