(8-3-99) 12

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 reverse 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. 44496712

TEST MATERIAL (PURITY): Trifloxystrobin (96.4%)

SYNONYMS: CGA 279202

CITATION: Herter, Th. (1994). Salmonella and Escherichia/Mammalian Microsome Mutagenicity Test, conducted at the Genetic Toxicology Laboratory of Novartis Crop Protection AG, Basle (Switzerland), Test No. 943074 (Novartis Nexus Number 500-94), dated September 26, 1994. MRID NO. 44496712. Unpublished.

SPONSOR: Novartis Crop Protection AG (formerly CIBA-GEIGY Limited). Greensboro, NC

EXECUTIVE SUMMARY: In a reverse gene mutation assay in bacteria (MRID 44496712), mutant cultures of Salmonella typhimurium strains TA 98, TA100, TA102, TA1535, TA1537 and Escherichia coli strain WP2 uvrA were treated for 48 hours at 37 degrees C with trifloxystrobin technical (purity 96.4%) at concentrations in triplicate ranging from 312.5 to 5000 ug/plate with and without mammalian metabolic activation in an initial experiment, and from 61.73 to 5000 ug/plate with/without activation in a confirmatory (independent) experiment. The mammalian metabolic activation system was prepared from Aroclor 1254-induced rat liver S9 fraction, supplemented with NADP(H)-generating co-factors. Strain-specific mutagens were used as positive controls in both experiments.

Whereas precipitation of test material was observed at the two highest doses in both assays, none of the tested concentrations of the test article with or without metabolic activation were toxic, or increased the incidence of revertants compared to the vehicle control (DMSO), in contrast to the positive responses of all mutagen-treated controls.

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 all major respects with the attached CALEPA's 6/4/98 Toxicology Study Evaluation Worksheet summary and conclusions for this study.

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