

US EPA ARCHIVE DOCUMENT

012255

RPA 202248

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: D227954
P. C. CODE: 123000
SUBMISSION NO.: S508413
MRID NUMBER: 44044701

TEST MATERIAL: RPA 202248
CHEMICAL NAME: 2-Cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl)-propan-1,3-dione

STUDY NUMBER: SA 96140

TESTING FACILITY: Rhone-Poulenc Agrochimie, Sophia Antipolis, France

SPONSOR: Rhone-Poulenc Agrochimie, Lyon, France

TITLE OF REPORT: RPA 202248. Oral LD₅₀ in the Rat

AUTHOR: P. Katchadourian

REPORT ISSUED: May 22, 1996

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID # 44044701), groups of five male and five female Sprague-Dawley rats received single oral administration of RPA 202248 in 0.5% aqueous methylcellulose at dose levels of 2000, 2710, 3690 and 5000 mg/kg. Two males and one female at 3690 and one male at 5000 mg/kg died by Day 3. The clinical signs of toxicity observed in both sexes, within few hours of dosing, included piloerection at all dose levels and hunched posture in males at 2710 mg/kg as well as in both sexes at 3690 and 5000 mg/kg/day. Reduced motor activity was noted in both sexes at 3690 and 5000 mg/kg/day. Based on the estimated acute oral LD₅₀ of >5,000 mg/kg in both sexes, RPA 202248 is placed in Toxicity Category IV.

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

I. MATERIALS**A. Test Material**

Name: RPA 202248

Chemical Name: 2-Cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl)propan-1,3-dione

Purity: 99.9%

Batch Number: SR0712

Description: White powder

Storage Conditions: At room temperature protected from light

The dosing formulation was prepared 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) (IOPS Caw)

Source: Iffa-Credo, L'Arbresle, France

Age: 8 weeks at initiation of dosing

Weight: Males - 237 to 281 g; Females - 173 to 191 g when dosed

Housing: Individually in stainless steel cage

Environmental Conditions: Temperature: 20-24°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/group were dosed with test solution (20 ml volume/kg b.w.) at 2000, 2710, 3690 or 5000 mg/kg via gavage. The animals were observed for mortality and clinical signs of toxicity on two occasions during Day 1 and at least once daily for the remainder of the 14-day observation period. Body weights were recorded ten days 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 2000 and 2710 mg/kg, none of the animals died during the study. No clinical signs or macroscopic postmortem findings were observed at 2000 mg/kg. Mortalities were noted at 3690 mg/kg on Day 2 (one female and two males) and at 5000 mg/kg/day on Day 3 (one male); treatment-related clinical signs of toxicity were observed within few hours of dosing. Piloerection was noted in animals at all dose levels and hunched posture was reported in males at 2710 mg/kg as well as in both sexes at 3690 and 5000 mg/kg/day. In addition, males and females at 3690 and 5000 mg/kg exhibited reduced motor activity. The surviving animals recovered on Day 5. Body weights were unaffected. There were no lesions observed on gross necropsy of animals sacrificed at study termination. The estimated acute oral LD₅₀ 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. Any deviations from the protocol were appropriately reported.

V. CONCLUSIONS

The acute oral LD₅₀ for RPA 202248 in male and female rats was >5,000 mg/kg. Toxicity Category IV.

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

One-Liner for RPA 202248

Study Type: Guideline: OPP §81-1
Acute Oral Toxicity
Species: Rat

Test Material: RPA 202248
Chemical Name: 2 - Cyano - 3 - cyclopropyl - 1 - (2 -
methylsulfonyl-4-trifluoromethylphenyl) -
propan-1,3-dione

EPA MRID No.: 44044701

Testing Facility: Rhone-Poulenc Agrochimie, Sophia
Antipolis, France

Study Number: SA 96140

Report Issued: May 22, 1996

Executive Summary: In an acute oral toxicity study (MRID # 43904810), groups of five male and five female Sprague-Dawley rats were orally administered RPA 202248 in 0.5% aqueous methylcellulose (20 ml/kg b.w.) at dose levels of 2000, 2710, 3690 and 5000 mg/kg. Two males and one female at 3690 and one male at 5000 mg/kg died by Day 3. The clinical signs of toxicity observed in both sexes, within few hours of dosing, included piloerection at all dose levels and hunched posture in males at 2710 mg/kg as well as in both sexes at 3690 and 5000 mg/kg/day. Reduced motor activity was noted in both sexes at 3690 and 5000 mg/kg/day. Based on the estimated acute oral LD₅₀ of >5,000 mg/kg in both sexes, RPA 202248 is placed in Toxicity Category IV.

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