

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

005820

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Carnel # 849 F.

Date:

December 12, 1984

Subject:

EPA File Symbol 10445-TA

Calgon Theabendazole Dispersion W.

From:

Deloris F. Graham A. 191/11

FHB/TSS

LEW 12/21/84

To:

Henry Jacoby

Product Manager (21)

Applicant: Calgon Corporation

P.O. Box 1346

Pittsburgh, PA 15230

Active Ingredient:

2-(4-thiazolyl)benzimidizole Iner: Ingredients 50%

Background: Submitted Dermal Sensitization Study to fulfill acute data requirements as requested in previous review dated January 20, 1984. Data under accession no. 252777. Method of support not indicated.

Recommendation:

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

Label:

(1) No additional labeling necessary for Dermal Sensitization.

Review:

(1) Dermal Sensitization Study: Merck Sharp & Pohme Research Laboratories; March 31, 1966.

<u>Procedure</u>: Thirteen guinea pigs received 0.05 ml of a 0.1 percent suspension of the test material (theabendazole) in physiological saline as first injection of the induction phase. The remaining nine injections were administered in 0.1 ml aliquats. Two weeks after tenth injection the animals received a 0.05 ml challenge dose. Observations were made at 1.4 and 24 hours after first and last injections.

Results: Three guinea pigs died during study. However, the deaths were reported as not drug related. Report indicated that reaction in the ten remaining animals was no greater two weeks after tenth injection than those after initial injection. Very, very slight to slight erythema noted. Very slight edema in some animals 24 hours after initial injection.

Study Classification: Core Minimum Data

Toxicity Category: Non-sensitizing

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