(8-3-99) 27

[CGA-279202 50 WG] (TXR 013599) Acute Oral Study (81-1)

EPA Toxicologist: Deborah C. Smegal_____, Date _____
Toxicology Branch II (7509C)
EPA Secondary Reviewer: _____, Date _____
(7509C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat
OPPTS 870.1100 [§81-1]

DP BARCODE: 243979 SUBMISSION CODE:S538757
P.C. CODE:129112 TOX. CHEM. NO.:

TEST MATERIAL (PURITY): CGA-279202 50WG (50.3% a.i.)

SYNONYMS: Trifloxystrobin (formulation)

CITATION: Kuhn J.O. 1997. Acute oral toxicity in rats. Stillmeadow, Inc. 12852 Park One Drive. Sugar Land, TX 77478. Laboratory Study Number: 3814-97. Novartis Nexus Number 597-97. December 2, 1997. MRID 44496625. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44496625),groups of fasted, albino HSD:Sprague Dawley rats (5/sex) were given a single oral dose of CGA-279202 50 WG (50.3% a.i.)in distilled water at a dose of 5,050 mg/kg and observed for 14 days.

Oral LD_{50} Males = >5,050 mg/kg
Females = >5,050 mg/kg
Combined = >5,050 mg/kg

CGA-279202 50 WG is classified as TOXICITY CATEGORY IV based on the LD_{50} in both males and females.

There were no treatment-related effects on mortality, body weight or necropsy findings. Clinical signs included diarrhea and piloerection in both sexes, as well as decreased activity, crusted nose and eye, decreased defecation, ptosis and swollen jaw in males. The symptoms subsided by day 4.

This acute oral study is classified as acceptable. This study satisfies the guideline requirement for an acute oral study (81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality were provided. Flagging statements were not provided.

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I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: CGA-279202 50 WG
   Description: tan granular solid
   Lot/Batch #: FL-970106; A-9360 B
   Purity: 50.3% a.i.
   CAS #:

2. Vehicle and/or positive control: deionized water

3. Test animals: Species: rats
   Strain: albino HSD: Sprague Dawley
   Age and/or weight at dosing: young adults, Males: 230-251 g; Females: 150-163 g
   Source: Harlan Sprague Dawley, Inc., Indianapolis, IN
   Acclimation period: 5 days
   Diet: PMI Feeds lab diet formula #5008 ad libitum except for 16 hours before dosing
   Water: administered municipal water ad libitum
   Housing: Each animal was housed individually in a suspended, wire bottom, stainless steel cage

   Environmental conditions:
   Temperature: 72 ±5°F
   Humidity: 30-80%
   Air changes: 10-12 per hour
   Photoperiod: 12 hours light/ 12 hours dark

B. STUDY DESIGN and METHODS:

1. In life dates - start: 10/9/97 end: 10/24/97

2. Animal assignment and treatment: Animals were assigned to the test groups noted in table 1. Following an overnight fast, rats were given a single dose of CGA-279202 50 WG by gavage in a volume of 12 ml/kg. They were then observed for mortality and clinical signs at least three times on the day of dosing, and at least once daily thereafter for 14 days. The rats were weighed prior to treatment and again on days 7 and 14. Necropsy was performed on the survivors, which were sacrificed on day 14.

TABLE 1. Doses and Mortality/Animals Treated

Dose (mg/kg)	Males	Females	Combined
5,050	0/5	0/5	0/10

3. Statistics: The oral LD_{50} exceeds the limit dose of 5,050 mg/kg, therefore, no statistics were used to calculate this value.

II. **RESULTS AND DISCUSSION:**

A. Mortality is given in table 1.

The calculated acute oral LD_{50}'s are as follows:
males: >5,050 mg/kg
females: >5,050 mg/kg
combined: >5,050 mg/kg

B. Clinical observations: There were no treatment-related effects on mortality. All animals survived to the scheduled sacrifice. Clinical signs included diarrhea and piloerection in both sexes, as well as decreased activity, crusted nose and eye, decreased defecation, ptosis and swollen jaw in males. The symptoms subsided by day 4.

C. Body Weight: There were no treatment-related effects on body weight in males or females.

D. Necropsy: No abnormalities were observed in post mortem examination of the animals that were sacrificed.

E. Deficiencies: There was no flagging statement in the report.

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