

114402

Date Out EAB: _____

TO: G. Werdiq
Product Manager 50
Registration Division (TS-767) JAN 27 1988

FROM: Patrick Holden, Team Leader
Ground-Water Team
Exposure Assessment Branch/HED (TS-769C)

THRU: Paul Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Attached please find the environmental fate review of:

Reg./File No.: _____

Chemical: Acifluorfen

Type Product: _____

Product Name: _____

Company Name: _____

Submission Purpose: Waiver

ACTION CODE: 400

Date In: 12/22/87

EAB # 80262

Date Completed: 01/15/88

TAIS (level II) Days

0.25

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

Monitoring study requested by EAB: ☒

Monitoring study voluntarily conducted by registrant: ☐

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12085)

44083 Hed
12-22-87

1. CHEMICAL NAME
ACIFLUORFEN

2. IDENTIFYING NUMBER

114402

3. ACTION CODE

400

4. ACCESSION NUMBER

N/A

TO BE COMPLETED BY PM

5. RECORD NUMBER

210,785

6. REFERENCE NUMBER

7. DATE RECEIVED (EPA)
12/21/87

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)
G.Werdig/B.Crompton

10. PM TEAM NUMBER
50

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

12-22-87

12. PRIORITY NUMBER

50

13. PROJECTED RETURN DATE

4-11-88

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)
☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

Please comment on Rhone-Poulenc's request for

a waiver of the retrospective small scale study

for acifluorfen

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	X ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								2

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.



RHÔNE-POULENC AG COMPANY

EPA Correspondence No. 445-87

December 18, 1987

Ms. Geraldine W. Werdig
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Data Call In Program
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Werdig:

Re: EPA Data Call In Notice for Groundwater Monitoring Data on the Sodium Salt of Acifluorfen

On December 14, 1987 we responded to the subject data call in notice. It was our understanding at that time that a verbal agreement had been reached between Rhone-Poulenc Ag Co. and BASF which would provide that Rhone-Poulenc Ag Co. would conduct and submit both a small scale prospective study to be conducted with Tackle Herbicide and a small scale retrospective study to be conducted on Blazer Herbicide. BASF would satisfy their data requirements by cost sharing in these studies. This was the basis for our submission. It was our intention to followup with submission of written evidence of the agreement in the near future.

Since that time however we have been informed by Ms. Betty Crompton of the EPA that we are not considered to be in compliance with the response requirements under the data call in notice. We were notified that while we responded that we were generating the data jointly with BASF, the response of BASF did not indicate a similar joint action. We are committed to maintaining the registration of Tackle Herbicide. We therefore wish to revise our selection of options for complying with the subject data call in notice. Attached please find a new Data Call In Summary Sheet. We are once again committing to conduct a small scale prospective study on Tackle Herbicide. We are requesting a waiver from the requirement to conduct a small scale retrospective study on the grounds that Tackle Herbicide has not been registered long enough to locate suitable sites for such a study. Registration was granted late in the 1986 season (April 14, 1986), allowing only a limited introduction of our product during the first year of sales. It would therefore be exceedingly difficult for us to locate acceptable test sites that would fulfill the requirements presented in the guidance document for the small scale retrospective study which was included with the data call in notice. This document notes the requirement for test sites with a minimum "of use in two of

the previous three years or three of the previous five years (or an equivalent use history)".

While we have previously submitted a protocol for a small scale retrospective study, we now request that the Agency return this protocol and consider instead our request for a waiver from this data requirement. We regret the confusion that has been caused over this issue. If you have any questions or comments, please let us know as soon as possible so that the proposed study can be initiated.

Sincerely,
Rhone-Poulenc Ag Co.

Margaret Cherny

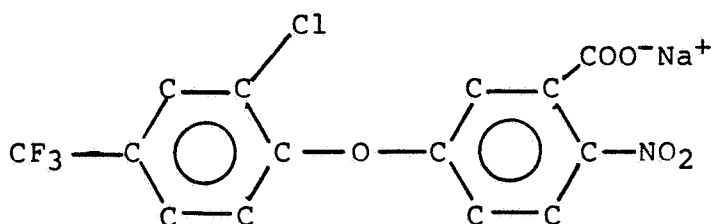
Margaret A. Cherny
Registrations Manager
Herbicides

1. CHEMICAL:

Common name: Acifluorfen, Blazer, Tackle

Chemical name: Sodium-5-[2-chloro-4-(trifluoromethyl)-phenoxy]-2-nitrobenzoate

Structure:



Sodium salt of acifluorfen

2. TEST MATERIAL:

Not applicable.

3. STUDY/ACTION TYPE:

This is a waiver request from Rhône-Poulenc Ag Company. They are requesting a waiver from the small-scale retrospective ground-water monitoring study.

4. STUDY IDENTIFICATION:

The submission is a letter from Rhône-Poulenc's Herbicide Registration Manager, Margaret Cherny, dated 12/18/87. EPA Correspondence No. 445-87.

5. REVIEWED BY:

Catherine Eiden
Ground-Water Team

Catherine Eiden
1/19/88

6. APPROVED BY:

Patrick Holden, Team Leader
Ground-Water Team

C.E. Holden
1/27/88

7. CONCLUSIONS:

The company requests a waiver from the small-scale retrospective ground-water monitoring study.

Historically, a data call-in notice was sent to both Rhône-Poulenc and BASF requiring a small-scale prospective and a retrospective ground-water monitoring study on acifluorfen. Both companies have registrations on products containing acifluorfen as the active ingredient. Rhône-Poulenc has a registration on Tackle. BASF has a registration on Blazer.

Rhône-Poulenc has agreed to submit a small-scale prospective ground-water study on Tackle. The study protocol has been discussed by Rhône-Poulenc and EAB's Ground-Water Team. EAB awaits the formal submittal of that protocol for approval.

Rhône-Poulenc claims they have not had the Tackle registration long enough to qualify for conducting a small-scale retrospective ground-water study, for lack of a use history. The Tackle registration was granted on 4/14/86.

EAB concludes that the RD should verify the use history of Tackle. If Tackle has been used for 3 years or more, then it qualifies for a small-scale retrospective study. The registrant must then try and locate sites with use histories showing 2 or more years of consecutive use. In this case, BASF and Rhône-Poulenc may want to cooperate.

If Tackle has been used less than 3 years, then EAB offers the following suggestion:

- ° Rhône-Poulenc is complying with the small-scale prospective ground-water study on acifluorfen. Grant them a waiver from the small-scale retrospective ground-water monitoring study. Verify that BASF has had a registration on acifluorfen for 3 years or more (therefore implying use for at least that long) and require the small-scale retrospective study from BASF for Blazer. This way EPA gets both studies, 1 from each registrant, in an effort to share the burden. The companies could cooperate in a joint effort.

8. RECOMMENDATIONS:

1. Verify Rhône-Poulenc's claim that they do not have a long enough use history with Tackle to qualify for a small-scale retrospective study.
2. If it is verified, grant a waiver.
3. If it is not verified, require the study.

4. Verify that BASF has a long enough use history to require the small-scale retrospective study.

5. If it is verified, require the study.

6. If both companies qualify for a small-scale retrospective study, they must both comply (same as for the small-scale prospective study) and it behooves them to share the cost through a joint effort.

9. BACKGROUND:

Not applicable.

10. DISCUSSION OF INDIVIDUAL STUDIES:

Not applicable.

11. ONE-LINER:

Not applicable.

12. CBI:

No CBI were contained with this package.