

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Robert Taylor, PM #25
Registration Division (H7505C)

From: Elizabeth Behl, Section Chief
Ground Water Technology Section
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (H7507C)

Dan Wells for EB
7/11/93
Henry Jacoby
7/19/93

Attached, please find the EFGWB review of...


DP Barcode:	D192308		
Common Name:	flumetsulam (DE-498)	Trade name:	Broadstrike
Company Name:	DowElanco Corporation		
ID #:	062719-EEG		
Purpose:	Response to letter from DowElanco regarding their intended response to recommendations made by GWTS in an earlier review. Draft review completed 7/6/93, revised 7/13/93.		

Type Product:	Action Code:	EFGWB #(s):	Review Time:
Herbicide	101	93-0818	0.7 days

STATUS OF STUDIES IN THIS PACKAGE:

STATUS OF DATA REQUIREMENTS:

Guideline #	MRID	Status ¹
None	unknown	



	Status ²
166-1	N

¹Study Status Codes:

A=Acceptable U=Upgradeable C=Ancillary I=Invalid.

²Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

DP BARCODE: D192308

CASE: 031451
SUBMISSION: S442721

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/20/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 101 RESB NC-FOOD/FEED USE
CHEMICALS: 129016 (1,2,4)Triazolo(1,5-a)pyrimidine-2-sulfonamide, N- 98.0000%

ID#: 062719-EEG dowelanco/de-498 98% technical manuf. use product
COMPANY: 062719 DOWELANCO
PRODUCT MANAGER: 23 JOANNE MILLER 703-305-7830 ROOM: CM2 237
PM TEAM REVIEWER: STEVEN ROBBINS 703-305-7546 ROOM: CM2 263
RECEIVED DATE: 06/16/93 DUE OUT DATE: 12/23/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 192308 EXPEDITE: N DATE SENT: 06/17/93 DATE RET.: / /
CHEMICAL: 129016 (1,2,4)Triazolo(1,5-a)pyrimidine-2-sulfonamide, N-(2,6-difl
DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 10/15/93 CSF: N LABEL: N
ASSIGNED TO DATE IN DATE OUT
DIV : EFED 06/22/93 / /
BRAN: EFGB 06/22/93 07/19/93
SECT: GTS 06/22/93 07/19/93
REVR : MBARRETT 06/22/93 07/19/93
CONTR: 93-0818 06/22/93 06/22/93

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: MIKE BARRET

Please review this response by DowElanco to your review of a partial progress report (review dated 6/1/93). This response addresses the points you made on page 4 of above mentioned review. Please advise as to the acceptability of this response to answer those deficiencies.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRAI.CH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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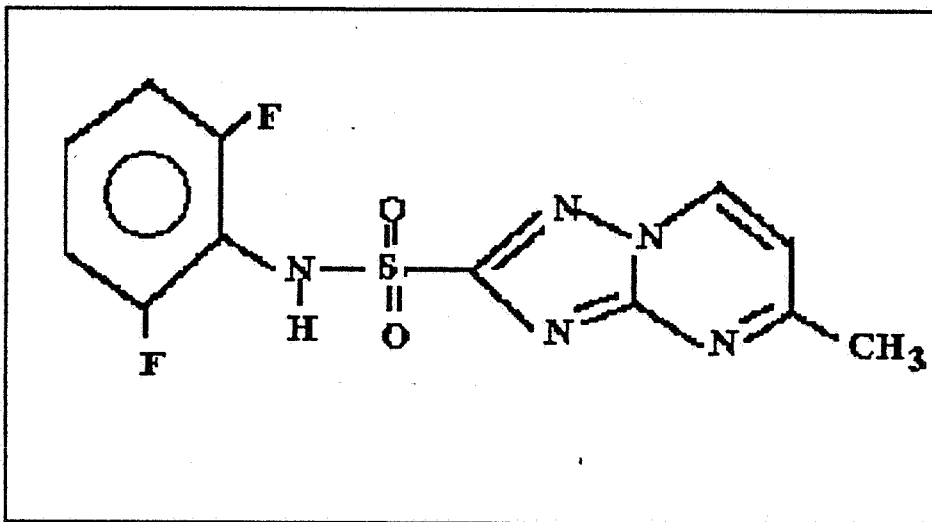
1. CHEMICAL:

Common Name: flumetsulam (company designation = DE-498)

Trade Name: Broadstrike

Chemical Name: N-(2,6-difluorophenyl)-5-methyl-1,2,4-triazolo (1,5a)pyrimidine-2-sulfonamide

Structure:



2. TEST MATERIAL: formulated products.

3. STUDY/ACTION TYPE:

Registrant has submitted a letter responding to recommendations concerning ground-water monitoring studies made in a previous review by the Ground Water Technology Section (GWTS).

4. STUDY IDENTIFICATION:

Lade, Dennis H. 1993. Letter dated 6/15/93 to Joanne I. Miller (PM-23). Subject: DE-498 (flumetsulam), response to GWTS review of June 2, 1993.

5. REVIEWED BY:

Michael R. Barrett, Ph.D. Signature: _____
Chemist
OPP/EFED/EFGB/Ground-Water Section

Date: 7/13/93

6. APPROVED BY:

Elizabeth Behl
Acting Section Chief
OPP/EFED/EFGWB/Ground-Water Section

Signature: Date: 7/13/93**7. CONCLUSIONS:**

No new data have been submitted since our last review (GWTS review dated 6/1/93, DP Barcodes D166604, D182848, D189831, and D190325; EFGWB nos. 91-0772, 92-1372, 93-0567, and 93-0619); further conclusions will be appropriate when complete ground-water monitoring studies are submitted.

8. RECOMMENDATIONS:

The registrant shall submit the following:

- ▶ A full interim report on the two Small-Scale Retrospective Ground-Water Monitoring studies by August 30, 1993. A final report should be submitted after termination of the studies has been approved by the Agency
- ▶ After completing their ground-water monitoring studies, an analysis of the relative likelihood of leaching to the saturated zone by soil type / geographic location.
- ▶ Data to support the registrant's conclusion that their unspecified analytical methods will consistently detect levels of flumetsulam in soil and water well below those which cause phytotoxic symptoms in susceptible plants / crops. If DowElanco believes that the data which have been submitted already to the Agency demonstrate this, then a discussion of the relevance of these data to this issue and a citation of or additional copy of the relevant submission should be submitted for review by GWTS. Note however, that Ecological Effects Branch indicates that they are requiring additional data on flumetsulam phytotoxicity in the form of seedling emergence studies (Mike Davy, personal communication, 7/12/93).

The label language regarding concerns for leaching to ground water which has been proposed by the registrant is slightly different from the recommended language. Unless there is a compelling reason to do otherwise, the label language should be as follows:

This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

GWTS believes that insufficient data are currently available to reliably quantify the extent of the potential impact on ground water from flumetsulam use. Therefore, conclusions cannot be made on the acceptability of registration with regards to environmental impact of residues in soil and water.

Small-scale prospective ground-water monitoring studies are appropriate for flumetsulam, which has the characteristics of pesticides known to leach to ground water. The Agency may require further ground-water monitoring studies to evaluate the extent of the hazard of flumetsulam leaching to ground water. However, GWTS will consider whether the two voluntary studies DowElanco is conducting can fulfill some of these data requirements. The registrant should continue all soil, soil-water, and ground-water sampling at the study sites until the environmental fate of flumetsulam has been completely described. Failure to do so may render the studies unusable to meet ground-water monitoring study data requirements.

9. BACKGROUND:

In 1991, DowElanco Corp. submitted a short protocol outlining their plans for two, self-initiated, small-scale prospective ground-water monitoring studies for flumetsulam. In March 1993, GWTS conducted a brief Leaching Assessment for this chemical (no DP Barcode assigned). In June 1993, GWTS conducted an additional, but still preliminary, Leaching Assessment (GWTS review dated 6/1/93, DP Barcodes D166604, D182848, D189831, and D190325; EFGWB nos. 91-0772, 92-1372, 93-0567, and 93-0619). The June 1993 GWTS review also responded to comments made by DowElanco in two letters accompanied by selected data and submitted to the Agency in late March and early April of 1993. DowElanco has now submitted a 2-page response to the June 1993 GWTS assessment, which is the subject of the current review.

10. DISCUSSION:

DowElanco discusses four different issues (from recommendations made in the June 1, 1993 review by GWTS) in their letter. GWTS responses to each of these issues as follows.

1. DowElanco has committed to providing full interim reports on their two self-initiated small-scale prospective ground-water monitoring studies in August 1993. These reports, if

sufficiently complete, should facilitate a more complete assessment by GWTS of the potential of flumetsulam to impact ground water.

2. DowElanco has agreed to place an advisory on the product label regarding a potential for flumetsulam to leach to ground water in vulnerable areas. This is appropriate, since the environmental fate database reveals flumetsulam has similar properties to other pesticides which have been demonstrated to leach to ground water (GWTS review dated 6/1/93, DP Barcodes D166604, D182848, D189831, and D190325; EFGWB nos. 91-0772, 92-1372, 93-0567, and 93-0619). The label language should follow the standard format which EFGWB has developed (see Recommendations section).
3. GWTS holds in reserve a decision as to whether to recommend geographic restrictions on flumetsulam use, pending submission of a complete data package including ground-water monitoring study results from DowElanco.
4. DowElanco notes that their current analytical method can reliably quantitate flumetsulam in water at 0.05 ug/L or ppb and states that the most sensitive plant species is only effected by exposure to 2.00 ug/L or higher levels of flumetsulam. EFGWB needs a complete submission of DowElanco's data on plant or crop sensitivity to flumetsulam, including the mechanism of exposure, the nature of observed effects, and the results of statistical analysis of the effect of flumetsulam applications. Mike Davy of the Ecological Effects Branch notes that data submitted to them indicates that certain crops (e.g. cotton, cucumber, rape, and sunflower) are extremely sensitive to flumetsulam and might be affected by residues below the detection limits of DowElanco analytical methods. EEB has required DowElanco to submit additional data on the effect of soil-applied flumetsulam on seedling emergence and development (Mike Davy, personal communication, 7/13/93). If DowElanco demonstrates that the analytical method can consistently detect levels in soil or water well below the threshold for phytotoxicity, then GWTS certainly would agree that a bioassay procedure would then be unnecessary.