

ITrifloxystrobini

(TXR 013599)

38  
(8-3-99)  
Primary Dermal Irritation Study (81-5)

EPA Reviewer: Deborah C. Smegal  
Toxicology Branch II(7509C)  
EPA Secondary Reviewer: Ching-Hung Hsu, Ph.D.  
Toxicology Branch II (7509C)

## DATA EVALUATION

### RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbits OPPTS  
870.2500 [§81-5]

DP BARCOD[ 243979  
P.C. CODE:1291 12

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

SUBMISSION  
CODE:S538757  
TOX. CHEM. NO.:

SYNONYMS: Trifloxystrobin formulation

CITATION:: Winkler, G. 1996. (Amended to Cantoreggi 5., 12/10/97)  
Acute Dermal Irritation  
ICorrosion Study in the Rabbit. Novartis Crop Protection AG. Stein, Switzerland.  
Laboratory Project Number: 963041. Novartis Nexus Number 479-96. April 18,  
1996. MRI D 44496636. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In a primary dermal irritation study (M RID 44496636), 3 male New Zealand White rabbits were dermally exposed to 0.5 g of CGA-279202 WG50 (50.8% a.i.), moistened with distilled water for 4 hours to 6 em<sup>2</sup> body surface area and covered with a gauze patch. Animals then were observed for 3 days. Irritation was classified according to Council Directive 67/548/EEC, adapted to technical progress by Commission Directive 93/21/EEC.

Grade I erythema was observed in all 3 animals 24 hours after patch removal and in I of3 animals 72 hours after patch removal. Erythema disappears in all animals 7 days after patch removal. No edema was observed. In this study, CGA-279202 50WG-B (50.8% a.i.) is a slight dermal irritant, and is classified in TOXICITY CATEGORY IV f)r primary dermal irritation.

This study is classified as acceptable because it satisfies the OECD guidelines for a primary dermal

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irritation study in the rabbit.

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

NB: This EPA-generated Executive Summary disagrees in a major respect with the attached CALEPA's Toxicology Study Evaluation Worksheet conclusions: three test animals were considered to be acceptable since it satisfies the OECD guideline.

SignOff Date:  
DP Barcode:  
HED DOC Number:  
Toxicology Branch:

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