Date:      May 31, 1983

Subject:   EPA Registration Number: 10445-32
           TK-50 Dispersion

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

To:        Henry Jacoby
           Product Manager (21)

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

Active Ingredients:
   2-(4-thiazoyl)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 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.
Review:


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 petechiae 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.


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.
Page___ 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.
[ ] 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.