

8/31/87

Shughnessy No.: 114402

Date out of EAB: AUG 31 1987

TO: Dick Mountfort
Product Manager 23
Registration Division (TS 767)

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

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Attached, please find the EAB review of...

Reg./File 359-708
Chemical Name: Acifluorfen
Type Product: Herbicide
Product Name: Tackle
Company Name: Rhone-Poulenc
Purpose: Review of registrant's response to EAB comments on the
confined rotational crop study, accession no. 256167,
and review of field rotational crop study submitted in
support of a label amendment.

Action Code: 305 EAB # (s): 70042

Date Received: 10/23/86 Total Reviewing Time: 4 days

Date Completed: 8/25/87

Monitoring Study Requested:

Monitoring Study Volunteered:

Deferrals to: Ecological Effects Branch

 Residue Chemistry Branch

 Toxicology Branch

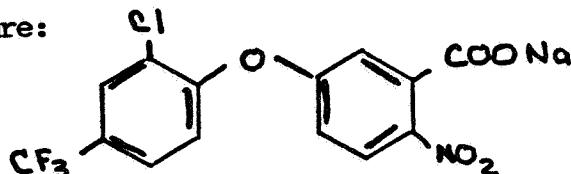
1. CHEMICAL:

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

Acifluorfen

trade name: Tackle 2 AS

structure:



physical/chemical properties:

Physical State: brown, crystalline powder
Melting Point: > 250°C
Solubility in H₂O: >25%

Shaughnessy #: 114402

2. TEST MATERIAL:

Aqueous formulation containing 2 lbs. of acifluorfen sodium per gallon. Application rate was 0.75 lb ai/A.

3. STUDY/ACTION TYPE:

- a. Review of Tackle residue data on field grown rotational crops to support the reduction of the rotational crop restriction from one year to four months for fall seeding of small grains and from one year to eight months for other rotational crops.
- b. Review registrant's response to EAB comments on the confined rotational crop study (acc.no. 256167), which was submitted in support of a reduction of the rotational crop restriction from one year to four months for fall seeding of small grains and from one year to eight months for other rotational crops.

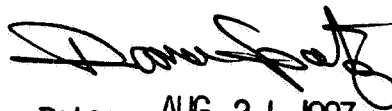
4. STUDY IDENTIFICATION:

- a. Perez, G.M. 1986. Tackle Residue Data on Field Grown Rotational Crops (1982-1984). Rhone-Poulenc Inc., Agrochemical Division, Monmouth Junction, NJ. Received by EPA 10/23/86, accession number 265702.
- b. Letter to Richard Mountfort of EPA dated Oct. 14, 1986 from Margaret A. McMullen of Rhone-Poulenc Inc. accession number: 265701.

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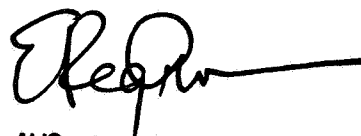
5. REVIEWED BY:

Dana Spatz
Chemist, Review Section 3
EAB/HED/OPP


Date: AUG 31 1987

6. APPROVED BY:

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

Date: 
AUG 31 1987

7. CONCLUSIONS:

EAB cannot concur with the proposed label amendment.

- a. This study (acc.no. 265702) does not meet EPA requirements for registering pesticides for the following reasons:
 - i. The stated application rate was not confirmed by soil analysis. There is no data giving residue levels in the soil at the time of treatment, at the time of planting rotational crops, nor at the time of rotational crop harvest.
 - ii. Because an acceptable confined rotational crop study has not yet been submitted, all possible degradates have not been completely identified. Therefore, it is impossible to know what residues to look for in a cold field study.
- b. The study (acc.no. 256167) does not meet EPA requirements for registering pesticides for the following reasons:
 - i. The confirmed application rate for the eight month treatment to planting interval was only about one-third the highest recommended rate.
 - ii. The ^{14}C residues in the soil and plants were not characterized.
 - iii. The measured concentrations of ^{14}C acifluorfen in the soil were inconsistent with the reported application rates, therefore, an accurate appraisal of the relationship between rate and crop uptake could not be determined.

The status of requirements for terrestrial food crop uses is as follows:

REQUIREMENTS SATISFIED

- a. Hydrolysis (161-1)
- b. Photodegradation in Water (161-2)
- c. Photodegradation in Soil (161-3)
- d. Aerobic Soil Metabolism (162-1)
- e. Anaerobic Soil Metabolism (162-2)
- f. Leaching and Adsorption/Desorption (163-1)
- g. Terrestrial Field Dissipation (164-1)

REQUIREMENTS NOT SATISFIED

- a. Confined Accumulation Studies on Rotational Crops (165-1)
- b. Laboratory Studies of Accumulation in Fish (165-4)

CONDITIONAL REQUIREMENTS

- a. Photodegradation in Air (161-4)
- b. Laboratory Volatility Studies (163-2)
- c. Field Volatility Studies (163-3)
- d. Long-Term Field Dissipation (164-5)
- e. Field Accumulation Studies on Rotational Crops (165-2)

8. RECOMMENDATIONS:

- a. Pending the results of an acceptable confined rotational crop study, this field study should be deferred. If required, the study should include a soil analysis and a verifiable application rate. Where possible, residues should be characterized and quantified. The application rate should be at least 1.1x the maximum label rate, (1 lb ai/A would be acceptable), to substantiate any claim for a 0.75 lb ai/A application rate at the proposed treatment to planting interval.

The registrant should not repeat the field study until an acceptable confined rotational crop study has been submitted to EAB and it is determined by EAB that the field study is required.

- b. The confined study (acc.no. 256167) should be repeated with special care that the application rates are consistent from interval to interval and that they are verifiable.

The results of the study should indicate at what interval no detectable residues occur when acifluorfen is applied at the maximum recommended rate.

Treatments exceeding the recommended 0.75 lb ai/A (apply 1 lb ai/A) should be included to fully substantiate the requested treatment to planting intervals.

Characterize and quantify residues in the soil and rotated crops.

Employ laboratory methods having a sensitivity of at least 0.01 ppm.

9. BACKGROUND:

- a. Rhone-Poulenc has submitted a field rotational crop study (acc. no. 265702) to support a proposed amendment to the Tackle label reducing the rotational crop restriction for winter wheat to four months and for all other crops to eight months from the current one year restriction. Current approved application rate is 0.50 lb ai/A; proposed application rate is 0.75 lb ai/A.
- b. Rhone-Poulenc submitted a confined rotational crop study (accession no. 256167) to support a proposed amendment to the Tackle label reducing the rotational crop restriction for winter wheat to four months and for all other crops to eight months from the current one year restriction. Current approved application rate is 0.50 lb ai/A; proposed application rate is 0.75 lb ai/A.

The study did not meet EPA requirements as cited in the Pesticide Assessment Guidelines, Subdivision N. This study has since been re-reviewed (July 15, 1986) at the request of the registrant and was again found to be deficient.

Now, for the second time, the registrant has responded to EAB's comments on this study, insisting that it is a valid study.

Three confined rotational crop studies have been submitted (reviews dated 6/25/84 and 3/29/85) to EAB and one was found to fulfill the data requirements for a maximum application rate of 0.50 lb ai/A with a one year rotational crop interval for root crops, leafy vegetable crops, and grain from cereal crops. Data requirements have not been fully satisfied for wheat straw and forage because the metabolite identification has not been confirmed.

Directions For Use

Acifluorfen is a selective postemergence herbicide for control of a number of important broadleaf weeds in soybeans. Application of Tackle should be made postemergence to actively growing seedling weeds that do not exceed the recommended maximum stage of growth listed in the Application Rate Table. Tackle is formulated as an aqueous solution containing two pounds of active ingredient per gallon. Do not apply more than three pints per acre, or make more than one application to soybeans per growing season. Do not plant rotational crops within eight months of Tackle application, except for fall seeding of small grains which may be planted four months after Tackle application.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

A. STUDY IDENTIFICATION

Perez, G.M. 1986. Tackle Residue Data on Field Grown Rotational Crops (1982-1984). Rhone-Poulenc Inc., Agrochemical Division, Monmouth Junction, NJ. Received by EPA 10/23/86, accession number 265702.

B. MATERIALS AND METHODS:

Tests were conducted from 1982 to 1984 in Geneseo, Illinois and Ieland, Mississippi in silt loam soil.

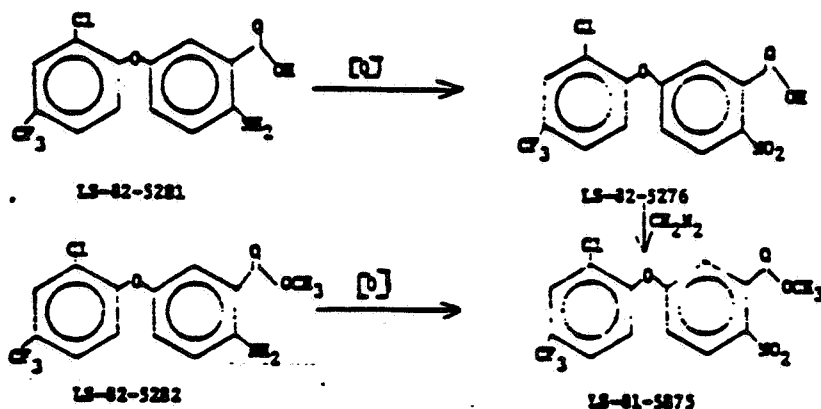
	<u>% sand</u>	<u>% silt</u>	<u>% clay</u>	<u>% OM</u>	<u>pH</u>	<u>CEC</u>
Illinois	17.2	56.2	26.6	3.5	5.5	19
Mississippi	24	59	17	2.4	5.9	7.8

Applications were made in 1982 and 1983 while rotated crops were harvested in 1983 and 1984 respectively. Following the application of the herbicide at 0.75 lb ai/A to the soybeans in a postemergent fashion, typical rotated crops for each region were planted. Residue samples were collected at different growing stages and at maturity from the rotated crops. Soybeans were the primary crop followed by the following rotational crops: corn, alfalfa, cotton, peanuts, winter wheat, potatoes, and turnips.

Except for winter wheat, the crops were planted the following year. The soybean sites were lightly tilled (3-4 inches) prior to bed preparation for the rotated crops.

After the random, representative residue samples were collected in the field, they were stored in freezers, shipped in dry ice, and stored at 0°C until they were ready to be analyzed.

Crop samples were analyzed following Rhone-Poulenc Agrochemical Analytical Method No. 160 for acifluorfen sodium (LS-80-1213) and its major metabolites: LS-82-5276, LS-81-5875, LS-82-5281, and LS-82-5282. The amino acid (LS-82-5281) and amino-ester (LS-82-5282) are oxidized to the corresponding nitro compounds. The salt/free acid (LS-80-1213/LS-82-5276) and above converted amino compounds are methylated to the methyl ester of acifluorfen (LS-81-5875). This methyl ester is measured using gas-liquid chromatography using an electron capture detector. Limit of detection is 0.02 ppm. Spikes were run in order to validate the procedure.



C. Reported Results

A summary of the Illinois rotational crop residue data is given in Table 1. A summary of rotational residue results from the Mississippi site is given in Table 2.

D. Study Author's Conclusions

This two year study shows that rotational crops, both above-ground and below-ground plants, may be grown after Tackle 2AS has been applied initially to soybeans at 0.75 lb ai/A. The winter wheat was planted within 3-4 months after the herbicide treatment while the other crops were planted the following year, ranging from 9 to 13 months after Tackle treatment.

E. Reviewer's Discussion and Interpretation of Study Results

Because the reviewer has no information on how much acifluorfen was actually applied, due to the fact that a soil analysis immediately posttreatment was not taken, a complete assessment of the results cannot be made. Also, the identity of all acifluorfen degradates has not been established in a confined rotational crop study, therefore, we don't know what residues to look for and hence, cannot make a judgement on the residue accumulation in rotated crops.

This study is not acceptable under the Pesticide Assessment Guidelines, Subdivision N (165-2).

The accuracy of the calculations performed in this study was verified by the reviewer. Sample calculations were included in the study.

The % recovery of the residues was acceptable. Climatological data was submitted and was deemed acceptable.

11. COMPLETION OF ONE-LINER:

One-liner not amended.

12. CBI APPENDIX:

Information in this submission is considered to be CBI by the registrant and must be treated as such.

Acifluorfen exposure assessment review

Page _____ is not included in this copy.

Pages 9 through 37 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☐ Description of the product manufacturing process
 - ☐ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☐ A draft product label
 - ☐ The product confidential statement of formula
 - ☐ Information about a pending registration action
 - ☒ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
