(8-3-99) 28

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

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Toxicology Branch II (7509C)
EPA Secondary Reviewer: _____, Date _____
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DATA EVALUATION RECORD

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

DP BARCODE: 243979
P.C. CODE: 129112

SUBMISSION CODE: S538757
TOX. CHEM. NO.:

TEST MATERIAL (PURITY): CGA-279202 Technical (96%)

SYNONYMS: Trifloxystrobiin

CITATION: Glaza S.M. 1994. Acute dermal toxicity study of CGA-279202 Technical in Rabbits. Covance Laboratories Inc. (Formerly Hazleton Wisconsin). 3301 Kinsman Boulevard. Madison, Wisconsin 53704. Laboratory Project ID: HWI 40702445. Novartis Nexus Number: 356-94. October 7, 1994. MRID 44496626. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44496626), groups of adult albino New Zealand rabbits (5/sex) were dermally exposed to CGA-279202 (96%)using an occlusive wrap,for 24 hours to 10% of the body surface area at a dose of 2,000 mg/kg. 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 is TOXICITY CATEGORY III based on males and females.

There were no treatment-related effects on mortality, clinical signs, body weight or macroscopic examination. The test material produced slight dermal irritation in 8 of 10 animals with signs of irritation subsiding in all animals within 7 days.

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. The flagging statement was omitted.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: CGA-279202 Technical
   Description: tan powder
   Lot/Batch #: P.405009
   Purity: 96%
   CAS #: 141517-21-7

2. Vehicle and/or positive control: Distilled water

3. Test animals:

   Species: Rabbit
   Strain: albino Hra:New Zealand SPF
   Age and weight at dosing: adult, 2,454 to 2,824 g
   Source: HRP, Inc., Kalamazoo, Michigan
   Acclimation period: 7 days
   Diet: Fed a measured amount of Laboratory Rabbit Diet HF #5326, PMI Feeds, Inc.
   Water: administered water ad libitum

   Housing: Individually housed in screen-bottom stainless steel cages in temperature- and humidity-controlled quarters.
   Environmental conditions:
   Temperature: 19 to 23°C
   Humidity: 50 ±20%
   Air changes: not provided
   Photoperiod: 12 hours light/ 12 hours dark

B. STUDY DESIGN and METHODS:

1. In life dates - not specified

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 Technical dermally to the shaved dorsal area (10% body surface area) at a rate of 0.05 g/cm^2, which was occlusively covered with a gauze patch and over wrapped with Saran Wrap® and Elastoplast® tape for 24 hours. Collars were used to restrain the test animals during the exposure period. The residual test substance was removed by tap water and disposable paper towels. The animals were observed at 1, 2.5, and 4 hours post exposure for clinical signs and twice daily thereafter for 14 days. 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 rabbits 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 observed during the study. Slight dermal irritation was observed in eight of the 10 animals, which subsided by day 7.

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

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

E. Deficiencies - In life dates, and air changes were not specified.

SignOff Date:	8/3/99
DP Barcode:	D243979
HED DOC Number:	013599
Toxicology Branch:	TOX2