DATA EVALUATION RECORD

7/19/2000

METABOLITE OF MESOTRIONE
(2-NITRO-4-METHYLSULFONYL BENZOIC ACID)

Study Type: §81-1, Acute Oral Toxicity

Work Assignment No. 2-01-52A (MRID 44505015)

Prepared for
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Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

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DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat
OPPTS Number: 870.1100

OPP Guideline Number: §81-1

DP BARCODE: D259369
P.C. CODE: 122990

SUBMISSION CODE: S541375
TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): 2-nitro-4-methylsulfonyl benzoic acid (97% purity)

SYNONYMS: None specified

CITATION: Robinson, P. (1996) 2-Nitro-4-methylsulfonyl benzoic acid: acute oral toxicity to the rat. Central Toxicology Laboratory, Macclesfield, Cheshire, UK. Laboratory Report No. CTL/P5210, Study No. AR6309. October 4, 1996. MRID 44505015. Unpublished.

SPONSOR: Zeneca AG Products, Wilmington, DE.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44505015), five young adult (~ 9-wks. old) Alpk:AP$_f$SD (Wistar-derived) rats/sex were given a single oral dose of 2-nitro-4-methylsulfonyl benzoic acid (97% purity) at 5,000 mg/kg. The test substance was administered in corn oil, and the animals were observed for clinical signs of toxicity and mortality for up to 14 days postdosing.

Oral LD_{50} Males = >5,000 mg/kg (observed)
Females = >5,000 mg/kg (observed)

2-Nitro-4-methylsulfonyl benzoic acid is classified as **TOXICITY CATEGORY IV** based on the observed LD_{50} values for both sexes.

All animals survived and appeared normal during the 14-day study. No treatment-related effects on body weight were observed, and necropsy after 14 days revealed no treatment-related gross abnormalities.

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This study is classified **acceptable (§81-1)** and satisfies the guideline requirement for an acute oral study in the rat on 2-nitro-4-methylsulfonyl benzoic acid (a metabolite of mesotrione).

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

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: 2-Nitro-4-methylsulfonyl benzoic acid
   Description: White solid
   Lot/Batch #: WRC 15483-30-1
   Purity: 97%
   Specific gravity: 1.640
   CAS #: Not provided

2. Vehicle: Corn oil

3. Test animals: Species: Rat
   Strain: Alpk:AP$_f$SD (Wistar-derived)
   Age: Young adult (approximately 9 weeks)
   Weight: 289-316 g males; 192-226 g females
   Source: Rodent Breeding Unit, Zeneca Pharmaceuticals, Alderley Park, Macclesfield, Cheshire, UK
   Acclimation period: ≥6 Days
   Diet: Diet (PCD) Special Diet Services Limited, Witham, Essex, UK, ad libitum
   Water: Tap water, ad libitum
   Housing: Five animals per cage, separated by sex, 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 cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: July 3, 1996 - July 26, 1996

2. Animal assignment and treatment: Following an overnight fasting period, ten rats (5 males, 5 females) were given a single oral dose of 2-nitro-4-methylsulfonyl benzoic acid at 5,000 mg/kg by gavage. The test material was administered in corn oil. The animals

were observed for signs of systemic toxicity within 2 hours of dosing, between 4 and 7 hours postdosing, and once daily thereafter for the remainder of the 14-day study. Body weights were recorded on days -1, 0 (immediately prior to dosing), 2, 3, 7, and 14. At 14 days, all animals were sacrificed, necropsied, and examined for gross pathological changes.

3. Statistics: Not applicable to this study.

II. RESULTS AND DISCUSSION:

A. Mortality: No mortalities occurred during the study.

Oral LD_{50} Males = >5,000 mg/kg (observed)
Females = >5,000 mg/kg (observed)

B. Clinical observations: No treatment-related clinical signs were observed in any animals throughout the study.

C. Body Weight: No treatment-related effects on body weight were observed. All animals gained weight during the study, with mean overall (days 0-14) increases of 36% in males and 29% in females.

D. Necropsy: No treatment-related gross abnormalities were observed in any of the animals upon necropsy. In one male, red areas/spots were noted on the lungs and in one female, dark areas/spots were noted on the liver; however these findings were incidental and not related to treatment.

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