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RPA 203328 Acute Oral Toxicity (81-1)

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DATA EVALUATION REPORT

STUDY TYPE:	Acute Oral Toxicity/Rats OPPTS 870.1100 [81-1]
EPA ID NUMBERS:	DP BARCODE: D224202 P. C. CODE: 123000 SUBMISSION NO.: S501233 MRID NUMBER: 43904812
TEST MATERIAL:	RPA 203328 Chemical Name: 2-methylsulfonyl-4-trifluoromethylbenzoic acid
STUDY NUMBER:	SA 95373
TESTING FACILITY:	Rhone-Poulenc Agrochimie, Sophia Antipolis, France
SPONSOR:	Rhone-Poulenc Ag Company, Lyon, France
TITLE OF REPORT:	RPA 203328. Oral Limit Test in the Rat
AUTHOR:	D. Bigot
REPORT ISSUED:	November 10, 1995

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID # 43904812), a group of five male and five female Sprague-Dawley rats were orally administered RPA 203328 in 0.5% methylcellulose and distilled water (20 ml/kg b.w.) at a dose level of 5000 mg/kg. The animals were observed for 15 days post-dosing. No mortalities were noted; the clinical signs of toxicity observed in two males and one female included dyspnea, piloerection, soiled fur, mucoid feces or increased salivation. The female also exhibited reduced motor activity, hunched posture and noisy breathing.

The acute oral LD_{50} for RPA 203328 was >5,000 mg/kg for both sexes.

The study is classified as **Acceptable** with a **Toxicity Category IV** and **satisfies** the requirements (81-1) for an acute oral toxicity study in rats.

I. MATERIALS

A. Test Material

Name: RPA 203328 (a metabolite of isoxaflutole)
Synonym: None
Chemical Name: 2-methylsulfonyl-4-trifluoromethylbenzoic acid
Purity: 99.7%
Batch Number: GH 705
Description: White powder
Storage Conditions: At room temperature protected from light

The dosing formulation was prepared prior to dosing by suspending the test substance in 0.5% methylcellulose in distilled water to produce required dosing concentrations (w/v).

B. Test Animals

Species: Sprague-Dawley rats (ICO OFA SD)
Source: Iffa-Credo, L'Arbresle, France
Age: 7 weeks at initiation of dosing
Weight: Males - 213 to 222 g; Females - 146 to 160 g when dosed
Housing: Individually in stainless steel cage
Environmental Conditions: Temperature: 20-24^{0}C
Relative Humidity: 40-70%
Photoperiod: 12 hours light/dark
Air Changes: 10 to 15/hour
Food and Water: Pelleted Certified Rodent Diet A04C (from Usine d'Alimentation Rationnelle, France) and tap water *ad libitum*
Acclimation Period: 14 days

II. METHODS

Animals were fasted overnight prior to dosing. Each animal received a single dose of the test solution. Five male and five female rats were dosed with test solution (20 ml volume/kg b.w.) at 5000 mg/kg via gavage. The animals were observed for mortality and clinical signs of toxicity on two occasions during Day 1 and daily for the remainder of the 14-day observation period. Body weights were recorded on one day prior to dosing, on the day of dosing and at 8 and 15 days post-dosing. At the end of the observation period, all animals were sacrificed and necropsied.

III. RESULTS

At 5000 mg/kg, none of the animals died during the study. The clinical signs observed in two males on Day 2 and one female on Day 2 and 3 included dyspnea, piloerection, soiled fur, mucoid feces or increased salivation. All males recovered by Day 3, while the female exhibited signs until Day 3 and then from Days 11 to 13 had reduced motor activity and hunched posture with dyspnea and noisy breathing. Body weights were unaffected by the treatment. There were no lesions observed on gross necropsy of animals sacrificed at study termination. The acute oral LD_{50} was >5000 mg/kg for males and females.

IV. COMPLIANCE

The following compliance documents were submitted: 1) signed statement by the sponsor indicating that the study was conducted in accordance with GLP Regulations; 2) signed Quality Assurance statement by the testing facility; 3) signed statement by the sponsor claiming no data confidentiality.

V. CONCLUSIONS

The acute oral LD_{50} for RPA 203328 in male and female rats was >5,000 mg/kg.

The study is classified as **Acceptable** with a **Toxicity Category IV** and **satisfies** the requirements (81-1) for an acute oral toxicity study in rats.

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One-Liners for RPA 203328

Study Type:	Guideline: OPP §81-1 Acute Oral Toxicity Species: Rat
Test Material:	RPA 203328
Chemical Name:	2-methylsulfonyl-4-trifluoromethylbenzoic acid
EPA MRID No.:	43904812
Testing Facility:	Rhone-Poulenc Agrochimie, Sophia Antipolis, France
Study Number:	SA 95373
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