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DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat
OPPTS Number: 870.1200 OPP Guideline Number: §81-2

DP BARCODE: D241261 SUBMISSION CODE: S534203
P.C. CODE: 070705 TOX. CHEM. NO.:
EPA REG. NO.: 3125-LRN

TEST MATERIAL (PURITY): R140/102 KBR 3023 Repellent Cream (19.91% KBR 3023)

SYNONYMS: All-Family Insect Repellent Cream; 2-(2-hydroxyethyl)-1-piperidinecarboxylic acid; 1-(1-methylpropoxy-carbonyl)-2-(2-hydroxyethyl)piperidine; 1-methylpropyl 2-(2-hydroxyethyl)-1-piperidinecarboxylate

CITATION: Warren, D., and M. Gastner (1996) Acute dermal toxicity study with R140/102 KBR 3023 Repellent Cream in rats. Bayer Corporation, Stilwell, KS. Laboratory Study Number 96-022-JP. December 19, 1996. MRID 44408755. Unpublished.

SPONSOR: Bayer Corporation, Agricultural Division, 17745 S. Metcalf, Stilwell, KS.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44408755), six young adult Sprague Dawley rats/sex were dermally exposed to R140/102 KBR 3023 Repellent Cream (19.91% KBR 3023) at 5,040 mg/kg (>2.5X limit dose) for 24 hours; the test substance was applied as received to approximately 10% of the total body surface area. An additional six animals/sex were exposed to deionized water and served as method controls. Animals were observed for clinical signs of toxicity and mortality for up to 14 days postdosing.

Dermal LD_{50} Males >5,040 mg/kg (males and females)

R140/102 KBR 3023 Repellent Cream is classified as **TOXICITY CATEGORY IV** based on the observed LD_{50} values in both sexes.

All animals survived the 14-day observation period, with no treatment-related signs of toxicity nor dermal irritation. A slight treatment-related effect on body weight was observed in females, whereas 4/6 test animals lost weight between 0 and 7 days, compared to 1/6 control females. All females then gained weight between 7 and 14 days, and exhibited overall increases that were comparable between test and controls. No treatment-related effect on body weight was observed in males, and necropsy after 14 days revealed no treatment-related gross abnormalities.

This study is classified **Acceptable (§870.1200)** and satisfies the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: R140/102 KBR 3023 Repellent Cream
   Description: White emulsion
   Lot/Batch #: 270696/0
   Purity: 19.91% KBR 3023
   CAS #: 119515-38-7

2. Vehicle: None employed

3. Test animals: Species: Rat
   Strain: Sas:CD(SD)BR
   Age: Young adult (approximately 8-10 weeks)
   Weight: 296-327 g males; 240-304 g females
   Source: Charles River Laboratories, Kingston, NY
   Acclimation period: ≥6 Days
   Diet: Purina Rodent Laboratory Chow (#5001-4), *ad libitum*
   Water: Tap water, *ad libitum*
   Housing: One animal/cage
   Environmental conditions:
   Temperature: 17.8-25.6 °C
   Humidity: 40-70%
   Air changes: Not specified
   Photoperiod: 12-Hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: September 4-19, 1996

2. Animal assignment and treatment: Fur from the dorsal and lateral areas of six young adult Sprague Dawley rats/sex was clipped 1 day prior to dermal administration of R140/102 KBR 3023 Repellent Cream at 5,040 mg/kg (>2.5X limit dose). The test substance was evenly applied as received to plastic-backed 2-ply gauze pads. Pads of 36, 40, or 44 cm^2 were used for animals within the weight ranges of 201-250, 251-300, or 301-350 g, respectively, so that at least 10% of the total body surface area was covered. To serve as controls, an additional six animals/sex were affixed with patches moistened

with deionized water. Each pad was secured with hypoallergenic tape, and the torso of each animal was wrapped with elastic bandage further secured with tape. Following a 24-hour exposure period, the coverings were removed and the test sites were gently wiped with water-moistened paper towels. The rats were observed for signs of toxicity, dermal irritation, and/or mortality at least once daily during the 14-day study. Body weights were recorded at 0 (prior to dosing), 7, and 14 days. At 14 days, surviving animals were sacrificed, necropsied, and examined for gross pathological changes.

3. Statistics: Group mean body weight changes were evaluated by Student's t-test.

II. RESULTS AND DISCUSSION:

A. Mortality: All animals survived the 14-day observation period.

Dermal LD_{50} >5,040 mg/kg (males and females)

B. Clinical observations: No treatment-related signs of toxicity nor dermal irritation were observed. Nasal staining was observed in 4/12 control animals (both sexes) between days 0 and 1, and urine staining was observed in one test and one control animal (both female) between days 1 and 2.

C. Body Weight: No treatment-related effect on body weight was observed in males, who exhibited overall (0-14 days) average group increases of 26% (both test and control groups). A slight effect was apparent in females, whereas 4/6 test animals lost weight between 0 and 7 days, compared to 1/6 control females. All females then gained weight between 7 and 14 days and exhibited overall group average increases of 6.8% for test and 8.6% for control animals.

D. Necropsy: Necropsy of animals sacrificed after 14 days revealed no treatment-related gross abnormalities.

E. Deficiencies: There were no deficiencies that affected the results of this study.