

US EPA ARCHIVE DOCUMENT

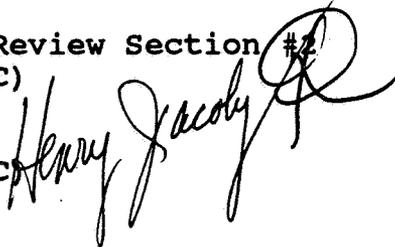
Shaughnessy No.: 121601

Date Out of EFGWB: MAY 9 1990

TO: Robert Taylor/V. K. Walters
Product Manager #25
Registration Division (H7505C)

FROM: Emil Regelman
Supervisory Chemist, Review Section #2
OPP/EFED/EFGWB (H7507C)

THROUGH: Henry Jacoby, Chief
OPP/EFED/EFGWB (H7507C)



Attached, please find the EFGWB review of:

Reg./File #(s): 524-GUI

Common Name: Acetochlor

Chemical Name: 2-chloro-N-ethoxymethyl-6'-ethylacet-o-
toluidide or 2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-
methylphenyl)-acetamide or N-(ethoxymethyl)-2'-methyl-6'-
ethyl-2-chloroacetanilide

Type of Product: Herbicide

Product Name: TOP-HAND, HARNESS

Company Name: MONSANTO AGRICULTURAL COMPANY

Purpose: Evaluation of Protocol for Confined Rotational Crop

Date Received: 12/13/1989 Action Code: 161

Date Completed: 4/16/1990 EFGWB #(s): 90-0333

Total Reviewing Time: 0.4 days

Deferrals to: Ecological Effects Branch/EFED
 Science Integration & Policy Staff/EFED
 Non-Dietary Exposure Branch/HED
 Dietary Exposure Branch/HED
 Toxicology Branch I, II/HED

1. CHEMICAL:

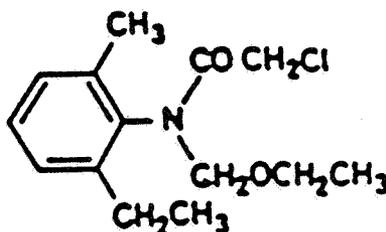
Chemical Name: 2-chloro-N-ethoxymethyl-6'-ethylacet-o-toluidide or 2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)-acetamide or N-(ethoxymethyl)-2'-methyl-6'-ethyl-2-chloroacetanilide

CAS No.: 34256-28-1

Common Name: Acetochlor

Trade Name: TOP-HAND, HARNESS

Chemical Structure:



Molecular Formula: C₁₄H₂₀ClNO₂

Physical/Chemical Properties of Active Ingredient:

Molecular Weight: 269.8 g/mol

Physical state: Oily

Color: Blue to purple

Vapor pressure: < 1 mm Hg

Boiling point: > 200 °C

Water solubility: 233 mg/L at 25 °C

Organic solubility: Very soluble in organic solvents including acetone, alcohol, benzene, carbon tetrachloride, chloroform, ether, ethyl acetate, and toluene.

Octanol/water partition coefficient: 1 x 10^{2.6}

Stability: Stable; first detectable heat evolution at 170 °C

2. TEST MATERIAL:

¹⁴C-Acetochlor-ring-¹⁴C

3. STUDY/ACTION TYPE:

Review of Protocol for a Confined (greenhouse) Rotational Crop Study.

4. STUDY IDENTIFICATION:

Letter from Dr. James L. Kuntsman -- Senior Registration Specialist, Monsanto Agricultural Company -- dated December 6, 1989, submitting a protocol entitled: "A Confined Rotational Crop Study With ¹⁴C-Aceto chlor Using Radishes, Lettuce, and Wheat," Monsanto Protocol No. 89-27-M21, Project No. 365, Monsanto Agricultural Company, KY.

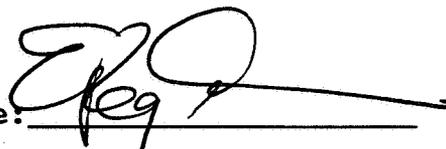
5. REVIEWED BY:

María Isabel Rodríguez
Chemist, Review Section #2
OPP/EFED/EFWGB

Signature: María Isabel Rodríguez
Date: May 9, 1990

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review Section #2
OPP/EFED/EFWGB

Signature: 
Date: MAY 9 1990

7. CONCLUSIONS:

EFWGB reviewed the proposed protocol entitled "A Confined Rotational Crop Study With ¹⁴C-Aceto chlor Using Radishes, Lettuce, and Wheat," and have several comments/recommendations to point out for the registrant. Please refer to Section 8 (Recommendations) of this review for details.

8. RECOMMENDATIONS:

The following information should be given to the registrant, Monsanto Agricultural Company, concerning the Protocol for Confined (greenhouse) Rotational Crop:

1. Analyses, including a description of data variability, for residues of parent compound and degradates in soil for each sampling interval should be reported.

2. On Section 7.1 the numbering should be 7.1.1, 7.1.1, and 7.1.3 instead of 7.11, 7.12, and 7.13.

3. It is not clear which is going to be used as the leafy vegetable since lettuce is mentioned in Section 7.1 and spinach is mentioned in Section 7.6.

4. It is not clear how many plots are going to be used for the study since on Section 7.7 it is mentioned that "the number of control plots are to be determined" and on Section 8.3.2. three control plots are mentioned.

5. On Section 8.2 numbering should be 8.2.1 and 8.2.2 instead of 8.21 and 8.22.

6. Solution concentration values on the application rates of the test substance (Section 8.3.4) do not agree with those in the treatment preparation (Section 8.2).

9. BACKGROUND:

Acetochlor [2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)-acetamide] is a chloroacetamide herbicide which provides pre-emergent control of many annual grass and broadleaf weed species on corn, soybeans, peanuts and sunflowers.

Confined Rotational Crop study was submitted by Monsanto Agricultural Company for an EUP (Acc. No. 071961) in 1984. The study was rejected (Review #4006 dated 1/25/1984 performed by Norma K. Whetzel) because of uncertainty in the application rates used, lack of adequate information on residue data (displayed in graph only) and on sampling intervals (no samples were taken at the time of treatment, planting, or harvesting).

The registrant submitted additional information (Acc. No. 071961 -- Review #70246 dated 3/23/1988 performed by Dr. Padma Datta) providing the application rates used in the study (1.3 and 1.4 lbs a.i./acre); soil residue data at the time of harvest of the last crop; and, explained that the requirements for soil residue data at the time of treatment and at the time of planting were not in effect when the study was conducted in May 1979. The study remained a data gap.

The registrant is now submitting a study Protocol entitled: "A Confined Rotational Crop Study With ¹⁴C-Acetochlor Using Radishes, Lettuce, and Wheat" (EFGWB #90-0333; Project #365; Monsanto Protocol #89-27-M21).

The general use-pattern for Acetochlor is terrestrial food crop and the environmental -fate data-requirements and their status are presented on the next page.

Data Requirements and
Guidelines Reference #

Status

1. Degradation Studies

- a. Hydrolysis (161-1) Acceptable
- b. Photodegradation
-In Water (161-2) Acceptable
-On Soil (161-3) Acceptable

2. Metabolism Studies -- lab.

- a. Aerobic Soil (162-1) Acceptable
- b. Anaerobic (162-2) Summarily reviewed

3. Mobility Studies

- a. Leaching and Adsorption/desorption (163-1) Summarily reviewed
- b. Volatility
-Lab (163-2) See note (1)

4. Dissipation Studies -- field

- a. Soil (164-1) Unacceptable

5. Accumulation Studies

- a. Rotational Crops
-Confined (165-1) Unacceptable
- b. In Fish (165-4) Acceptable

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(1) Waived for ICI (April 24, 1989; EFGWB Review #90170)

10. DISCUSSION OF INDIVIDUAL STUDIES:

Not applicable; no individual studies were submitted.

11. COMPLETION OF INDIVIDUAL STUDIES:

Last update was made on 4/19/1989.

12. CBI INDEX:

No claim for confidentiality was made on the submitted document.

Use this form for individual studies & to submit pesticide applications.



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460
Data Review Record
Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number
50064
EFED

Date Received
1-29-90

1. Product Name Harvest					Chemical Name Acetochlor		
2. Identifying Number 524-641	3. Record Number 258595	4. Action Code 161	5. MRID/ Accession Number -	6. Study Guideline or Narrative			
7. Reference No. 3	8. Date Rec'd (EPA) 12/13/89	9. Prod/Review Mgr/DCI Taylor/DK/lellan	10. PM/RM Team No. 25	11. Date to HED/EFED/RD/BEAD 1/29/90	12. Proj Return Date 3/29/90	13. Date Returned to RD/SRRD	

Instructions
Protocol for Confined Rotational Crop Study

This Section Applies to Review of Studies Only

14. Check Applicable Box <input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870) <input type="checkbox"/> Generic Data (Reregistration)(660) <input type="checkbox"/> Product Specific Data (Reregistration)(655)	15. No. of Individual Studies Submitted
16. Have any of the above studies (in whole or in part) been previously submitted for review? <input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No	17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure Nondietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> EA <input type="checkbox"/> NDE <input type="checkbox"/> AC <input type="checkbox"/> BA	
EFED	<input checked="" type="checkbox"/>	Ecological Effects Environmental Fate & Groundwater	<input type="checkbox"/> EEB <input type="checkbox"/> EFGWB	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
SRRD		Special Review	<input type="checkbox"/> SR	
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry Precautionary Labeling		
BEAD		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets) Label Attached

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

December 6, 1989

Office of Pesticide Programs - H7505C
Document Processing Desk (APPL)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

EFGWB

Attention: Mr. Robert J. Taylor
Product Manager (25)

524-611
Protocol

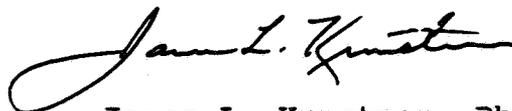
Subject: Registration of Acetochlor, Submission of Confined
Rotation Crop Protocol for Review and Comment

Dear Sir:

Monsanto has previously submitted a Confined Rotation Crop Study for acetochlor (MRID #131390) which was rejected by the Agency. Additional documentation and data was submitted in support of this original study (MRID #160233), but the Agency rejected this information as well and in a review dated April 27, 1989 (EFGWB #'s 90097 & 90098) a new confined rotation crops study was requested. Attached is a protocol Monsanto is proposing to use for the conduct of this repeat study. As indicated in the above mentioned review - we are submitting this protocol for your review and comment. We therefore request that this protocol be routed to the Environmental Fate branch and reviewed as quickly as possible. We greatly appreciate your prompt attention to this matter.

If you have any questions concerning the current request, please contact Dr. Kevin Cannon or myself.

Sincerely,



James L. Kunstman, PhD.
Senior Registration Specialist

Attachment

cc: R.P. Schneider
K.F. Cannon

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page ___ is not included in this copy.

Pages 8 through 20 are not included.

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 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.

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.
