

(TXR 013599)

(8-3-99) 20

Trifloxystrobin

Unscheduled DNA Synthesis (84-2)

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

Date: _____

Date: _____

DATA EVALUATION RECORD

STUDY TYPE: Other genotoxicity: unscheduled DNA synthesis in primary rat hepatocytes cultures; OPPTS 870.5550 [84-2]

DP BARCODE: D243979

SUBMISSION CODE: S538757

P.C. CODE: 129112

TOX. CHEM. NO.: [N/A]

MRID NO.: 44496719

TEST MATERIAL (PURITY): Trifloxystrobin technical (96.4%)

SYNONYM(S): CGA-279202

CITATION: Herter, Th. (1995). Autoradiographic DNA Repair Test on Rat Hepatocytes, conducted at the Genetic Toxicology Laboratories of Novartis Crop Protection, AG, Basle (Switzerland), Test No. 943077 (Novartis Nexus Number 769-95), dated June 9, 1995. MRID 44496719. Unpublished.

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

EXECUTIVE SUMMARY: In an unscheduled DNA synthesis assay (MRID 44496719), triplicate primary rat hepatocyte cultures were exposed for 16-18 hours in two independent trials to trifloxystrobin technical (96.4% a.i.) in dimethylsulfoxide at concentrations ranging from 0.39 to 50.0 $\mu\text{g/mL}$. In addition to solvent (DMSO) controls, additional cultures were treated with 2-acetaminofluorene (2-AAF, 45 μM), to serve as positive control. Following treatment, all cultures were exposed to tritiated thymidine, and prepared by standard autoradiographic procedures for the determination of silver grain counts, a measure of unscheduled DNA repair synthesis.

Trifloxystrobin was tested up to cytotoxic concentrations. In contrast to the positive control, which induced the appropriate response, there was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), was induced.

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Section 16

This study is acceptable and satisfies the FIFRA Test Guideline (84-2) for other genotoxic/mutagenicity 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 CALEPA 6/4/98 conclusions for the same study.

6/4/98

Trifloxystrobin

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Trifloxystrobin

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Trifloxystrobin

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