Date: August 9, 1982

Subject: EPA File Symbol: 1624-RRA
20 Mule Team Boric Acid

005381

From: Deloris F. Graham DFG 8/16/82
FHB/TSS I 8/16/82

To:, Henry Jacoby
Product Manager (21)

Applicant: United States Borax and Chemical Corp.
P.O. Box 4111
Anaheim, CA 92803

Active Ingredient:
Boric Acid (H_3BO_3) 100%

Background: Submitted Acute Dermal, Acute Inhalation and Primary Dermal Irritation Studies as requested by the Agency to complete requirements for a conditional registration. Studies conducted by Bio/dynamics Inc. and Hill Top Research, Inc. Acute Dermal and Primary Dermal Studies under accession number 247814. Acute Inhalation Study not accessioned . Method of support not indicated.

Recommendations:

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

(2) The appropriate signal word is [redacted] WARNING .

Label:

(1) The following statement must be deleted from precautionary statement and placed under Directions For Use.

"Avoid contamination of food and feed. Do not leave container where children or animals may gain access".

Review:

(1) Acute Inhalation Toxicity Study: Bio/dynamics, Inc.; Project # 82-7563; June 29, 1982.

Procedure: 5M and 5F Sprague-Dawley rats were exposed for four hours to an airborne concentration of 0.16 mg/l (nominal concentration was 16 mg/l) under adequate chamber conditions. Average mass median diameter was 8.52 micrometers with a geometric standard deviation range of 2.97 to 38.17. Chamber temperature was 69°F and the mean relative humidity was 94%. Observations were made every 15 minutes during first hour of exposure, hourly

1 4/5

through exposure period, four hours past exposure, and daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. Toxic signs included lacrimation, labored breathing, mucoid or red nasal discharge, dried red nasal discharge, hunched appearance, reduced righting reflex, moist rales, brown anogenital fur, soft stool and swollen cervical area. Small transient weight losses seen in most rats. All rats appeared contaminated with test material. At necropsy, 3M and 1F showed foci or areas of lung discoloration. Since these are considered common pathological findings in Sprague-Dawley rats they were not considered as due to exposure to the test material. LC_{50} greater than 0.16 mg/l airborne concentration.

Study Classification: Core Guideline Data

Toxicity Category: II-WARNING

(2) Acute Dermal Toxicity Study: Hill Top Research, Inc.; Project # 82-0280-21; March 15, 1982.

Procedure: 5M and 5F New Zealand rabbits received 2g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations were made at 1 1/2, 2 1/2 and 4 1/2 hours during the day of treatment, then twice daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. Transient diarrhea observed in two rabbits. Erythema, edema, atonia and disgramation also observed. Necropsy revealed enlarged fallopian tubes in 4/5 females and one of these rabbits showed pale yellow, congested kidneys and gas filled intestines. LD_{50} greater than 2g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

(3) Primary Skin Irritation Study: Hill Top Research, Inc.; Project # 82-0280-21; March 15, 1982.

Procedure: Six New Zealand rabbits received 0.5g of the test material at two abraded and two intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after exposure.

Results: At 24 hours 2/6 had erythema (2/6=1). No edema present. At 72 hours, 1/6 erythema (1/6=1). Primary Irritation Index was 0.1.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

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Page_____ is not included in this copy.

Pages 3 through 5 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.
