[Trifloxystrobin] (TXR 013599) (8-3-99) 25 Acute Oral Study (81-1)

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DATA EVALUATION RECORD

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

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

TEST MATERIAL (PURITY): CGA-279202 Technical (96.4% a.i.)

SYNONYMS: Trifloxystrobin

CITATION: Winkler, G. 1996. Acute oral toxicity in the mouse. Novartis Crop Protection AG (formerly Ciba-Geigy Limited), Stein, Switzerland. Laboratory Project ID: 963002. Novartis Nexus Number 482-96. March 18, 1996. MRID 44496623. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44496623),groups of fasted, Tif:MAG (SPF)mice (5/sex) were given a single oral dose of CGA-279202 Technical(96.4% a.i.)in 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80 at a dose of 5,000 mg/kg, or vehicle only and observed for 14 days.

**Oral $LD_{50}$ Males = >5,000 mg/kg**
**Females = >5,000 mg/kg**
**Combined = >5,000 mg/kg**

CGA-279202 Technical 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 of toxicity included piloerection and hunched posture in all animals that subsided within 3 days post exposure.

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

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 Technical
   Description: solid
   Lot/Batch #: batch No. P.405009
   Purity: 96.4% a.i.
   CAS #: 141517-21-7

2. Vehicle and/or positive control: 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80

3. Test animals: Species: mice
   Strain: albino Crl:CD (SD)BR
   Age and/or weight at dosing: young adult, 21-27 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 3, with standardized 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: 2/16/96 end: 3/1/96

2. Animal assignment and treatment: Animals were assigned to the test groups noted in table 1. Following an overnight fast, mice were given a single dose of CGA-279202 Technical by gavage in a volume of 20 ml/kg. They were then observed for mortality twice daily, and clinical signs of toxicity daily for 14 days. The mice 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 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 0 | 0/5 | 0/5 | 0/10 |

| | | | |
|---|---|---|---|
| 5,000 | 0/5 | 0/5 | 0/10 |

3. Statistics: The oral $LD_{50}$ exceeds the limit dose of 5,000 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: >5,000 mg/kg
females: >5,000 mg/kg
combined: >5,000 mg/kg

B. Clinical observations: There were no treatment-related effects on mortality. All animals survived to the scheduled sacrifice. Clinical signs of toxicity included piloerection and hunched posture in all treated males and females, which subsided within 3 days post treatment. No clinical signs were noted in controls.

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: The animals were dosed at a volume of 20 ml/kg body weight, which exceeds the 10 ml/kg body weight volume.

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| Toxicology Branch: | TOX2 |