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EPA Reviewer: Whang Phang, Ph.D. Signature: Why Phang
Review Section III, Toxicology Branch II Date: 9/10/93
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: Primary dermal irritation in rabbits

EPA Registration No.: 057978-G

Tox Chem. No.:

MRID No.: 424845-04

PC No.: 128972

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

SYNONYM(S): Sodium hydroxymethylglycinate

SPONSOR: Sutton Laboratories, Inc., Chatham, NJ

STUDY NUMBER: Laboratory Project ID No. MB 92-1544 C

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

TITLE OF REPORT: Primary Dermal Irritation in Albino Rabbits: Suttocide A 50% Solution

AUTHOR(S): D.R. Gerven

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

CONCLUSIONS: Primary Skin Irritation Index (72 hours): 0.0; the test material did not produce any dermal irritation in six rabbits (4 males and 2 females).

CORE CLASSIFICATION: Core Guideline. This study satisfies the requirements of Guideline Series 81-5 for a primary dermal irritation 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: IV

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Inert ingredient information may be entitled to confidential treatment

A. MATERIALS

Test Compound: Suttocide A, 50% Solution

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
Storage conditions: Room temperature and humidity
Stability: Not reported

Dose level: 0.5 mL liquid, as received (50% solution)

Test Animals

Species: Rabbit
Strain: New Zealand White
Source: Ace Animals (location not specified)
Number and sex of animals: 4 males, 2 females
Housing: 1 animal/cage
Age: Not reported
Body weight (at initiation): Males, 2.1-3.1 kg; females, 2.2-2.8 kg

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

B. TEST PERFORMANCE

1. Skin Preparation: Approximately 24 hours prior to testing, the dorsal area of the trunk of each animal was clipped, and a single test site (measuring ≈10 cm^2) on each animal was selected.

2. Test Material Application: The test material was applied to a gauze patch that was placed onto the test site (0.5 mL of 50% Suttocide A/site) and covered with a semi-occlusive dressing. The dressing was secured with non-irritating tape. After the 4-hour exposure, the wrappings and patch were removed and residual test material was gently washed away with distilled water.

3. Observation Period: x 0.5-1 hr x 24 hr x 48 hr
x 72 hr ____ other (specify)

4. Scoring System: Reactions at test sites were scored for erythema and edema according to the method of Draize. Average erythema and edema scores were calculated for each observation interval, and the sum of these average scores was divided by four observation periods to arrive at a primary irritation index.

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C. REPORTED RESULTS: There were no reported signs of dermal irritation (erythema or edema) or systemic toxicity in any of the treated animals.

Therefore, the Primary Irritation Score for the test material was 0.0, and Suttocide A, 50% Solution is classified as Toxicity Category: IV.

D. REVIEWERS' COMMENTS: The reviewers agree with the study author's interpretation of the reported findings. Exposure to Suttocide A, 50% Solution for 4 hours did not elicit a dermal reaction in any of the animals.

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.)

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