(8-3-99) 30

[CGA-279202] (TXR 013599) Acute Dermal Study (81-2)

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DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rats
OPPTS 870.1200 [§81-2]

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

TEST MATERIAL (PURITY): CGA-279202 WG50 (50.8% a.i.)

SYNONYMS: Trifloxystrobiin (formulation)

CITATION: Winkler G. 1997. CGA-279202 WG50. Acute dermal toxicity in the rat. Novartis Crop Protection AG (formerly Ciba-Geigy Limited), Stein, Switzerland. Laboratory Project ID: 963149. Novartis Nexus Number: 466-96. February 3, 1997. MRID 44496628. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44496628), groups of young adult albino Tif:RAI f (SPF)rats (5/sex) were dermally exposed to CGA-279202 WG50 (50.8% a.i.) in distilled water, for 24 hours to 10% of the body surface area at a dose of 2,000 mg/kg using a semi-occlusive dressing. Animals then were observed for 14 days.

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

CGA-279202 WG50 is TOXICITY CATEGORY III based on males and females.

There were no treatment-related effects on mortality, clinical signs, body weight or macroscopic examination. Grade 1 erythema was observed at the application site in all males on day 1, which subsided by day 2.

This acute dermal study is classified as acceptable. It satisfies the guideline requirement for an acute dermal study (81-2) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. A Flagging statement was omitted.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: CGA-279202 WG50
   Description: solid
   Lot/Batch #: P. 509005
   Purity: 50.8% a.i.
   CAS #: Not available

2. Vehicle and/or positive control: distilled water

3. Test animals:

   Species: Rat
   Strain: albino Tif:RAI f (SPF)
   Age and weight at dosing: young adult; 201 to 252 g
   Source: Novartis Pharma, Inc. Microbiological Laboratory, 4332 Stein, Switzerland
   Acclimation period: 5 days
   Diet: fed a rat diet, NAFAG 890, NAFAG, Gossau/SG, Switzerland, ad libitum
   Water: administered water ad libitum

   Housing: The animals were individually housed in macrolon type 3 cages, 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: 12/4/96 end: 12/19/96

2. Animal assignment and treatment - Animals were assigned to the test groups noted in table 1. Animals were given a single dose of CGA-279202 WG50 dermally to the shaved dorsal area (10% body surface area), which was covered with a gauze-lined semi-occlusive dressing fastened around the trunk with an adhesive elastic bandage for 24 hours. The residual test substance was removed with lukewarm water. The animals were observed twice daily on weekdays and once on weekend days for mortality, while clinical signs were monitored daily. The animals were weighed before application, and then on days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	males	Females	Combined
2,000	0/5	0/5	0/10

3. Statistics - No statistics were performed, and no dermal LD_{50} was calculated because none of the rats died during the observation period.

II. **RESULTS AND DISCUSSION:**

A. Mortality is given in table 1.

The dermal LD_{50}:
Males = >2,000 mg/kg
Females = >2,000 mg/kg
Combined = >2,000 mg/kg

B. Clinical observations - There were no treatment-related clinical observations or mortality observed during the study. All animals survived the observation period. Transient, but slight local erythema at the skin application site was noted in all males on day 1 post treatment, which subsided thereafter.

C. Body Weight - There were no treatment-related effects on body weight.

D. Necropsy - No abnormalities were noted in the terminal macroscopic examination.

E. Deficiencies - None.

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