Confidential

Shaughnessy No.: 121601

Date Out of EFGWB: APR 27 1989

To: Robert Taylor
Product Manager #25
Fungicide-Herbicide Branch
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Chemistry Review Section #2
Environmental Fate & Ground Water Branch (H7507C)

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

Attached, please find the EFGWB review of...

Reg./File # ~~524-822/824/827/828~~ 524-GUI & 524-EUP-AT

Common Name: Acetochlor

Type Product : Herbicide

Product Name : Harness®

Company Name : Monsanto

Purpose : Review the status of anaerobic soil metabolism (§162-2), leaching and adsorption/desorption (batch equilibrium) (§163-1), and, confined rotational crops (§165-1) studies data requirements.

Date Received: 10/3/88 Action Code(s): 161,711

Date Completed: 4/24/89 EFGWB #(s): 90097/90098

Total Reviewing Time:(decimal days): 2.2 days

Deferrals to: _____ Ecological Effects Branch, EFED

_____ Science Integration & Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch, F-H Support/HED

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1. CHEMICAL: Common name(s):

Acetochlor

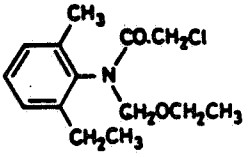
Chemical name:

2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)-acetamide

Trade name(s):

Harness®

Structure:



Formulations:

86.4% a.i., herbicide.

Physical/Chemical properties:

Molecular weight:	269
Form:	liquid
B. P.:	> 200°C
M. P.:	> 0°C
Vapor Pressure:	< 1 mm Hg
Hydrolysis Rate:	Nondetectable at pH 5-9
Solubility :	In water, 223 ppm; very soluble in ether, acetone, benzene, alcohol, chloroform, and ethylacetate.
Stability:	Stable (first detectable heat evolution at 170°C)

2. TEST MATERIAL:

N/A.

3. STUDY/ACTION TYPE:

Review the status of anaerobic soil metabolism (§162-2), leaching and adsorption/desorption (batch equilibrium) (§163-1), and, confined rotational crop (§165-1) studies data requirements.

4. STUDY IDENTIFICATION:

N/A.

5. REVIEWED BY:

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

Signature: PKDatta

Date: 4/27/89

6. APPROVED BY:

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

Signature: [signature]

Date: APR 27 1989

7. CONCLUSIONS:

The anaerobic soil metabolism (§162-2) and leaching and adsorption/ desorption (batch equilibrium) (§163-1) studies were submitted to the Agency in 1981, but were only summarily reviewed. (For details, see EAB review #732, 1/5/81).

A confined rotational crops study was reviewed and rejected twice by EAB now EFGWB. (For details, see EAB Reviews #4006, 1/24/84, and EAB #70246, 3/23/88 and the Background Section of this review).

A summary of the status of the environmental fate data requirements for acetochlor is in the attached Table A.

8. RECOMMENDATIONS:

RD should forward the anaerobic soil metabolism (§162-2) and leaching and adsorption/ desorption (batch equilibrium) (§163-1) studies to EFGWB for full review. The format of these studies should comply with the P R Notice 86-5 requirements.

Monsanto must submit a new study on confined rotational crops (§165-1) following the guidance in Subdivision N of the Pesticide Assessment Guidelines, 1982.

If as results, this new confined rotational crops (§165-1) study show residue of concern continue to occur at 12 months in one or more crop groupings, the registrant has the following options:

a/ Conduct a field study to establish acceptable rotational interval in field crops.

b/ Petition to DEB to approve tolerances on all crops to be rotated.

c/ Reduction on application rate to reduce residues in a crop to be rotated

8. RECOMMENDATIONS: (Cont'd)

A submission of a protocol is strongly encouraged prior to initiation of this study considering the continuing failure by this registrant to submit acceptable confined rotational crops study (§165-1) and considering that a significant residue of concern appears to be present in all crop groupings at the application significantly below the maximum label rate.

RD should require Monsanto to submit a protocol and subsequent study within a shortest reasonable timespan.

9. BACKGROUND:

The anaerobic soil metabolism (§162-2) and leaching and adsorption/desorption (Batch equilibrium) (§163-1) studies were submitted by Monsanto for an Experimental Use Permit (EPA file #524-EUP-LA) in 1981. EFGWB (old EAB) briefly summarized those studies and intended to review upon request for registration by Monsanto. (For details see EAB review #732, 1/5/81).

The confined rotational crops study was submitted by Monsanto for an EUP (EPA file #524-GUI) in 1984. EAB (now EFGWB) rejected the study on the basis of (1) uncertainty of the rate of application used, (2) a lack of residue data (displayed in graph only), and, (3) no samples were taken at the time of treatment, at the time of planting, or at the time of harvest of rotational crops. Monsanto reported soil residue data only at the time of harvest of the last crops.

On 10/1/86, Monsanto submitted additional information (Acc. No. 071961) required by EAB review #4006, 1/24/84, to fulfill the data requirements for confined rotational crops to support continued registration of acetochlor.

For the confined rotational crops study (§165-1), Monsanto provided (1) the application rates used in the study (1.3 and 1.4 lbs. a.i./acre); (2) soil residue data at the time of harvest of the last crop; and, (3) explained that the requirements for soil residues data at the time of treatment and at the time of planting were not in effect when this study was conducted in May 1979. This explanation was insufficient to address EAB's concerns. Therefore, the confined rotational crops study (§165-1) remains inadequate to support the data requirements. (For details refer to the EAB review #70246, 3/23/88).

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: N/A.

11. COMPLETION OF ONE-LINER: See attached one liner.

12. CBI APPENDIX: N/A.

Attachments:

1. Table A.
2. Summary of requirement status.

Y

ENVIRONMENTAL FATE & GROUND WATER BRANCH
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY

Common Name: **ACETOCHLOR** Date: 04/19/89
Chem. Name : 2-CHLORO-N-(ETHOXYMETHYL)-N-(2-ETHYL-6-METHYL-PHENYL)-
: ACETAMIDE
Shaugh. # : 121601 CAS Number: 34256-28-1
Type Pest. : Herbicide
Formulation: EC
Uses : POSTEMERGENCE BROADLEAVED WEED CONTROL
:
:

Empir. Form: $C_{14}H_{20}NO_2Cl$ VP (Torr): <1
Mol. Weight: 269 Log Kow : 2.6
Solub.(ppm): 223 @ 20 C Henry's :

Hydrolysis (161-1)
pH 5:[*] STABLE
pH 7:[*] STABLE
pH 9:[*] STABLE
pH :[ ]
pH :[ ]
pH :[ ]

Photolysis (161-2, -3, -4)
Air :[ ]
Soil :[#] INSIGNIFICANT
Water:[#] "
:[ ]
:[ ]
:[ ]

MOBILITY STUDIES (163-1)

Soil Partition (Kd)

	SOIL	%OM	Kd
1.[*]	SOIL	%OM	Kd
2.[ ]	LINTONIA	0.7	.4
3.[ ]	RAY	1.2	1.1
4.[ ]	SPINKS	2.4	1.6
5.[ ]	DRUMMER	3.4	2.7
6.[ ]			

Rf Factors
1.[ ] DRUMMER SOIL RETAINED ABOUT
2.[ ] 57% OF APPL. ACETOCHLOR WHILE
3.[ ] LINTONIA RETAINED ONLY 4%.
4.[ ]
5.[ ]
6.[ ]

METABOLISM STUDIES (162-1,2,3,4)

Aerobic Soil (162-1)
1.[*] RAY SOIL: 8 DAYS 22 C
2.[*] DRUMMER SOIL: 10 DAYS "
3.[*] SPINKS SOIL: 12 DAYS "
4.[ ]
5.[ ]
6.[ ]
7.[ ]

Anaerobic Soil (162-2)
1.[ ] RAPID MICROBIAL DEGRADATION
2.[ ]
3.[ ]
4.[ ]
5.[ ]
6.[ ]
7.[ ]

Aerobic Aquatic (162-4)
1.[ ] 8-12 DA (SOIL?)
2.[ ]
3.[ ]
4.[ ]

Anaerobic Aquatic (162-3)
1.[ ]
2.[ ]
3.[ ]
4.[ ]

[*] - Acceptable Study. [#] = Supplemental Study

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Common Name: **ACETOCHLOR** Date: 04/19/89

VOLATILITY STUDIES (163-2,3)

[ ] Laboratory:
[ ] Field:

DISSIPATION STUDIES (164-1,2,3,5)

Terrestrial Field (164-1)

1.[ ] % ACETOCHL. AND EXTRACT. IN SOIL, AEROBIC CONDITIONS AT 22 C

	SOIL	DAYS	ACETOCHL.	ORG. SOL.	WAT. SOL.	CO2	SOIL BOUND
2.[ ]							
3.[ ]	RAY	0	91.1	97.1	0.8	0.0	1.5
4.[ ]	"	21	15.3	24.6	45.0	3.5	62.8
5.[ ]	DRUMMER	0	93.8	101.5	0.9	0.0	1.1
6.[ ]	"	21	19.8	33.8	37.5	3.2	41.4

Aquatic (164-2)
1.[ ]
2.[ ]
3.[ ]
4.[ ]
5.[ ]
6.[ ]

Forestry (164-3)
1.[ ]
2.[ ]

Other (164-5)
1.[ ]
2.[ ]

ACCUMULATION STUDIES (165-1,2,3,4,5)

Confined Rotational Crops (165-1)
1.[ ] DO NOT ROTATE
2.[ ]

Field Rotational Crops (165-2)
1.[ ]
2.[ ]

Irrigated Crops (165-3)
1.[ ]
2.[ ]

Fish (165-4)
1.[*] BLUEGILL SUNFISH 35X EDIBLE, 150X VISCERA, 84X WHOLE FISH.
2.[ ] DEPURATION AT 14 DAYS =52%, 90%, 85% FOR EDIB., VISC., WHOLE

Non-Target Organisms (165-5)
1.[ ]
2.[ ]

Common Name: **ACETOCHLOR** Date: 04/19/89

GROUND WATER STUDIES (158.75)

1.[ ]
2.[ ]
3.[ ]

DEGRADATION PRODUCTS

1. MULTIPLE DEGRADATES. OF THE THREE MAJORS (DERIVATIVES OF
2. METHYL OXANILIC ACID, SULFINYLACETIC ACID, AND SULFOACETANILIDE),
3. NONE ACCOUNTED FOR MORE THAN 18% OF THE ACETOCHLOR APPLIED.
4.
5.
6.
7.
8.
9.
10.

COMMENTS

References:
Writer : J. HANNAN

[*] - Acceptable Study. [#] = Supplemental Study

TABLE A

GENERIC DATA REQUIREMENTS FOR ACETOCHLOR (Monsanto)

Data Requirement	Test Substance[1]/	Use Pattern[2]/	Does EPA have satisfactory data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[3]/
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A	Yes	Acc.#099814	No[4]/	
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A	Yes	Acc.#071961	No[5]/	
161-3 - On Soil	TGAI or PAIRA	A	Yes	Acc.#071961	No[5]/	
161-4 - In Air	TGAI or PAIRA	N/A	No	None	No	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A	Yes	Acc.# 099814	No[6]/	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	None	Yes[7]/	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	No	None	No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	No	None	No	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	No	None	Yes[7]/	
163-2 - Volatility (Lab)	TEP	N/A	No	None	No	
163-3 - Volatility (Field)	TEP	N/A	No	None	No	

TABLE A

GENERIC DATA REQUIREMENTS FOR ACETOCHLOR

Data Requirement	Test Substance[1]	Use Pattern[2]	Does EPA have satisfactory data ?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.290 Environmental Fate (continued)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A	No	Acc.# 71958 Acc.# 99814	Yes[8]	
164-2 - Aquatic (Sediment)	TEP	N/A	No	None	No	
164-3 - Forestry	TEP	N/A	No	None	No	
164-4 - Combination and Tank Mixes	TEP	N/A	No	None	No	
164-5 - Soil, Long-term	TEP	A	No	None	No[9]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	Acc.# 071961	Yes[8]	
165-2 - Rotational Crops (Field)	TEP	A	No	None	Reserved [10]	
165-3 - Irrigated Crops	TEP	A	No	None	No	
165-4 - In Fish	TGAI or PAIRA	A	Yes	Acc.# 071961	No[11]	
165-5 - In Aquatic Nontarget Organisms	TEP	A	No	None	No	

TABLE A

GENERIC DATA REQUIREMENTS FOR ACETOCHLOR

Data Requirement	Test Substance[1]	Use Pattern[2]	Does EPA have satsfactory data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No	None	No[12]	
202-1 - Drift Field Evaluation	TEP	A	No	None	No[12]	
§158.75 Other Exposure						
Ground water monitoring	TEP	A	No	None	Reserved[13]	

C)

TABLE A

GENERIC DATA REQUIREMENTS FOR ACETOCHLOR

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

4/ Acetochlor is stable during hydrolysis at pH 3, pH 6 and pH 9.

5/ Acetochlor does not undergo photolysis in water and soil environments.

6/ The half-life of acetochlor under aerobic soil conditions was found to be 8-12 days.

7/ The study was submitted in 1981 in conjunction with an EUP and was summarily reviewed. The study needs to be resubmitted for a full review.

8/ The study must be repeated following the guidance in Subdivision N of the Pesticide Assessment Guidelines, 1982.

9/ The study is not required because >50% of acetochlor dissipates within 8-12 days, depending on soil type.

10/ Since crop rotation restriction is imposed at present, this study may be required.

11/ Acetochlor and its degradates do not accumulate in fish (acetochlor octanol/water ratio = 300).

12/ Spray drift studies are not required because acetochlor is classified as category III.

13/ Ground water monitoring studies are deferred pending results of terrestrial field dissipation study (§164-1).

Acetochlor: Summary of the status of data requirements

§158-290 - Environmental Fate Studies Required for Terrestrial Food Crops:

1/ The following studies were reviewed and found to be acceptable to fulfill the data requirements to support registration under 40 CFR §158.290:

161-1 - Hydrolysis
161-2 - Photodegradation in Water
161-3 - Photodegradation on Soil
162-1 - Aerobic Soil Metabolism
165-4 - Fish Accumulation

2/ The following studies were reviewed and found to be unacceptable:

164-1 - Terrestrial Field Dissipation
165-1 - Confined Rotational Crops

3/ The following studies were submitted to the Agency in 1981, but were only summarily reviewed by EAB (EFGWB):

162-2 - Anaerobic Soil Metabolism
163-1 - Leaching and Adsorption/Desorption (Batch Equilibrium)

4/ The following study may be required pending results of the studies listed in #2 above:

165-2 - Field Rotational Crops
§158.75 - Ground water monitoring

5/ The following Spray Drift studies are not required because acetochlor is classified as category III:

§158.440 - Spray Drift:

201-1 - Droplet Size Spectrum

202-1 - Drift Field Evaluation

6/ Additional Environmental Fate data requirements:

None (For Terrestrial Food Crop use only)

Pack No. 100471FF
Date Received 10/28/88

ATTACHMENT 1

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

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: Harness + Top Hand — CHEMICAL NAME: acetochlor

2. IDENTIFYING NUMBER	3. RECORD NUMBER	4. ACTION CODE	5. MRID/ACCESSION NUMBER	6. STUDY GUIDELINE OR NARRATIVE
524-611T	234023	101	99814	132-1
524-644T	234024	101	71958	132-3
524-EUP-AT	234027	711	40811901	132-4
524-EUP-AT	234028	711	40811962	162-2
				163-1
				164-1
				165-1
				165-2

7. REFERENCE NUMBER	8. DATE RECEIVED (EPA)	9. PRODUCT/REVIEW MANAGER/DCI	10. PM/RM TEAM NUMBER	11. DATE SENT TO (HED/EFED/RD/BEAD)
	10/3/88	Taylor/UK Walters	25	10/28/88

12. PROJECTED RETURN DATE	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS:
1/28/89		Request to assess previous submitted studies and additional data for these studies

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED ____

☐ ADVERSE 6(a)(2) DATA (405) ☐ SPECIAL REVIEW DATA (870) ☐ GENERIC DATA (660) (REREGISTRATION) ☐ PRODUCT SPECIFIC DATA (65 (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	
HED		SCIENCE ANALYSIS & COORD.	SAC	PC
		TOXICOLOGY/HFA	TOX/HFA	PL
		TOXICOLOGY/IR	TOX/IR	
		DIETARY EXPOSURE	DEB	EA
		NON-DIETARY EXPOSURE	NDE	AC
EFED		ECOLOGICAL EFFECTS		BA
	✓	ENVIRONMENTAL FATE & GROUND H2O	EEB	
SRRD		SPECIAL REVIEW	EFGWB	
		REREGISTRATION		
		GENERIC CHEMICAL SUPPORT	SR	
RD		INSECTICIDE-RODENTICIDE	RER	
		FUNGICIDE-HERBICIDE	GSC	
		ANTIMICROBIAL		
		PRODUCT CHEMISTRY	IR	
		PRECAUTIONARY LABELING	FH	
BEAD		ECONOMIC ANALYSIS	AM	
		ANALYTICAL CHEMISTRY		
		BIOLOGICAL ANALYSIS		

☐ CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS) ☐ LABEL ATTACHED

20. DATA REVIEW CRITERIA

A. Policy Note #31
☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
☐ 2 = data of particular concern from registration standard
☐ 3 = data necessary to determine tiered testing requirements

B. Section 18
☐ 1 = data in support of section 3 in lieu of section 18

C. Inert Ingredients
☐ 1 = data in support of continued use of List 1 inert

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review
Include original + two (2) copies with each submission