

[Trifloxystrobin]

(TXR 013599)

(8-3-99) 32
Acute Inhalation Study (81-3)

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

STUDY TYPE: Acute Inhalation Toxicity - Rat
OPPTS 870.1300 [§81-3]

DP BARCODE: 243979
P.C. CODE: 129112

SUBMISSION CODE: S538757
TOX. CHEM. NO.:

TEST MATERIAL (PURITY): CGA-279202 Technical (95.9% a.i.)

SYNONYMS: Trifloxystrobin

CITATION: Holbert M.S. 1995. Acute inhalation toxicity study in rats. Stillmeadow, Inc. 12852 Park One Drive. Sugar Land, TX 77478. Laboratory Study Number: 1815-95. Novartis Nexus Number 119-95. April 5, 1995. MRID 44496630. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 44496630), groups of young adult HSD:Sprague Dawley rats (5/sex) were exposed by inhalation via nose only to aerosolized CGA-279202 (95.9% a.i.) for 4 hours to concentrations of 1.39 and 4.65 mg/L (mean gravimetrically-derived concentration) with a mean MMAD (GSD) of 2.6 (1.9) and 4.9 (2.0) μ m, respectively. Animals then were observed for 14 days.

LC₅₀ Males = > 4.65 mg/L
Females = > 4.65 mg/L
Combined = > 4.65 mg/L

No animals died, except for one female at 4.65 mg/L that was not treatment related. Piloerection, ptosis, and decreased activity were observed in all animals, which subsided by day 4. No treatment-related abnormalities were noted upon necropsy, including the respiratory tract. Necropsy findings on the animal that died (not treatment related) revealed red lungs and signs of nasal discharge and polyuria. There were no treatment-related effects on body weight in males. Decreased weight gain was noted in two females at each dose level between days 0 and 7, which rebounded by day 14. One female exposed to 1.39 mg/L lost weight between days 7 and 14, while another female exposed to 4.65 mg/L failed to gain weight between days 0 and 7.

CGA-279202 Technical (95.9% a.i.) is TOXICITY CATEGORY IV based on an absence of treatment-related mortality in both sexes at a concentration above the limit concentration.

This acute inhalation study is classified as acceptable, and satisfies the guideline requirement for an acute inhalation study (81-3) in the rat.

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

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SignOff Date:
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