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DATA EVALUATION REPORT

STUDY TYPE: Acute oral toxicity in rats;
EPA Guideline 81-1

EPA Identification No.: MRID No. 425160-06
DP Barcode No. D185350
Submission No. S427885
PC Code 129051
Case 281895
ID No. 0F03918

TEST MATERIAL: SAN 582H sulfonate sodium salt

SYNONYMS: SAN 582H Sulfonate metabolite; metabolite M-27.

STUDY NUMBER: 92-6291

SPONSOR: Sandoz Agro, Inc.

TESTING FACILITY: Bio/dynamics, Inc. East Millstone, NJ.

TITLE OF REPORT: Acute Oral Toxicity Study in Rats

AUTHOR(S): Donna L. Blasczak

REPORT ISSUED: September 14, 1992

CONCLUSION:

Toxicity Category: IV

Core Classification: Minimum

LD_{50} - Greater than 5000 mg/kg body weight, for both sexes

MATERIALS:

1. Test compound: SAN 582 Sulfonate sodium salt, Description: colorless crystals, Lot/Batch #: 4997, Purity: 99.45%

2. Test animals: Species: rat, Strain: Sprague-Dawley derived (CD) [Crl:CD BR], Age: Young adult (approximately 9-12 weeks old), Weight: 284-308 g (males) and 208-223 g (females), Source: Charles River Breeding Laboratories, Inc. Kingston, NY.

METHODS:

Rats were fasted overnight before dosing. Test material was administered orally by gavage in deionized water (20 ml/kg) at a concentration of 25% w/v. The study was conducted in two phases: a range finding study and a single-dose study. In the range finding study 1 male and 1 female/dose level were dosed with test material at doses of 50, 100, 500, 1000, and 5000 mg/kg. On the basis of no mortality in the range finding study the single dose study was conducted at 5000 mg/kg (a limit dose) using 5 males and 5 females.

In the single dose study, animals were observed for mortality twice daily. For observations of pharmacologic and toxicologic signs, each animal was removed from its ca ge and examined approximately 1, 2, and 4 hours after dosing and daily thereafter for 14 days. Rats were weighed on days -1, 0, 7 and 14. On day 14 all animals were sacrificed and gross necropsy was performed.

RESULTS (Single dose study):

No mortality was observed during the 14-day observation period and weight gain was observed on days 7 (3-70 g) and 14 (22-126) of observation vs day -1. Treatment-related clinical signs were yellow anogenital staining during days 1 and 2 and watery stool on day 1. No macroscopic postmortem anomalies were seen at gross necropsy.

A signed quality assurance statement and a signed GLP compliance statement were present.

The author concluded that under the conditions of the study, the oral LD_{50} of SAN 582H sulfonate metabolite (M-27) is greater than 5000 mg/kg body weight.