

US EPA ARCHIVE DOCUMENT

copied

FILE COPY

Shaughnessey No. 121601

Date Out EFB: 25 JAN 1984

To: Taylor/Walters
Product Manager 25
Registration Division (TS-767)

From: Samuel Creeger, Chief *SC*
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached please find the environmental fate review of:

Reg./File No: 524-GUI

Chemical: Acetochlor

Type Product: Herbicide

Product Name: Harness

Company Name: Monsanto

Submission Purpose: registration data for corn, soybeans, peanuts and sorghum grain

ZBB Code: 3(c)(5)

ACTION CODE: 110

Date in: 10/7/83

EFB # 4006

Date completed: 1/24/84

Tais (level II) Days

61 4.5

Deferrals To:

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

1.0 INTRODUCTION

Monsanto Company has submitted data in support of the registration of acetochlor (2-chloro-N-6-ethoxymethyl-N-(2-ethyl-methylphenyl) acetamide) for use on corn, soybeans, grain sorghum and peanuts.

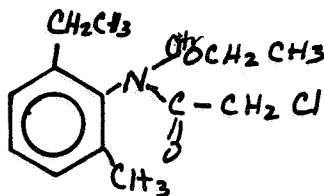
2.0 CHEMICAL STRUCTURE

Chemical Name: 2-chloro-N-6-ethoxymethyl-N-(2-ethyl-methylphenyl) acetamide

Common Name: acetochlor

Trade Name: Harness®

Chemical Structure:



3.0 DIRECTIONS FOR USE

See attached proposed label.

4.0 DISCUSSION OF DATA

4.1 The Environmental Photochemistry of Acetochlor. L.J. Letendre and G.H. Klemm. Report No. MSL-2748. December 1982. Acc. No. 071961.

Procedure:

Aqueous Photolysis

Uniformly ¹⁴C-phenyl labeled acetochlor and 2-¹³C-acetochlor were mixed with unlabeled acetochlor to give an approximate 1:1 ratio of unlabeled material and ¹³C-labeled material. The specific activity of the acetochlor isotopic mixture used for the aqueous photolysis study was 0.98 mCi/mole and that used for the soil photolysis study was 1.27 mCi/mole.

A 50 ppm solution of the acetochlor mixture in sterile deionized water was subjected to light from a 500 watt xenon arc lamp mounted in a parabolic mirror and filtered by a Pyrex® plate to exclude irradiation below 285 nm. This lamp had 7 times the intensity of the sun at noon on June 1, 1982 in St. Louis, Mo. The spectral distribution graph is shown on page 1A. A 10 cm cylinder held the acetochlor solution at 22°C by means of a cooling coil passing through the cylinder and containing a 5°C ethylene glycol/water mixture. The entire area of the solution was covered by the light beam.

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page 3 is not included in this copy.

Pages _____ through _____ 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.

Aliquots were taken for analysis at the equivalent of 1, 3, 8, 17, and 34 days of sunlight exposure. dark control was kept at 22°C for the duration of the experiment and analyzed at the end the experiment. Samples were extracted with dichloromethane and aliquots of both phases counted andd subjected to GC and GC/CI-MS analyses.

Soil Photolysis

A Ray silty loam soil was treated at a rate of 3 lb ai/A with a hexane solution of acetochlor. The soil characteristics were as follows:

<u>Percentage</u>					
<u>Sand</u>	<u>Silt</u>	<u>Clay</u>	<u>OM</u>	<u>Water holding capacity</u>	<u>CEC</u>
4.6	84.2	10.0	1.2	23.9	10.4

A circular portion of the soil TLC plate (8 cm in diameter, 1 mm thick) was divided into six equal sections with ca. 1.5 mm between adjacent sections. The plate was placed on a cooling plate and held at 15°C. One section was covered with aluminium foil to serve as a control. The plate was subjected to light from the same xenon arc lamp used in the aqueous study which had been reflected by a dichroic mirror which allows the ir to pass while reflecting the uv and vis portions with ca. 80% efficiency in the 285-440 nm range. The light was filtered by a Pyrex® plate to exclude irradiation below 285 nm. Samples were taken after the equivalent of 3, 5, 15 and 35 days of sunlight exposure. The dark control was analyzed at the end of the experiment.

Samples were extracted with acetonitrile and the extract partitioned with dichloromethane. The amount of radioactivity in both phases was determined by LSC. The organic layer was concentrated and analyzed by GC/RAD and GC/MS. Unextractable soil residues were determined by combustion/LSC.

Results:

Tables I and II on page 2A summarize the results of the aqueous and soil studies.

Conclusions:

Although the registrant states that GC/RAD shows all of the dichloromethane soluable radioactivity was attributable to acetochlor, no supporting data were given for this statement. The registrant must show sample GC chromatograms that match with the radioactive region as compared to an acetochlor standard GC chromatogram. If this can be shown, then we could conclude that acetochlor is stable to both aqueous and soil photolysis.

TABLE I

Partitioning of Photolysis Solution Between
Water and Dichloromethane

<u>Sample Period</u>	<u>Dichloromethane Soluble</u>	<u>Aqueous Soluble</u>	<u>Total Recovery</u>
1	102.7	0.9	103.6
3	101.1	1.6	102.7
8	98.6	1.8	100.4
17	103.5	1.3	104.8
34	94.8	2.1	96.9
control	103.6	0.5	104.1

All values represent percent of applied radioactivity.

(All of the dichloromethane soluble radioactivity was attributable to acetochlor as demonstrated by GC/RAD analysis).

TABLE II

Partitioning of Radioactivity in the
Soil Photolysis Experiment

<u>Sample Period (Days)</u>	<u>Organic Soluble</u>	<u>Aqueous Soluble</u>	<u>Unextractable Residue</u>	<u>Total Recovery</u>
1	94.3	1.7	0.6	96.6
3	87.3	3.6	0.7	90.7
5	84.5	5.3	0.7	90.5
15	80.7	6.8	1.1	88.4
35	83.8	8.5	1.5	93.8
control	88.7	1.2	0.6	90.5

All values represent percent of applied.

(All of the dichloromethane soluble radioactivity was shown to be acetochlor by GC/RAD analysis).

4.2 Bioconcentration of Acetochlor in Bluegill Sunfish under Dynamic Flow-through Conditions. J.M. Malik. Report No. MSL-2443. August 1982. Acc. No. 071961.

Procedure:

Bluegill sunfish of mean weight 4.03 g and initial mean standard length of 49.8 mm were held in culture tanks on a 16 hour daylight photoperiod for 14 days prior to testing. The test solution containing a mixture of unlabeled acetochlor and ¹⁴C-phenyl labeled acetochlor at 0.17 mg/l was allowed to flow through the test system for 24 hours to equilibrate.

Duplicate control and test chambers holding 110 fish each were observed daily for fish mortality and adverse behavior. During the 30 day uptake period water and fish were sampled on day 1, 3, 7, 10, 14, 22 and 30. The water was analyzed by LSC. The fish were analyzed as either fillet and viscera or whole fish.

Following the uptake period, the addition of ¹⁴C-acetochlor was terminated, the water in the test aquaria siphoned until a depth of ca. 3 inches remained in each aquaria and ca. 70 liters of well water added. This water was removed as before and 70 liters of well water added. The fish were then exposed to the flowing water for 14 days. Water and fish were sampled on day 1, 3, 7, 10, and 14 and analyzed as in the uptake phase.

On day 7, 22, and 30 of uptake and 3 and 14 of depuration, fish were taken for metabolite analysis.

Results:

Tables 2 and 3 on pages 3A and 3B summarize uptake and depuration of acetochlor by Bluegill sunfish. Table 4 on page 3C shows the bioconcentration factor calculations.

Although samples of fish were taken for metabolite analysis, no discussion of how or if the analysis was actually done or the results of such an analysis was given in the study.

Conclusions:

The acetochlor bioconcentration factor (BCF) for whole fish is 84, for fillet ca. 35, and for viscera ca. 150. These values are consistent with the low (ca. 300) octanol/water partition coefficient. Depuration at 14 days for whole fish is 85%, fillet 52% and viscera 90%. ←

Metabolites were not identified in viscera and edible tissues containing the highest residue levels during accumulation. If this information is available, it should be submitted to complete the agency records. Because of the low bioaccumulation factors and the low octanol/water partition coefficient, we can consider the fish accumulation data requirement satisfied without the metabolite information.

Acetochlor will not accumulate in fish.

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page _____ is not included in this copy.

Pages 7 through 9 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.

- 4.3 Uptake and Characterization of Acetochlor [2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide] Residues in Primary, Emergency Replant and Rotational Crops. C.L. Livingston. Report No. MSL-2988. May 1982. Acc. No. 071961.

Procedure:

Plastic pots of Spinks sandy loam soil were placed in 2 greenhouses and amended with either acetochlor-phenyl-¹⁴C (an isotopic mixture with acetochlor which was ¹³C-enriched at the C-2 position and the mixture ratio adjusted such that the ¹²C/¹³C ration was 50/50) at 1.3 lb/A or acetochlor-carbonyl-¹⁴C at 1.4 lb/A. Soybeans were planted in the pots immediately prior to the addition of the acetochlor. Half of the pots were designated controls and no acetochlor was added. Half of each treated or control group were designated for an emergency replant study and half for a rotational crop study.

Immature soybean plants were harvested from 3 pots on day 30 and analyzed. Emergency replant crops of either barley, cabbage, or radish were planted in these pots and grown to maturity, harvested and analyzed. Subsequent rotational crops were then planted in the pots and grown to maturity.

Soybeans in the other pots were grown to maturity, harvested, separated into beans and foliage and analyzed. Rotational crops were then planted in the pots.

Plant residues were analyzed by combustion and LSC for radioactivity. Barley was separated into straw and grain and radishes were separated into bulbs and greens. Soil residues were taken 485 days from the initial treatment and analyzed for radioactivity by combustion/LSC.

Homogenized plant parts were extracted with acetone/water (60:40, v/v) followed by further homogenation (4 times). The filter cake from the extraction was analyzed for radioactivity by combustion/LSC. The extract was concentrated by rotary evaporation. The concentrated aqueous extracts and the evaporation distillates were analyzed by LSC.

The aqueous extracts were chromatographed on an AG 1-X2 resin column and aliquots taken from each of the fractions for LSC. Major fractions thus identified were pooled and concentrated by rotary evaporation and assayed by LSC.

Crop residues were also subjected to acid hydrolysis followed by methylene chloride extraction. The extract was then chromatographed on HPLC/LSC to assay for the presence of possible substituted N-phenylacetamide hydrolysis products.

Results:

The tables on pages 5A-5L and the figure on page 5M summarize the results.

Uptake of acetochlor into primary crop (soybeans) was 1.2 ppm in foliage and .2 ppm in grain when harvested at maturity. When harvested at 30 days residues in the forage were 13.2 ppm from the carbonyl-labeled acetochlor and 1.99 ppm from the phenyl-labeled.

Residues in follow crops were 0.2 ppm and 0.4-1.13 ppm in barley grain and straw, respectively; 0.09-0.2 in cabbage; and 0.03-0.04 ppm and 0.16-0.18 ppm in radishes and radish greens, respectively, in normal crop rotation. When planted after premature harvesting of the primary crop, residues were 0.22-0.94 ppm in barley grain, 1.64-2.38 ppm in barley straw, 0.16-0.38 ppm in cabbage, 0.07-0.14 ppm in radishes and 0.38-0.65 in radish greens. With increasing time of planting after application, the amount of acetochlor taken up decreases. Five month rotation crops have residues which range from 0.03 to 1.13 ppm from all experiments, while those from the 1 year rotation crops ranged from 0.01 to 0.63 ppm.

Conclusions:

It is hard to determine from the label what the application rates are. We are therefore not able to determine that the application rates used in this study are normal rates.

Soil residues were only taken for analysis at the time of harvest of the last crop. The data on the analysis of these samples was only displayed in a graph; no raw data was given. Soil residues should be taken at the time of treatment, at time of planting of rotational crops and at the time of harvest of the rotational crops. We can make no judgement about the residues of acetochlor in soil during the rotational crop cycle, from the data given.

This study does not completely satisfy the EAB confined rotational crop data requirement.

- 4.4 Applicator Exposure Studies with HARNESS® Herbicide Under Actual Field Use Conditions. D.D. Arras. Report No. MSL-2887. April 1983. Acc. No. 071974.

This is not a first tier data requirement in EAB. Therefore, it was not reviewed at this time. However, if the study needs to be reviewed to support assessments by other branches in HED, the study should be resubmitted.

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page _____ is not included in this copy.

Pages 12 through 24 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.

5.0 CONCLUSIONS

- 5.1 The following data requirements have been satisfied previously (review of 3/5/81): hydrolysis and aerobic soil metabolism.
- 5.2 The following studies were submitted with the previous submission, but not reviewed at that time: adsorption/desorption, leaching, and anaerobic soil metabolism.
- 5.3 No supporting data was given for the assertion that all dichloromethane soluble radioactivity in the aqueous and soil photodegradation studies was attributable to acetochlor. We could conclude that acetochlor is stable to both aqueous and soil photolysis if this were shown to be true.
- 5.4 Acetochlor does not accumulate in fish:
- 5.5 The confined rotational crop study lacked adequate soil residue data. We could, however, use data from the aerobic soil metabolism study. It was also unclear that the application rates used were label rates.

The following residues were found in crops:

<u>Crop</u>	<u>Interval (appn to planting)</u>	<u>Total ¹⁴C residues (ppm)</u>
Barley grain	1 month	0.22 - 0.94
	5 months	0.14 - 0.30
	1 year	0.10 - 0.26
Barley straw	1 month	1.64 - 2.38
	5 months	0.41 - 1.13
	1 year	0.23 - 0.63
Cabbage	1 month	0.16 - 0.38
	5 months	0.09 - 0.22
	1 year	0.08 - 0.21
Radishes	1 month	0.07 - 0.14
	5 months	0.02 - 0.13
	1 year	0.01 - 0.08
Radish greens	1 month	0.38 - 0.65
	5 months	0.15 - 0.29
	1 year	0.07 - 0.14

These data do not support any rotational crop restriction.

25

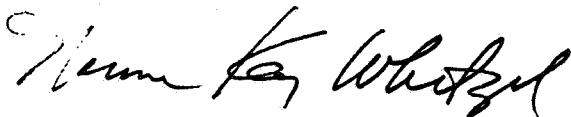
5.6 The applicator exposure study is not a first tier data requirement in EAB. Therefore, it was not reviewed at this time. However, if the study needs to be reviewed to support assessments by other branches in HED, the study should be resubmitted.

6.0 RECOMMENDATIONS

Hydrolysis, aerobic soil metabolism, and fish accumulation data requirements have been satisfied for acetochlor. Registrant should be advised to submit the documentation requested in 5.3 above to satisfy the photodegradation data requirement and in 5.5 above to satisfy completely the confined rotational crop data requirement.

The adsorption/desorption, leaching, anaerobic soil metabolism and field dissipation data requirements are outstanding. These studies should be submitted for review.

Until registrant has submitted the information requested and it has been reviewed and accepted, the EAB data requirements for terrestrial crop use have not been satisfied.



Norma Kay Whetzel
January 24, 1984
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page _____ is not included in this copy.

Pages 27 through 40 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.
