EPA Reviewer: Whang Phang, Ph.D. Signature: Whang Phang
Review Section III, Toxicology Branch II Date: 9/14/93
Health Effects Division (H7509C)
EPA Section Head: James Rowe, Ph.D. Signature: James N. Rowe
Review Section III, Toxicology Branch II Date: 9/15/93
Health Effects Division (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Acute dermal toxicity in rabbits

EPA Registration No.: 057978-G

Tox Chem. No.:

MRID No.: 424845-02

PC Number: 128972

TEST MATERIAL: Suttocide A, 50% solution (Integra 44)

SYNONYM(S): Sodium hydroxymethylglycinate

SPONSOR: Sutton Laboratories, Inc., Chatham, NJ

STUDY NUMBER: MB 92-1554 B

TESTING FACILITY: MB Research Laboratories, Inc., Spinnerstown, PA

TITLE OF REPORT: Acute Dermal Toxicity in Rabbits/LD_{50} in Rabbits: Suttocide A 50% Solution

AUTHOR(S): D.R. Gerven

STUDY COMPLETED: July 27, 1992; amended final report submitted August 27, 1992

CONCLUSIONS: (Limit Test)
Estimated acute dermal LD_{50} in males: >2000 mg/kg
Estimated acute dermal LD_{50} in females: >2000 mg/kg
Estimated acute dermal LD_{50} in sexes combined: >2000 mg/kg

CORE CLASSIFICATION: Core Guideline. This study satisfies the requirements of Guideline Series 81-2 for an acute dermal toxicity study. It is recommended, however, that future submissions provide a full description of the environmental conditions under which the test animals have been maintained.

TOXICITY CATEGORY: III

Inert ingredient information may be entitled to confidential treatment

A. MATERIALS

Test Compound: Suttocide A, 50% solution (Lot No. SA-118)

Identification number: Lot number SA-118
Active ingredient: Sodium hydroxymethylglycinate (See DER 2-99/276, MRID No. 424845-03 for purity and formulation information for lot number SA-118.)
Formulation: 49.8% sodium hydroxymethylglycinate, [redacted]
Purity: 49.8%
Physical description: Clear liquid
Specific gravity: 1.27
Storage conditions: Room temperature and humidity
Stability: Not reported

Dose level: 2000 mg/kg, administered as received (50% solution)
Dosing volume: 3.1-3.8 mL

Controls: None

Test Animals

Species: Rabbit
Strain: New Zealand White
Source: Ace Animals (location not specified)
Sex: Male and female
Age: Not reported
Body weight (at initiation): Males, 2.0-2.4 kg; females, 2.0-2.1 kg
Housing: 1 animal/cage
Number of animals/dose: 10 (5/sex)

Environmental conditions: Temperature: Not reported
Humidity: Not reported
Air changes per hour: Not reported
Photoperiod: 12 hours

B. TEST PERFORMANCE

Site Preparation: Approximately 24 hours prior to application of the test material, the dorsal area of the trunk of each animal was clipped free of hair. The prepared site was ≈10% of the body surface area.

Application: Using a syringe, the test material was applied to the test site under a gauze patch. The patch was taped in place, and gentle pressure was applied in order to spread the test material. The torso of each animal was wrapped with plastic secured with tape. After the 24-hour exposure, residual test material was gently washed off with distilled water.

Observation Period: 14 days

Observation Frequency: Animals were observed for signs of toxicity at 1, 2, and 4 hours postdosing and once daily thereafter for 14 days; animals were observed for mortality twice daily throughout the observation period.

Dermal responses at the application site were scored for erythema and/or edema according to the method of Draize on days 1, 7, and 14.

Body Weight Interval: Days 0, 7, and 14

Gross Pathology: YES __X__; NO _____

Histopathology: YES _____; NO __X__

C. REPORTED RESULTS

Mortality: No animals died following dermal exposure to the test material.

Clinical Observations: With the exception of occasional changes in the stool (e.g., diarrhea or "few feces") of treated females between days 5-9, there were no signs of toxicity reported in any treated animals throughout the 14-day observation period. At the end of the exposure period, three of five males and five of five females had very slight to moderate-severe erythema (grades 1-3); one male and two females had very slight to slight edema (grades 1-2). By day 7, the application site of one male had severe erythema with moderate eschar (grade 4) and very slight edema; the dermal reactions in all other animals had subsided by this observation interval. On day 14, all application sites appeared normal.

Body Weights: All animals gained weight during the 14-day study; both males and females gained an average 13% of their initial body weight (range 10-19%).

Gross Necropsy: There were no treatment-related macroscopic findings. Spontaneous changes in the kidney (pitting) were noted in one male, and ovarian abnormalities (white masses measuring ≈6-8 cm) were reported in one female.

LD_{50} Determination: Based on the absence of mortality in this study, the estimated acute dermal LD_{50} for males, females, and both sexes combined is >2000 mg/kg. This value corresponds to Toxicity Category: III.

D. REVIEWERS' COMMENTS: The reviewers agree with the study author's interpretation of the reported findings. In a limit test with 2000 mg/kg Suttocide A, 50% Solution, there were no reported deaths or toxic signs; the compound is, therefore, assigned to Toxicity Category III.

The following reporting deficiencies were noted, but were judged not to have affected the outcome of the study:

- The age of the study animals was not reported; however, based on the body weights of the animals, it appears that the animals were young adults.
- A full description of the environmental conditions in the animal room, including the temperature, humidity and number of air changes per

hour, was not provided. The report did indicate that the animal room was temperature controlled.

E. QUALITY ASSURANCE MEASURES: Was the test performed under GLPs? Yes. (A quality assurance statement, signed and dated on August 27, 1992, was submitted with the report.)