DATA EVALUATION RECORD

7/19/2000

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

Study Type: §81-1, Acute Oral Toxicity

Work Assignment No. 2-01-52B (MRID 44505016)

Prepared for
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Disclaimer

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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 SUBMISSION CODE: S541375
P.C. CODE: 122990 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): 2-Amino-4-methylsulfonyl benzoic acid (99% purity)

SYNONYMS: AMBA

CITATION: Lees, D. (1996) AMBA (2-amino-4-methylsulfonyl benzoic acid): acute oral toxicity to the rat. Central Toxicology Laboratory, Macclesfield, Cheshire, UK. Laboratory Report No. CTL/P/5282, Study No. AR6339. December 11, 1996. MRID 44505016. Unpublished.

SPONSOR: Zeneca AG Products, Wilmington, DE.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44505016), five young adult (~ 8- to 12-wks. old) Alpk:AP$_f$SD (Wistar-derived) rats/sex were given a single oral dose of 2-amino-4-methylsulfonyl benzoic acid (99% 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-Amino-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.

This study is classified **acceptable (§81-1)** and satisfies the guideline requirement for an acute oral study in the rat on AMBA (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-Amino-4-methylsulfonyl benzoic acid
   Description: Yellow solid
   Lot/Batch #: 16010-09-01
   Purity: 99% (w/w)
   CAS #: Not provided

2. Vehicle: Corn oil

3. Test animals: Species: Rat
   Strain: Alpk:AP$_f$SD (Wistar-derived)
   Age: Young adult (approximately 8-12 weeks)
   Weight: 373-433 g males; 235-254 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: 55±15%
   Air changes: Approximately 25-30 changes/hour
   Photoperiod: 12-Hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: September 3, 1996 - September 17, 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-amino-4-methylsulfonyl benzoic acid at 5,000 mg/kg by gavage. The test material was administered in corn oil at a standard volume of 10 mL/kg. 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 25% in males and 15% in females.

D. Necropsy: No treatment-related gross abnormalities were observed in any of the animals upon necropsy. However, in one male, prominent Peyer's patches were observed on the ileum; this finding was incidental and not related to treatment.

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