

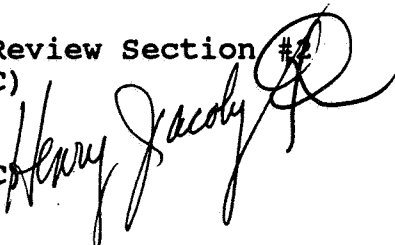
Shaughnessy No.: 121601

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:

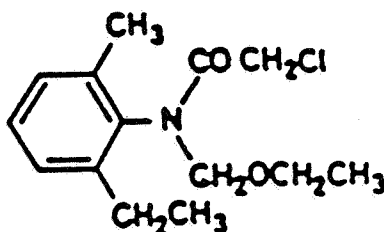
Chemical Name: 2-chloro-N-ethoxymethyl-6'-ethylacet-o-toluidide or 2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)-acetamide or N-(ethoxymethyl)-2'-methyl-6'-ethyl-2-chloroacetanilide

CAS No.: 34256-28-1

Common Name: Acetochlor

Trade Name: TOP-HAND, HARNESS

Chemical Structure:



Molecular Formula:  $C_{14}H_{20}ClNO_2$

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:  $1 \times 10^{2.6}$

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

2. TEST MATERIAL:

$^{14}C$ -Acetochlor-ring- $^{14}C$

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 <sup>14</sup>C-Aceto-chlor Using Radishes, Lettuce, and Wheat," Monsanto Protocol No. 89-27-M21, Project No. 365, Monsanto Agricultural Company, KY.

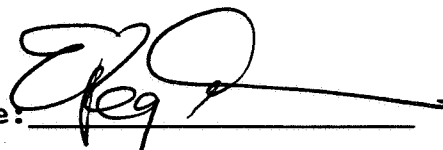
5. REVIEWED BY:

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 <sup>14</sup>C-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 <sup>14</sup>C-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.

4

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<br>reviewed |

3. Mobility Studies

- |    |  |                       |
|----|--|-----------------------|
| a. | Leaching and<br>Adsorption/desorption<br>(163-1) | Summarily<br>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.


 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

Date Received

 50064  
 EFED

1-29-90

1. Product Name

~~Harmon~~ Harmon

Chemical Name

Acetochlor

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
524-GUI	258595	161	-	

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
3	12/13/89	Taylor/VK/Chellu	25	1/29/90	3/29/90	

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	<input type="checkbox"/> DEB	<input type="checkbox"/> EA		
EFED		Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> AC	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18	
		Ecological Effects	<input type="checkbox"/> EEB	<input type="checkbox"/> BA		
SRRD		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB		C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert	
		Special Review				
		Reregistration	<input type="checkbox"/> SR			
RD		Generic Chemical Support	<input type="checkbox"/> RER			
		Insecticide-Rodenticide	<input type="checkbox"/> GSC			
		Fungicide-Herbicide				
		Antimicrobial	<input type="checkbox"/> IR			
BEAD		Product Chemistry	<input type="checkbox"/> FH			
		Precautionary Labeling	<input type="checkbox"/> AM			
		Economic Analysis				
		Analytical Chemistry				
		Biological Analysis				
<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)						<input type="checkbox"/> 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

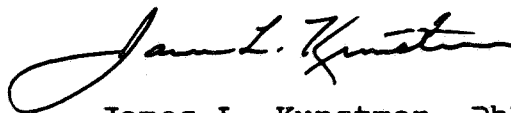
Subject: Registration of Acetochlor, Submission of Confined  
Rotation Crop Protocol for Review and Comment

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

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RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page \_\_\_\_ is not included in this copy.

Pages 8 through 20 are not included.

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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.

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