

ITrifloxystrobin

(TXR 013599)

(8-3-99)

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Primary Dermal Irritation Study (81-5)

EPA Reviewer: Deborah C. Smegal

Date

Toxicology Branch I I(7509C)

EPA Secondary Reviewer: Ching-Ilung Hsu, Ph.D

Toxicology Branch II (7509C)

Date

DATA EVALUATION RECORD

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

DP BARCODE 243979

SUBMISSION CODE:5538757

P.C. CODE: 129112

TOX. CHEM. NO.:

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

SYNONYMS: Trifloxystrobin

CITATION: Glaza, S.M. 1994. Primary Dermal Irritation Study of CGA-279202 Technical in Rabbits. Covance Laboratories Inc. 3301 Kinsman Boulevard. Madison, WI 53704. Laboratory Project Number: HWI 40702446. Novartis Nexus Number 358-94. October 5, 1994. MRID 44496635. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID~44496635), Hra:~ZW)SPF rabbits (3/sex) were dermally exposed to 0.5 g of CGA-279202 technical (96% a.i.), moistened with distilled water for 4 hours to 6.25 cm² body surface area using a semiocclusive dressing. Animals then were observed for 3 days. Irritation was scored by the method of Draize technique.

Grade I erythema was observed in 3 animals 24 hours after patch removal, with all signs of erythema subsiding in all animals by 72 hours after patch removal. Grade I edema was also observed in one animal 24 hours after patch removal, which subsided within 48 hours after patch removal. **In this study, CGA-279202 technical is a slight dermal irritant. CGA-279202 technical is classified in TOXICITY CATEGORY IV for primary dermal irritation based on both sexes.**

This study is classified as acceptable and satisfies the guideline requirement for a primary dermal irritation study (81-5) 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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NB: This EPA-generated Executive Summary agrees in all major respects with the attached CALEPA's Toxicology Study Evaluation Worksheet summary and conclusions for this study.

SignOff Date:

8/3/99

DP Barcode:

D243979

HED DOC Number:

013599

Toxicology Branch:

TOX2