DATA EVALUATION REPORT

METABOLITE OF MESOTRIONE (MNBA) 11/30/2000

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT [870.1200 (81-2)]
MRID 45196004

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Arlington, VA 22202

Prepared by
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Task Order No. 00-73A

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Disclaimer

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Registration Action Branch 1 (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat [OPPTS 870.1200 (§81-2)]

DP BARCODE: D268682
P.C. CODE: 122990

SUBMISSION CODE: S584635
TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): MNBA (Metabolite of Mesotrione, 97% w/w)

SYNONYMS: 2-Nitro-4-methylsulfonyl benzoic acid

CITATION: Lees, D. (1996) MNBA: Acute dermal toxicity study in rats. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. Report ID CTL/P/4963, May 12, 1996. MRID 45196004. Unpublished.

SPONSOR: Zeneca Ag Products Inc., 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850-5458

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45196004) approximately 10 cm x 4 cm of the body surface area of five male and five female young adult Wistar derived rats was dermally exposed to 2000 mg/kg MNBA (97% w/w 2-nitro-4-methylsulfonyl benzoic acid, Batch Reference No. 15483-30-1) for 24 hours (Limit Test). The animals were observed for 14 days.

None of the animals died during the study. No clinical signs related to the test material and no skin irritation were noted. Slight desquamation was noted on all males until day 9. With the exception of one male rat, all rats lost weight between days 1 and 3. Between days 3 and 6, all rats gained weight. Two females lost weight between days 6 and 8. All rats gained weight between days 8 and 15. No macroscopic abnormalities were noted at necropsy.

The dermal LD_{50} for males, females, and combined was > 2000 mg/kg (Limit Test).

MNBA is in TOXICITY CATEGORY III based on the LD_{50}.

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal study [870.1200 (81-2)] 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: MNBA

Description: white solid
Lot/Batch #: 15483-30-1
Purity: 97% w/w
CAS No.: not reported

2. Vehicle and/or positive control

Deionized water

3. Test animals

Species: rat
Strain: Alpk:AP$_f$SD
Age and/or weight at dosing: young adult; males: 214-252 g, females: 206-225 g
Source: Barriered Animal Breeding Unit, Zeneca Pharmaceuticals, Alderley Park
Acclimation period: at least 6 days
Diet: PCD supplied by Special Diet Services Limited, Witham, Essex, UK, *ad libitum*
Water: mains water, *ad libitum*
Housing: individually in multiple rat racks
Environmental conditions:
Temperature: 21±2°C
Humidity: 40-70%
Air changes: approximately 25-30 changes/hour
Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 10, 1996; end: January 24, 1996

2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rats given a single 2000 mg/kg dose of MNBA moistened with 1 mL of deionized water applied to approximately 3/4 of a 10 cm x 5 cm clipped area on the dorsal lumber region. The application site was covered with a gauze patch, and with a patch plastic film and the trunk wrapped with adhesive bandage (occlusive dressing). The covering was removed 24 hours later and the site cleansed with swabs of absorbent cotton wool

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soaked in warm water. The animals were observed for clinical signs of toxicity between one and four hours after treatment and at least daily up to day 15. They were weighed prior to test material application (day 1), and on study days 3, 6, 8, and 15. All rats were sacrificed and necropsied.

3. Statistics

Calculation of the dermal LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rats died during the study.

The dermal LD_{50} for males, females, and combined was > 2000 mg/kg. This places MNBA in TOXICITY CATEGORY III.

B. CLINICAL OBSERVATIONS

No clinical signs related to the test material and no skin irritation were noted. Slight desquamation was noted on all males until day 9.

C. BODY WEIGHT

With the exception of one male rat, all rats lost weight between days 1 and 3. Between days 3 and 6, all rats gained weight. Two females lost weight between days 6 and 8. All rats gained weight between days 8 and 15.

D. NECROPSY

No macroscopic abnormalities were noted.

E. DEFICIENCIES

None were identified.

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