UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: January 13, 1982

002832

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

FROM: Deloris F. Graham
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

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

Active Ingredient:
Boric Acid (H_3BO_3 ..... 100%

Background:

Submitted 3 Acute Oral studies conducted by Hazleton Laboratories, an Eye Irritation Study conducted by Hill Top Research, and a Primary Dermal Study conducted by International Bio-Research. Data under accession number 246338. Alternate method of support.

Recommendations:

1. The three acute oral studies and the Eye Irritation Study are acceptable to support conditional registration of this product. However, for future submissions, please note:

   (a) In the Acute Oral Study conducted by Hazleton in 1961, only 5 M animals were used and 5 M and 5 F animals must be used.

2. The Primary Dermal Irritation Study was Core Supplementary, therefore unacceptable for support conditional registration. A 24-hour exposure period, with 2 abraded and 2 intact skin sites per animal must be used. A minimal 72-hour observation period IS REQUIRED.

3. An Acute Dermal and Acute Inhalation Study were not submitted. Each study must be submitted and/or cited.

Label:

1. Labeling comments reserved until previously mentioned deficient data is submitted.

EPA FORM 1320-6 (REV 3-76)

002832

Review:

1. Acute Oral Toxicity Study: Hazleton - Nuclear Sciences Corporation; January 25, 1961.

   Procedure: Five groups consisting of 5 M rats of Long-Evan strain weighing between 85-110 g per group received one of the following doses: 1, 2.15, 4.64, 6.81 and 10 g/kg. Necropsy performed on all animals. Observations made 1, 2, 4 and 24 hours post-treatment, then daily through 7 days.

   Results: At 4.64 g/kg, 6.81 g/kg, and 10 g/kg, 5/5 animals died. Toxicologic signs observed included depression; shallow, rapid respiration, diarrhea; peloerection; ataxia with depressed placement and righting reflexes ptosis, bloody crusts. Necropsy revealed erythemic lungs, slightly congested adrenal, livers showed pale area. LD_{50} was 3.16 g/kg.

   Study Classification: Core Minimum Data. An equal number of male and female animals must be used.

   Toxicity Category: III - CAUTION.

2. Acute Oral Toxicity Study: Hazleton Laboratories, Inc. March 19, 1962.

   Procedure: Six groups consisting of 5 M and 5 F Sprague Dawley rats each weighing between 214 to 307 grams received one of the following doses: 2.0, 2.51, 3.16, 3.98, 5.01 and 6.31 g/kg. Observations made at 1, 2, 4 and 24 hours, then once daily for 14 days. Necropsy performed on all animals.

   Results: At 3.16 k/kg, 2/5 M died; at 3.98 g/kg, 4/5 M and 2/5 F died; at 5.01 g/kg, 5/5 M and 2/5 F died; at 6.31 g/kg, 5/5 M and 5/5 F died. Toxicologic signs observed included slight depression, slightly labored respiration; diarrhea; consolidated areas on the lungs; a bloody crust around the nose; ataxia; ptosis; sprawling of the limbs; depressed righting and placement reflexes; congestion of the lungs; kidneys and adrenals congested; marked inflammation of the pyloric portion of the stomach and intestines; slight tremors and lacrimation. LD_{50} for males was 3.45 g/kg with 95% confidence limits between 2.95 and 4.04 g/kg. LD_{50} for females was 4.08 g/kg with 95% confidence limits between 3.64 and 4.56 g/kg.

   Study Classification: Core Guideline Data.

   Toxicity Category: III- CAUTION.

3. Acute Oral Toxicity Study: Hazleton Laboratories, Inc., March 16, 1962.

   Procedure: Four groups, consisting of 3 mongrel dogs each received one of the following doses: 1.0, 1.59, 2.51 and 3.98 g/kg. Observations continuously first eight hours after treatment, then daily for 7 days.

2

Results: With one exception, all dogs receiving boric acid vomitted 20 to 45 minutes after dosage. The dogs were rested for six days and restudied at new dosage levels of 158, 251, 398 and 631 mg/kg. No mortalities. Approximately 37 to 45 minutes after dosage two dogs vomitted a foamy white liquid. One hour after administration, 3 dogs showed mild emesis. No signs of systemic toxicity.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

4. Eye Irritation Study: Hill Top Research, Inc; Report S-152A; May 16, 1968.

Procedure: 100 mg of test material was administered to 12 albino rabbits. The eyes of 6 of the rabbits was washed with water four seconds post-treatment. Observations made at 1 hour post-treatment, then daily for 14 days.

Results: On day 1 in unwashed and washed group, no corneal opacity of iris irritation present. 5/6 of unwashed group and 2/6 of the washed group had redness (5/6 = 1) (2/6 = 1); 4/6 of unwashed group had discharge (4/6 = 1). At day 4, no irritation present in either group.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

5. Primary Dermal Irritation Study: International Bio-Research; December 3, 1973.

Procedure: Six albino rabbits received 0.5 g of the test material at 1 abraded and 1 intact skin site per animal under occlusive wrap for 4 hour exposure. Observations made at 24 and 48 hours after initial treatment.

Results: No irritation present.

Study Classification: Core Supplementary Data.

RIN 5117-93 BORIC ACID TOX REVIEW 002832

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Pages 4 through 6 are not included.

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____ 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.

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