

US EPA ARCHIVE DOCUMENT

011948

RPA 200761

Acute Oral Toxicity (81-1)

Reviewed by: Sanjivani B. Diwan, Ph.D. *Sanjivani Diwan* Date: 4/25/96
Section I, Toxicology Branch II (7509C)
Secondary Reviewer: Yiannakis M. Ioannou, Ph.D. *Y.M. Ioannou* Date 4/25/96
Section I, Toxicology Branch II (7509C)

DATA EVALUATION REPORT

STUDY TYPE: Acute Oral Toxicity/Rats (81-1)

EPA ID NUMBERS: DP BARCODE: D224025
P. C. CODE: 129121
MRID NUMBER: 438840-01
SUBMISSION No.: S499256

TEST MATERIAL: RPA 200761
Synonym: 5-Amino-1-(2,6-dichloro-4-trifluoromethylphenyl-4-trifluoromethylsulfinylpyrazole-3-carboxylic acid

STUDY NUMBER: SA 95214

TESTING FACILITY: Rhone-Poulenc Agrochimie, Lyon, France

SPONSOR: Rhone-Poulenc Agrochimie, Lyon, France

TITLE OF REPORT: RPA 200761: Oral Limit Test in the Rat

AUTHOR: P. Katchadourian

REPORT ISSUED: July 7, 1995

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID # 438840-01), a group of five male and five female Sprague-Dawley rats were orally administered RPA 200761 as a suspension in corn oil at a dose of 2000 mg/kg. The animals were observed for mortality and clinical signs of toxicity for 15 days post-dosing. There were no deaths during the study. No clinical signs of toxicity were observed during the treatment and observation period. The acute oral LD₅₀ for RPA 200761 was greater than 2000 mg/kg.

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

I. MATERIALS

A. Test Material

Name: RPA 200761*

Synonym: 5-Amino-1-(2,6-dichloro-4-trifluoromethylphenyl-4-trifluoromethylsulfinylpyrazole-3-carboxylic acid

Purity: 97.5%

Batch number: 57TDS112A

Description: White powder

Storage Conditions: In an air-tight, light-resistant container at approximately 4°C.

* A metabolite of Fipronil

For dosing, the test material was freshly prepared as a suspension at the appropriate concentration in corn oil to produce the required dosing concentrations (w/v).

B. Test Animals

Species: Sprague-Dawley rats

Source: Iffa-Credo, L'Arbresle, France

Age: 6-7 weeks at the start of the study

Weight: Males - 187 to 200 g; Females - 138 to 155 g
when dosed

Housing: Individually in stainless steel cage

Environmental Conditions: Temperature: 22±2° C

Relative Humidity: 55±15%

Photoperiod: 12 hours light/dark

Air Changes: 10-15/hour

Food and Water: Certified Rodent Pellet diet AO4C (Usine d'Alimentation Rationnelle, Villemeisson-sur-Orge, France) and filtered tap water *ad libitum*

Acclimation Period: Five days

II. METHODS

After an overnight fast, five male and five female rats were dosed with 2000 mg/kg RPA 200761 via gavage using a metal cannula attached to a graduated syringe. The dosing volume was adjusted to give 10 ml of dose per 1000 g of body weight. The animals were observed for mortality and clinical signs of toxicity at approximately 1 hour after dosing and at least once more on Day 1 (day of dosing) and once daily for the remainder of the 14-day observation period. Body weights were recorded prior to dosing and at 8 and 15 days post-dosing. At the end of the observation period, all animals were sacrificed and necropsied.

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III. RESULTS

None of the animals died during the study. No deaths, clinical or systemic signs of toxicity were observed during the treatment and observation period. All the animals gained weight over the course of the study. There were no lesions on gross necropsy. The acute oral LD₅₀ was greater than 2,000 mg/kg.

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 LD₅₀ for RPA 200761 in rats was greater than 2,000 mg/kg.

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