

US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 121601

Date Out of EFGWB: APR 24 1989

To: Robert Taylor/V. Walters
Product Managers team #25
Fungicide-Herbicide Branch
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist *A. Reiter, for ER.*
Environmental Chemistry Review Section #2
Environmental Fate and Ground Water Branch *EFED* (H7507C)

Thru: Henry Jacoby, Acting Chief *Henry Jacoby*
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of . . .

Reg./File # : ~~234-865~~ 524-EUP-AT

Common Name : Acetochlor

Type Product : Herbicide

Product Name : Top-Hand, Harness

Company Name : Monsanto Agricultural Company

Purpose : Evaluation of additional information for previously submitted
terrestrial field dissipation study (164-1).

Date Received: 10/31/88 Action Code: 101 & 711

Date Completed: 4/14/89 EFGWB #(s): 90094

Total Reviewing Time: (decimal days): 3.5 days

Deferrals to: _____ Ecological Effects Branch, EFED
_____ Science Integration and Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
_____ Dietary Exposure Branch, HED
_____ Toxicology Branch, F-H Support/HED

1. CHEMICAL: Common name:

Acetochlor.

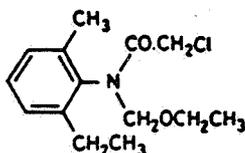
Chemical name:

2-Chloro-N-ethoxymethyl-6'-ethylacet-o-toluidide or
N-(ethoxymethyl)-2'-methyl-6'-ethyl-2-chloroacetanilide.

Trade name(s):

Top-Hand, Harness.

Structure:



Formulations:

7 lb ai/gal EC.

Physical/Chemical properties:

Molecular formula: C₁₄H₂₀ClNO₂.
Molecular weight: 269.8.
Physical state: Blue to purple oil.
Solubility: (25C) 233 mg/L water.

2. TEST MATERIAL:

7 lb ai/gal EC.

3. STUDY/ACTION TYPE:

Evaluation of a terrestrial field dissipation study.

4. STUDY IDENTIFICATION:

Lottman, C.M. 1988. Residues of acetochlor in field soils following preemergent treatment with acetochlor alone or in tank mix combinations with atrazine, Dyanap, Linuron, and Metribuzin - Addendum to MSL-1260 and MSL-1717. Laboratory Project ID MSL-8095. Prepared and submitted by Monsanto Agricultural Company, St. Louis, MO. (40811901)

5. REVIEWED BY:

Padma Datta, Ph.D.
Chemist
Chemistry Review Section #2
EFGWB/EFED/OPP

Signature: PKDatta

Date: 2/24/89

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
Chemistry Review Section #2
EFGWB/EFED/OPP

Signature: Alan Reith, for E.R.
Date: APR 24 1989

7. CONCLUSIONS:

This study is not acceptable because of the following deficiencies: (1) The sampling procedure was inadequate to accurately determine the dissipation of acetochlor, (2) The half-life of acetochlor could not be estimated due to an inadequate number of data points, (3) The length of storage prior to analysis and the freezer stability of acetochlor were not reported, (4) There was evidence of contamination of soil samples of 6-12 inches depth; those samples contained up to 1.9 ppm of acetochlor immediately after treatment, which may have masked leaching, (5) No information re the amount of a.i./gallon or the nature of the formulation used was provided, (6) No pretreatment soil sample data were provided. Several plots at time 0 had levels of acetochlor that greatly exceeded the maximum theoretical amount possible (for which, applications of 4 and 6 lbs a.i./A is equivalent to ca 2 and 3 ppm, respectively), (7) Meteorological data were not summarized, and, (8) The analytical method used was not specified (MSL-1260 or MSL 1717 method). Both are gas chromatographic methods with sensitivities of 0.05 ppm for acetochlor but do not measure its degradates.

8. RECOMMENDATION:

Monsanto must repeat the study on terrestrial field soil dissipation study because most of the deficiencies cited in the Conclusions Section of this report cannot be addressed by the submission of supplemental data.

9. BACKGROUND:

On 8/30/88, Monsanto Company submitted this study as additional information to fulfill the data gaps of the previously submitted field soil dissipation studies (164-1).

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See attached individual DER.

11. COMPLETION OF ONE-LINER:

See attached one-liner.

12. CBI APPENDIX:

All data reviewed here are considered "company confidential" by the registrant and must be treated as such.

ACETOCHLOR ADDENDUM

Task 1: Review and Evaluation
of Individual Studies

March 31, 1989

FINAL REPORT

Contract No. 68-02-4250

Submitted to:
Environmental Protection Agency
Washington, DC 20460

Submitted by:
Dynamac Corporation
The Dynamac Building
1100 Pennsylvania Ave
Washington, DC 20004

DATA EVALUATION RECORD

STUDY 1

CHEM 121601

Acetochlor

§164-1

FORMULATION—90—FORMULATION NOT IDENTIFIED

STUDY ID 40811901

Lottman, C.M. 1988. Residues of acetochlor in field soils following preemergent treatment with acetochlor alone or in tank mix combinations with atrazine, Dyanap, Linuron, and Metribuzin - Addendum to MSL-1260 and MSL-1717. Laboratory Project ID MSL-8095. Prepared and submitted by Monsanto Agricultural Company, St. Louis, MO.

DIRECT REVIEW TIME = 24

REVIEWED BY: W. Hurtt

TITLE: Staff Scientist

EDITED BY: K. Patten

TITLE: Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

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APPROVED BY: P. Datta

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-9733

SIGNATURE:

PK Datta

APR 24 1989

CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study cannot be used to fulfill data requirements.
2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of acetochlor.
3. This study is unacceptable because the sampling protocol was inadequate to accurately assess the dissipation of acetochlor; in general, 67-100% of the acetochlor dissipated from the field plots between the first and second (~30 days) samplings. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because freezer storage stability data were not provided; the soils may not have been sampled

deep enough to determine the depth of leaching; and the test substance was not completely characterized.

4. Since the sampling intervals were inadequate to accurately assess the dissipation of acetochlor, the problems with this study cannot be resolved with the submission of additional data. A new study is required.

METHODOLOGY:

Acetochlor (Top-Hand, formulation not further characterized) was applied at 4 or 6 lb ai/A to 28 plots of varying sizes and soil types located at 14 sites in 11 states and Canada (Table 1). Applications were made in both May and June of 1978 and 1979. Prior crop and pesticide history of the plots were varied and ranged from no crop cover or pesticide use to any one of a number of field crops (e.g., corn) or specialty crops (e.g., tobacco) in conjunction with an herbicide, as per standard agronomic practice. Soil samples (0- to 6- and 6- to 12-inch depths) were collected at approximately 0, 30, 60, 90, 180, and 360 days posttreatment and stored frozen (temperature not specified) for an unknown duration prior to analysis.

Soil subsamples were extracted with a mixture (2:1, v:v) of isooctane:-isopropyl alcohol by shaking on a mechanical shaker for 20 minutes. The soil-solvent mixture was filtered and evaporated to dryness in a rotary evaporator. The residue was redissolved in hexane and cleaned-up on a mixed alumina Florisil column. The eluant from the column was evaporated to dryness without heat, redissolved in hexane, and quantified using GC with either electron-capture or electrolytic conductivity detection (depending on which of two similar analytical methods was used).

DATA SUMMARY:

Acetochlor (Top-Hand, MON-097), at 4 or 6 lb ai/A, dissipated rapidly with a half-life of <<30 days in field plots located throughout 11 states and Canada (Table 1). In the 0- to 6-inch depth of 25 of the 28 treated plots, 67-100% of the acetochlor applied to the soil dissipated between 0-1 and ≈30 days posttreatment (first and second sampling intervals). In general, by ≈60 or 90 days posttreatment (third sampling interval), acetochlor was either below the detection limit (0.05 ppm) or had degraded to <50% of its 30-day concentration. In the three plots in which acetochlor did not have a half-life of <30 days, ≈70-86% of the applied acetochlor degraded between the second and third samplings. Accurate half-lives (based on three points with >50% degradation between sampling periods) could not, therefore, be calculated for any of the 28 plots.

The time 0 concentration of acetochlor in the 0- to 6-inch soil depth was variable, ranging from <0.05 to 14.0 ppm in the plots treated at 4 lb ai/A and from 0.08 to 23.0 ppm in the plots treated at 6 lb ai/A.

It could not be determined if acetochlor leached into the lower soil horizons because contamination was an obvious problem. Acetochlor was detected in the 6- to 12-inch depth in the majority of plots at up to 1.9 ppm immediately after treatment. By day 30, the concentration of acetochlor in 23 plots had decreased to <0.05 ppm and in three plots had decreased by 70-87% of the time 0. In two plots, the concentration of acetochlor in the 6- to 12-inch depth increased between 0 and 30 days.

COMMENTS:

1. The soil sampling protocol was inadequate to accurately assess the dissipation of acetochlor. At the majority of sites, 67-100% of the applied acetochlor dissipated from the soil between the first and second samplings (0 and 30 days). Between the second and third samplings (30 and 60 or 90 days), >50% of the remaining acetochlor dissipated; in most cases, acetochlor was not detected at the third sampling. Accurate half-lives could not be determined from the data because too few data points (samples in which acetochlor was detected) were available to permit valid statistical calculations.
2. Freezer storage stability data were not provided to confirm that acetochlor did not degrade during storage. The length of sample storage prior to analysis was not reported.
3. It could not be determined if the soils were sampled deep enough to define the depth of leaching. Contamination of the 6- to 12-inch depth was an obvious problem, since immediately after treatment the soils contained up to 1.9 ppm of acetochlor. Although the concentration of acetochlor increased between 30 and 60 days in only two soils, the dissipation of the high concentrations of acetochlor present in other soils at time 0 may have masked leaching.
4. The test substance was characterized only as "Top-Hand". No information was provided concerning the nature of the formulation or the amount of active ingredient per gallon.
5. The soil sampling procedures were not described, other than an occasional reference in a field data sheet to sampling with a spade.
6. No pretreatment soil sample data were provided to confirm that the plots were not contaminated with acetochlor prior to the experimental treatment, although the field data sheets contained information that suggested pretreatment samples were occasionally obtained and the plot diagrams usually indicated a control plot was included. This was a significant omission with regard to several plots which at time 0 had levels of acetochlor that greatly exceeded the maximum theoretical amount possible (one acre of soil 6 inches deep weighs 2 million pounds; 4 and 6 lb ai/A are equivalent to ≈ 2 and 3 ppm, respectively).
7. Meteorological data (primarily precipitation and temperature) were submitted by the registrant as unsummarized field records. Because the

study is unacceptable, the reviewer did not take the time to sort through the voluminous field records and extract the pertinent information.

8. Site characteristics were incomplete; slope, depth to the water table, and management practices following application of acetochlor were not provided.
9. The study author noted that the treatments were originally applied at 1x and 1.5x rates (4 and 6 lb ai/A, respectively) based on a maximum label rate of 4 lb ai/A. The maximum label rate is currently 3 lb ai/A. In the cases of approximately one-third of the plots, the application rate was not confirmed by the time 0 concentration in the 0- to 6-inch soil depth.
10. Two analytical methods were provided in the supporting documentation (MSL-1260 and MSL-1717), both of which detected the parent compound only and had sensitivities of 0.05 ppm. It was not specified which method was used or whether both methods were used.

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page ___ is not included in this copy.

Pages 9 through 14 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.

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

ATTACHMENT 1

Confidential Business Information-Does Not Contain National Security Information(E.O. 12065)
This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME <i>Nannex + Top Hand</i>		CHEMICAL NAME <i>Neotribler</i>		
2. IDENTIFYING NUMBER <i>524-GUF</i> <i>524-GUP-PT</i>	3. RECORD NUMBER <i>234065</i> <i>234066</i>	4. ACTION CODE <i>161</i> <i>711</i>	5. MRID/ACCESSION NUMBER <i>263303</i>	6. STUDY GUIDELINE OR NARRATIVE <i>Crop Rotation</i>
7. REFERENCE NUMBER <i>2.1</i>	8. DATE RECEIVED (EPA) <i>10/28/88</i>	9. PRODUCT/REVIEW MANAGER/DCI <i>Taylor/VK Walters</i>	10. PM/RM TEAM NUMBER <i>25</i>	11. DATE SENT TO (HED/EFED/RD/BEAD) <i>10/31/88</i>
12. PROJECTED RETURN DATE <i>2/28/89</i> <i>3/6/89</i> <i>3/31/89</i>	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS: <i>Request to accept previously submitted crop rotation study</i>		

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

- ADVERSE 6(a)(2) DATA (405) GENERIC DATA (660) PRODUCT SPECIFIC DATA (655)
 SPECIAL REVIEW DATA (870) (REREGISTRATION) (REREGISTRATION)

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:

18. TO	TYPE OF REVIEW	19. REVIEWS ALSO SENT TO	20. DATA REVIEW CRITERIA
HED	SCIENCE ANALYSIS & COORD.	___ SAC ___ PC	A. Policy Note #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 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
	TOXICOLOGY/HFA	___ TOX/HFA ___ FL	
	TOXICOLOGY/IR	___ TOX/IR	
	DIETARY EXPOSURE	___ DEB ___ EA	
	NON-DIETARY EXPOSURE	___ NDE ___ AC	
EF ED	ECOLOGICAL EFFECTS	___ EEB ___ BA	
	ENVIRONMENTAL FATE & GROUND H2O	___ EFGWB	
SRRD	SPECIAL REVIEW	___ SR	
	REREGISTRATION	___ RER	
	GENERIC CHEMICAL SUPPORT	___ GSC	
RD	INSECTICIDE-RODENTICIDE	___ IR	
	FUNGICIDE-HERBICIDE	___ FH	
	ANTIMICROBIAL	___ AM	
2AD	PRODUCT CHEMISTRY		
	PRECAUTIONARY LABELING		
	ECONOMIC ANALYSIS		
	ANALYTICAL CHEMISTRY		
	BIOLOGICAL ANALYSIS		

- CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS) LABEL ATTACHED

White - Data Coordinator

Yellow - Data Review Section

Green - Return with completed review

Include original + two (2) copies with each submission

Pink - PM/RM/DCI