

[Trifloxystrobin]

(TxR 013599)

(8-3-99) 35

Primary Eye Irritation Study (81-4)

EPA Reviewer: Deborah C. Smegal
Toxicology Branch II (7509C)
EPA Secondary Reviewer:
Toxicology Branch II (7509C)

_____, Date ____

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DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS 870.2400 [§81-4]

DP BARCODE: 243979
P.C. CODE: 129112

SUBMISSION CODE: S538757
TOX. CHEM. NO.:

TEST MATERIAL (PURITY): CGA 279202 WG 50 (A-9360 B) (50.8% a.i.)

SYNONYMS: Trifloxystrobin

CITATION: Winkler, G. 1996 (Amended to Cantoreggi S. On 5/1/97). Acute Eye Irritation/Corrosion Study in the Rabbit. Novartis Crop Protection AG. Stein, Switzerland. Laboratory Project Number: 963042. Novartis Nexus Number: 480-96. May 8, 1996. MRID 44496633. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In a primary eye irritation study [MRID 44496633], 53 mg (0.1 mL) of CGA 279202 WG 50 (A-9360 B) formulation (50.8% a.i.) as a finely ground powder was instilled into the conjunctival sac of the left eye of 3 young adult male white New Zealand rabbits (Chbb:NZW). Animals then were observed for 3 days according to OECD protocol. Irritation was scored by the OECD scoring system.

No corneal opacity or iritis was observed. Grade 1 conjunctival irritation were observed in all 3 treated eyes 24 hours post treatment, with irritation clearing by 2 days post treatment. Body weights were unaffected by treatment. **In this study, CGA 279202 WG 50 formulation (50.8% a.i.) produced minimal eye irritation and is classified in TOXICITY CATEGORY III for primary eye irritation.**

This study is classified as acceptable non-guideline, because it satisfies the OECD guideline No. 405, adopted February 24, 1987 for primary eye irritation in the rabbit.

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

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