(TXR 013599) (8-3-99) 21

Trifloxystrobin

Bacterial/Mammalian Activation; Gene Mutation (84-2)

EPA Reviewer: Irving Mauer, Ph.D. Date: _____
Toxicology Branch 2, Health Effects Division (7509C)
EPA Secondary Reviewer: Ching-Hung Hsu, Ph.D. Date: _____
Toxicology Branch 2, Health Effects Division (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Salmonella and Escherichia/mammalian activation gene mutation assay; OPPTS 870.5100 [84-2]

DP BARCODE: D243979 SUBMISSION CODE: S538757

P.C. CODE: 129112 TOX. CHEM. NO.: [N/A]

MRID NO.: 44496717

TEST MATERIAL (PURITY): NOA-414412 Technical (metabolite of trifloxystrobin; 95±2%)

SYNONYMS: [None]

CITATION: Deparade, E. (1997). Salmonella and Escherichia/Mammalian-Microsome Mutagenicity test, conducted at the Genetic Toxicology Laboratory of Novartis Crop Protection, AG, Basle (Switzerland), Test No. 973065 (Novartis Nexas Number 751-97), dated October 29, 1997. MRID 44496717. Unpublished.

SPONSOR: Novartis Crop Protection Inc. (formerly CIBA-GEIGY Ltd), Greensboro, NC.

EXECUTIVE SUMMARY: In a reverse gene mutation assay in bacteria (MRID 44496717), triplicate cultures of Salmonella typhimurium strains TA98, TA100, TA102, TA1535, TA1537 and Escherichia coli strain WP2 *uvr*A were exposed in two trials to test article in dimethylsulfoxide (DMSO) for 48 hours at five concentrations ranging from 312.5 to 5000 *ug*/plate in the presence and absence of the post-mitochondrial supernatant (S9 fraction) from Arochor 1254-induced male rat liver. In addition to vehicle (DMSO) controls, additional cultures were treated with strain-specific mutagens as positive controls. Following the two days incubation, the frequencies of revertant colonies in test cultures were compared to DMSO controls, using the criterion of multiplicity (1.5 to 2.0 x-fold) to define a positive response for the test article.

In none of the treated cultures at any concentration was an increase in revertant colonies over negative controls observed, in contrast to the strong positives in all mutagen treated cultures.

This study is classified as acceptable and satisfies the requirement for FIFRA Test Guideline 84-2 for in vitro mutagenicity (bacterial reverse gene mutation) data.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

NB: This EPA-generated Executive Summary agrees in major respects with the attached "one-liner" summary from CALEPA's 6/4/98 Toxicology Study Evaluation Worksheet for this study.

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HED DOC Number: [illegible]

Toxicology Branch: TOX2

SignOff Date:	8/3/99
DP Barcode:	D243979
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Toxicology Branch:	TOX2