

Shaughnessy No.: 114402

Date Out of EAB: JUL 15 1986

To: Richard Mountfort
Product Manager 23
Registration Division (TS-767C)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 359-TNI
Chemical Name: Acifluorfen, Sodium Salt
Type Product : Herbicide
Product Name : Tackle
Company Name : Rhone-Poulenc
Purpose : Request re-review of report on confined rotational crop
accumulation studies, Accession No. 256167

Action Code(s): 166

EAB #(s) : 5762

Date Received: 7/12/85

Monitoring Submitted: _____

Date Completed: 7/14/86

Monitoring Requested: _____

Total EAB Reviewing Time: 5.0 days

TAIS CODE 61

Deferrals to:

_____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

1. CHEMICAL: Common name:

Acifluorfen

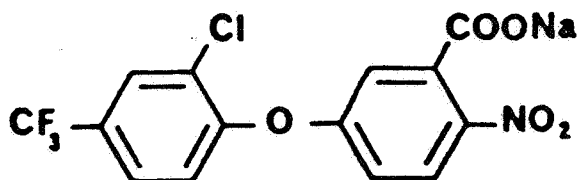
Chemical name:

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

Trade name(s):

Blazer, Blazer 2L, Blazer 2S, MC 10978, RH-6201, Tackle 2AS

Structure:



Formulations:

2 lb liquid concentrate; 2 lb/gal water soluble salt

Physical/Chemical properties:

Physical state: Brown crystalline powder

Melting point: >250°C

Solubility in water: >25%

2. TEST MATERIAL:

Active ingredient (¹⁴C-MC-10978, uniformly labeled in the nitrophenyl ring, specific activity 5.0 μCi/mg)

3. STUDY/ACTION TYPE:

Submission of data to support the reduction of the rotational crop restriction from 1 year to 8 months.

4. STUDY IDENTIFICATION:

Hutchinson, C. and M. Jaber. 1984. ¹⁴C-Tackle (MC-10978): Confined rotational crop study. Project No. 171-07. Prepared by Wildlife International Ltd. and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 256167.

5. REVIEWED BY:

Hudson L. Boyd
Chemist
EAB/HED/OPP

Signature: Hudson L. Boyd

Date: 7/14/86

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review Section #3, EAB/HED/OPP

Signature: Emil Regelman

Date: JUL 15 1986

7. CONCLUSIONS:

This study does not meet EPA requirements for registering pesticides because the stated application rates were not confirmed by soil analyses, the confirmed rate for the 8-month treatment to planting interval was only about one-third the highest recommended rate, and the [¹⁴C] residues in the plants were not characterized. It appears that the study was conducted under less than controlled conditions. It also appears that the registrant ignored earlier discussions and recommendations (April and May 1982) relative to test protocols and Subdivision N requirements.

8. RECOMMENDATIONS:

The study should be repeated with special care that application rates are consistent from interval to interval and that they are varifiable. If control plots show acifluorfen residues, provide an explanation.

Conduct rotational crop studies to determine at what interval no detectable residues occur when acifluorfen is applied at the maximum recommended rate. Restrict planting of any rotational crop to that interval.

To fully substantiate the claim that an 8-month treatment to planting interval is sufficient, include treatments exceeding the recommended 0.75 lb ai/A; apply 1 lb/A for that interval.

Employ laboratory methods having a greater sensitivity than 0.01-0.2 ppm. That is less sensitivity than would be expected of an LSC method.

Where possible, characterize (identify) and quantify residues in the rotated crops.

9. BACKGROUND:

A. Introduction

Rhone-Poulenc has submitted a study (Acc. No. 256167) to support a proposed amendment to the Tackle label reducing the rotational crop restriction for all crops to eight months from the current one year.

Two previously submitted rotational crop studies (Dynamac review of 8/26/83) were found to be scientifically valid but inadequate to support the confined accumulation data requirement. The two most notable deficiencies, low rates of application relative to the proposed application rate and failure to adequately identify metabolites were partially addressed in the 6/25/84 review.

Tentatively identified residues in wheat planted 12 months after treatment at 0.16 lb ai/A (ASD Report #82/046) included parent Acifluorfen, MC-10879 and MC-10074. In addition, MC-10108 and MC-14621 could have been present, but confirmation was not made due to inadequate methodology.

B. Directions for Use

Acifluorfen is a selective pre- and postemergence herbicide used to control a wide spectrum of annual broadleaf weeds and grasses in soybeans, peanuts, and rice.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See attached review.

11. COMPLETION OF ONE-LINER:

One-liner not amended.

12. CBI APPENDIX:

The data discussed here are considered as CBI by the registrant and must be treated as such.

ACIFLUORFEN (SODIUM SALT OF)

Final Report

**Task 1: Review and Evaluation of
Individual Studies**

Contract No. 68-02-4250

JULY 11, 1986

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

CASE GSO ACIFLUORFEN STUDY 1 PM --

CHEM 114402 Acifluorfen

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID NONE CONTENT CAT 01
Hutchinson, C. and M. Jaber. 1984. ¹⁴C-Tackle (MC-10978): Confined rotational crop study. Project No. 171-07. Prepared by Wildlife International Ltd. and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 256167.

SUBST. CLASS = S.

DIRECT RVW TIME = 6 (MH) START-DATE END DATE

REVIEWED BY: K. Patten
TITLE: Staff Scientist
ORG: Dynamac Corp., Rockville, MD
TEL: 468-2500

APPROVED BY: H. Boyd
TITLE: Chemist
ORG: EAB/HED/OPP
TEL: 557-7463

SIGNATURE: *Andrew H Boyd*

DATE: 7-14-86

CONCLUSIONS:Confined Accumulation - Rotational Crops

This study cannot be validated because the measured concentrations of [¹⁴C]acifluorfen in the soil were inconsistent with the reported application rates; therefore, an accurate appraisal of the relationship between application rate and crop uptake could not be determined. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because the [¹⁴C]residues in the soil and plants were not characterized.

MATERIALS AND METHODS:

[¹⁴C]Acifluorfen (Tackle, radiopurity 98.7%, specific activity 5.03 μ Ci/mg, uniformly labeled in the nitrophenyl ring) was applied at 0.75 lb ai/A to three plots (4 x 6 feet) of loam soil (34.4% sand, 47.0% silt, 18.6% clay, 1.9% organic matter, pH 7.5) located near St. Michaels, Maryland, on June 8, 1983. There were three untreated control plots. Each plot was surrounded with aluminum sheeting that was buried to a depth of ~12 inches and extended ~12 inches above the soil surface. The plots were planted at either 1, 4, or 12 months posttreatment with rye, radishes, turnips, Swiss chard, and sweet corn (12-month only).

A fourth plot, similar to those described, was treated at 0.75 lb ai/A on October 7, 1983. The plot was planted at 8 months posttreatment with rye, radishes, turnips, Swiss chard, and sweet corn.

Six soil samples (0- to 3-, 3- to 6-, and 6- to 12-inch depths) were taken from each plot at the times of treatment, crop planting, and crop harvest. When possible, vegetation samples were collected prior to and at maturity. All samples were kept frozen until analysis.

The plant and soil samples were dried, ground, and analyzed for total [^{14}C]residues by LSC following combustion.

RESULTS:

In the soil of the control plots, [^{14}C]acifluorfen residues were <0.02 ppm at all sampling intervals. In mature crops grown in the control plots, [^{14}C]residues were <0.03 ppm.

Immediately after treatment, [^{14}C]residues in the plots treated in June (used for 1-, 4-, and 12-month rotation) ranged from 0.69 to 1.53 ppm in the 0- to 3-inch soil depth (Table 1). However, in the plot treated in October (8-month rotation), residues ranged only from 0.13 to 0.46 ppm immediately after treatment. At the time the crops were planted, all plots contained measurable concentrations of [^{14}C]residues.

Crops planted 1 and 4 months after the application of [^{14}C]acifluorfen either failed to germinate or were malformed; the malformed plants contained as much as 0.43 ppm of [^{14}C]residues at harvest (Table 2). Crops planted 8 months posttreatment contained <0.04 ppm of residues at maturity. In the 12-month rotation, crops contained <0.02 ppm of residues at maturity.

DISCUSSION:

1. Judging from the measured concentrations of [^{14}C]acifluorfen in the soil immediately posttreatment, the registrant failed to achieve the stated application rate. The plot used for the 8-month rotation, which was treated at a different time than the other three plots, contained less radiolabeled material immediately after treatment than the other plots; the actual application rate appears to be ~ 0.33 lb ai/A.
2. Although crops planted 1 and 4 months after the application of [^{14}C]acifluorfen either failed to germinate or were malformed, these data were reviewed for comparative purposes. Because of phytotoxicity at 1 and 4 months posttreatment, the registrant claims they will not seek a rotational crop interval shorter than 8 months. Therefore, they did not feel it necessary to characterize [^{14}C]residues in the crops from these rotations.
3. The protocol stated that the sensitivity of the LSC method would be 0.01-0.02 ppm. This is relatively insensitive for an LSC method, and the registrant should explain the apparent lack of sensitivity.

4. Soil and plant samples containing detectable residues should be analyzed to determine the nature of those residues.
 5. Although adequate meteorological data were supplied by the company, the information was illegible in the report provided to review.
 6. Soil CEC was not reported.
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Table 1. [^{14}C]Acifluorfen residues (ppm) in loam soil treated with [^{14}C]acifluorfen (radiopurity 98.7%) at 0.75 lb ai/A.^a

Treatment-to-sampling interval (days)	Sampling depth (inches)		
	0-3	3-6	6-12
<u>One-month rotation^b</u>			
0	0.69-1.53	0.03-0.25	0.04-0.11
30	0.36-0.55	0.06-0.13	0.02-0.05
62	0.39-1.67	0.14-1.05	<0.02-0.06
78	0.24-0.40	0.06-0.21	<0.02-0.08
121	0.26-1.08	0.06-0.67	<0.02-0.09
<u>Four-month rotation^b</u>			
0	1.00-1.24	0.08-0.17	0.06-0.13
121	0.06-0.19	<0.02-0.08	<0.02-0.97
162	1.74-4.51 ^c	0.02-0.17	<0.02-0.38
<u>Eight-month rotation^d</u>			
0	0.13-0.46	0.03-0.14	<0.02-0.04
258	0.11-0.14	0.11	0.03-0.04
293	0.10	0.07-0.09	0.01-0.02
349	0.10-0.11	0.08	0.05-0.06
<u>Twelve-month rotation^b</u>			
0	0.85-1.14	0.06-0.31	0.09-0.10
371	0.16-0.17	0.03-0.04	<0.02
414	0.12-0.13	0.02-0.03	<0.02

^a Range of three samples.

^b Treated on June 8, 1983.

^c The registrant suggests these high concentrations are due to contamination of the soil samples, probably in the laboratory.

^d Treated on October 7, 1983.

Table 2. [^{14}C]Acifluorfen residues (ppm MC-10978 equivalents) in crops planted in loam soil 1-12 months after the soil was treated with [^{14}C]acifluorfen (radiopurity 98.7%) at 0.75 lb ai/A.^a

Crop		Planting-to-harvest interval (days)	Rotation interval (months)			
			1	4	8	12
Rye	Foliage	32-42	0.12	0.04	--	--
		46-53	--	--	0.04	<0.02
		90-100	--	--	0.03	<0.02
	Grain	90-100	--	--	<0.02	<0.02
Turnips	Roots	32-42	0.22	0.10	--	--
		46-53	--	--	<0.02	<0.02
	Leaves	32-42	0.07	0.03	--	--
		46-53	0.43	--	0.02	<0.02
Radishes	Roots	32-42	0.24	0.04	--	--
		46-53	0.08	--	0.02	<0.02
	Leaves	32-42	0.08	0.03	--	--
		46-53	0.36	--	0.03	<0.02
Swiss chard	Leaves	32-42	0.11	--	--	--
		46-53	0.06	--	<0.02	<0.02
Sweet corn	Foliage plus stalks	46-53	--	--	<0.02	<0.02
		90-100	--	--	<0.02	--

^a Average of 3 samples.