

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.5100 [§84-2]; Bacterial Reverse Gene Mutation Assay

Work Assignment No. 4-01-128 R (MRID 46808240)

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Pesticides Health Effects Group
Sciences Division
Dynamac Corporation
1910 Sedwick Road, Bldg 100, Ste B.
Durham, NC 27713

Primary Reviewer

David A. McEwen, B.S.

Signature: _____

Date: _____

Secondary Reviewer

Stephanie E. Foster, M.S.

Signature: _____

Date: _____

Program Manager:

Michael E. Viana, Ph.D., D.A.B.T.

Signature: _____

Date: _____

Quality Assurance:

Mary L. Menetrez, Ph.D.

Signature: _____

Date: _____

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel

US EPA ARCHIVE DOCUMENT

XDE-570 (FLORASULAM)/129108

OPPTS 870.5100 / DACO 4.5.4 / OECD 471

EPA Reviewer: Karlyn J. Bailey Signature: _____
 Registration Action Branch 2, Health Effects Division (7509P) Date: _____
 EPA Secondary Reviewer: Myron Ottley, Ph.D. Signature: _____
 Registration Action Branch 3, Health Effects Division (7509P) Date: _____

Template version 02/06

DATA EVALUATION RECORD – SUPPLEMENT

See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: *In vitro* Bacterial Gene Mutation (*Salmonella typhimurium*/ *E. coli*)/ mammalian activation gene mutation assay; OPPTS 870.5100 [' 84-2]; OECD 471 (formerly OECD 471 & 472).

PC CODE: 129108**DP BARCODE:** D331116**TXR#:** 0054348**TEST MATERIAL (PURITY):** XDE-570 (Florasulam; 99.2% a.i.; Lot # 930910)**SYNONYMS:** XR-570, XRD-570, DE-570, N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-*c*)pyrimidine-2-sulfonamide

CITATION: Lawlor, T.E. (1995) Mutagenicity test on XDE-570 in the *Salmonella*/mammalian-microsome reverse mutation assay (Ames test) pre-incubation method with a confirmatory assay. Corning Hazleton Inc., Vienna, VA. Laboratory Project Study ID: CHV Study No. 16246-0-422R; Dow Study No. DR-0312-6565-016, December 28, 1995. MRID 46808240. Unpublished.

SPONSOR: Dow AgroSciences Canada, Inc., 2100- 450 1 St. SW, Calgary, AB, Canada

EXECUTIVE SUMMARY - In two independent trials of a reverse gene mutation assay in bacteria (MRID 46808240), *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, and *Escherichia coli* strain WP2uvrA were exposed to XDE-570 (Florasulam; 99.2% a.i.; Lot # 930910) in dimethylsulfoxide (DMSO) at concentrations of 0, 0.333, 1, 3.33, 10, 33.3, or 100 µg/plate (*S. typhimurium*) and 0, 10, 33.3, 100, 333, 1000, or 3330 µg/plate (*E. coli*) both in the presence and absence of S9-activation. The S9 fraction was derived from the livers of male Sprague-Dawley rats induced with Aroclor 1254. The pre-incubation method was used in both the initial and confirmatory assays. Standard strain-specific mutagens served as positive controls.

XDE-570 was tested up to cytotoxic concentrations, as indicated by the reduced numbers of revertants at 33.3 µg/plate and above in the *S. typhimurium* strains and at 3333 µg/plate in the *E. coli* strain. There were no marked increases in the mean number of revertants/plate in any strain. The positive controls induced the appropriate response in all strains in the presence and absence of S9-activation. **There was no evidence of induced mutant colonies over background.**

The study is classified as **acceptable/guideline** and satisfies the guideline requirement for Test Guideline OPPTS 870.5100; OECD 471 for *in vitro* mutagenicity (bacterial reverse gene mutation) data.

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