(8-3-99) 26

[CGA-279202 WG 50] (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 WG50 (50.8% a.i.)

SYNONYMS: Trifloxystrobin (formulation)

CITATION: Winkler, G. 1997. Acute oral toxicity in the rat. Novartis Crop Protection AG (formerly Ciba-Geigy Limited), Stein, Switzerland. Laboratory Project ID: 963148. Novartis Nexus Number 468-96. January 8, 1997. MRID 44496624. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44496624),groups of fasted, albino Tif:RAI f (SPF)rats (5/sex) were given a single oral dose of CGA-279202 WG50(50.8% a.i.)in distilled water at a dose of 2,000 mg/kg and observed for 14 days.

Oral LD_{50} Males = >2,000 mg/kg
Females = >2,000 mg/kg
Combined = >2,000 mg/kg

CGA-279202 WG50 is classified as TOXICITY CATEGORY III based on the LD_{50} in both males and females.

There were no treatment-related effects on mortality, clinical signs, body weight or necropsy findings.

This acute oral study is classified as acceptable. This study satisfies the guideline requirement for an acute oral study (81-1) in the rat. This study follows OECD Guideline and OECD principles of GLP.

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

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: CGA-279202 WG50
   Description: solid
   Lot/Batch #: batch No. P.509005
   Content of CGA-279202: 50.8% a.i.
   CAS #:

2. Vehicle and/or positive control: distilled water

3. Test animals: Species: rats
   Strain: albino TIF:RAI f (SPF)
   Age and/or weight at dosing: young adults, 174 - 213 g
   Source: CIBA-GEIGY Limited, Laboratory Animal Breeding, Pharma Division. 4332 Stein, Switzerland
   Acclimation period: 5 days
   Diet: NAFAG 890 ad libitum
   Water: administered ad libitum,
   Housing: Groups of 5 same sex were housed in Macrolon cages type 4, with standardized soft wood bedding.

   Environmental conditions:
   Temperature: 22 ±2°C
   Humidity: 55 ±10%
   Air changes: 15 per hour
   Photoperiod: 12 hours light/ 12 hours dark

B. STUDY DESIGN and METHODS:

1. In life dates - start: 12/2/96 end: 12/18/96

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 WG 50 by gavage in a volume of 10 ml/kg. They were then observed for mortality twice daily, and clinical signs of toxicity daily 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
2,000	0/5	0/5	0/10

3. Statistics: The oral LD_{50} exceeds the limit dose of 2,000 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: >2,000 mg/kg
females: >2,000 mg/kg
combined: >2,000 mg/kg

B. Clinical observations: There were no treatment-related effects on mortality or clinical signs. All animals survived to the scheduled sacrifice.

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.

SignOff Date:	8/3/99
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