Subject: EPA File Symbol: 47916-UT
Copper Hydroxide Flowable

MRID
00145516-20

005805

From: Deloris F. Graham
FHB/SSB

E 2/1/85

To: Henry Jacoby
Product Manager (21)

Applicant: Wesley Industries, Inc.
P.O. Box 490
Montrose, Alabama 36559

Active Ingredient:
Cupric Hydroxide 37.5%
Inert Ingredients 62.5%

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Skin Irritation (Rabbit) Studies conducted by Stillmeadow, Inc. Data under accession numbers: 253596, 253597, 253598, 253599 and 253600. Method of support not indicated.

Recommendations:

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

(2) A Waived Sensitization 1/11
(2) A request to waive Dermal Sensitization was submitted based on information in a FOIA Freedom of Information Search by Ms. Barbara Barber and subsequent discussions

Data declined by Petition Product Manager (21) and applicant was not made available to TSS Reviewer.

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(3) Appropriate signal word is CAUTION.

Label:

(1) Under the Heading "Environmental Hazards" the word "CAUTION" must be deleted.

(2) The general instructions statements should be placed under the heading "Directions for Use".

(3) Additional labeling may be necessary upon submission of Dermal Sensitization data.

Review:

(1) Skin Irritation Study: Stillmeadow, Inc.; Project No. 3235-84; March 15, 1984; EPA Acc. # 253596

Procedure: Six rabbits received 0.5 ml of the test material at intact skin sites under occlusive wrap for 24 hour exposure period. Observations made at 24, 48 and 72 hours after treatment.

Results: at 24 hours, 1/6 had slight erythema (1/6=1) and edema (1/6=1); 5/6 pale green discoloration of test site hairs. At 72 hours, irritation had cleared. Maximum irritation score reported to be 0.3

Study Classification: Core-Guideline Data

Toxicity Category: IV - CAUTION

Project No. 3233-84, Mar. 30, 1984; EPA Acc. # 253597.

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Procedure: Five male and five female rabbits were administered 2020 mg/kg of the test material at intact skin sites under occlusive wrap for 24 hour exposure period. Observations made at ½, 3 and 6 hours after exposure, then once daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities, toxic signs or abnormalities at necropsy reported. LD50 reported to be greater than 2020 mg/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(3) Acute Oral Toxicity Study: Stillmeadow, Inc.; Project No. 3232-84; April 16, 1984; EPA Acc. # 253598.

Procedure: Four groups consisting of five male and five female rats each received one of the following doses orally: 2000, 2440, 3000, 3660 mg/kg. Two groups consisting of five males each received one of the following doses orally: 4470 or 5450 mg/kg. Observations made frequently on day of treatment, then once daily thereafter for 14 days. Necropsy performed on all animals.

Results: at 2000 mg/kg 1/5F died; at 2440 mg/kg, 3/5M and 1/5F died; at 3000 mg/kg, 1/5M and 2/5F died; at 3660 mg/kg, 2/5M and 5/5F died; at 4470 mg/kg, 1/5M died; at 5450 mg/kg, 5/5M died

decreased defecation, diarrhea, discoloration of feces, emaciation, epistaxis, exophthalmus, hematuria, lacrimation, melanuria, piloerection, polyuria, ptosis, respiratory gurgle, salivation and soft stool.

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Necropsy report revealed diarrhea, epistaxis, melanuria, polyuria and salivation; discoloration of the contents of the gastrointestinal tract, mucosa tested drawn into abdominal cavity, discoloration of adrenal glands, test material in esophagus and mouth, gastrointestinal tract distended with gas, perirenal blood vessels pronounced on cecum, discoloration of contents of urinary ~~bladder~~ bladder, fur around perineum, lung, lung adhered to other tissues, consolidation of livers.

LD50 for males was reported to be 3286 mg/kg with 95% confidence limits between 2584 and 4180 mg/kg. LD50 for females was reported to be 2304 mg/kg with 95% confidence limits between 1973 and 2506 mg/kg. LD50 for males and females combined was reported to be 3092 mg/kg with 95% confidence limits between 2600 and 3628 mg/kg.

Study Classification: Core Guideline Data

Study Category: III (A/T/D)

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits are washed with deionized water for one minute thirty seconds after treatment. Observations were made at 1, 24, 48 and 72 hours and at 4, 7, and 10 days after treatment.

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Results: At 24 hours, 1/6 animals of the ~~unwashed~~ unwashed group had corneal opacity (1/6=10); 5/6 of the unwashed group and 1/3 of the washed group had iris irritation (5/6=5) (1/3=5); 4/6 & 3/3 conjunctive redness (4/6=2) (2/3=1, 1/3=2); 6/6 and 2/3 chemosis (~~4/6~~, 4/6=2, 2/6=3)(1/3=1, 1/3=3); 4/6 + 1/3 discharge (2/6=1, 1/6=2, 3/6=3)(1/3=2).

At 48 hrs, 1/6 + 1/3 conjunctive redness (1/6=1)(1/3=1). Irritation had cleared in both animals by day 10.

~~Study Classification: Core Guideline Data~~

~~Toxicity Category: III - CAUTION~~

(5) Acute Inhalation Toxicity Study: Stillmeadow, Inc.; Project No. 3236-89; April 18, 1984; EPA Acc. # 253660.

Procedure: Five male and five female rats were exposed for four hours to an aerosol concentration. Particle size [illegible]

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3.134 micrometers. Mean temperature was 73.2°F and relative humidity was 99%. Observations made frequently on day of exposure, then once daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities reported. Toxic signs reported included activity decrease, constricted pupils, dilated pupils, exophthalmos, nasal discharge, piloerection, polyuria, ptosis, salivation, swollen neck. Necropsy findings reported included discoloration of lungs, urinary bladder full, sediment in urinary bladders and [illegible]. LC50 reported to be greater than 2.74 mg/L.

Study Classification: Core Guideline [illegible]

Toxicity Category: III [illegible]

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Page _____ is not included in this copy.

Pages 7 through 11 are not included in this copy.

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.

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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.