



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 6/25/96.

SUBJECT: PP#5F4505. Section 3 Registration and Permanent
Tolerance Petition to Expand the Use of Acetochlor End-
Use Products to Include Postemergence Application to
Corn.

DP Code: D214735, D214738	Trade Name: Acetochlor EC
Case #: 015532, 286543	Reg #: 66478-2
Chem #: 121601	40 CFR: 180.470
Caswell: 003B	MRID #: 436164-01
	436164-02

TO: Vickie Walters/Robert Taylor, PM Team 25
Registration Division (7505C)

FROM: G. Jeffrey Herndon *G. Jeffrey Herndon*
William Dykstra *W. Dykstra*
Charles Lewis *Chuck Lewis*
Pilot Interdisciplinary Risk Assessment Team
Risk Characterization and Analysis Branch
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THRU: Michael Metzger, Acting Branch Chief *Michael S. Metzger*
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

INTRODUCTION

The Acetochlor Registration Partnership (ARP) wishes to expand the use of products containing the herbicide acetochlor to include applications to corn after the corn plants have emerged from the soil surface. The current Section 3 registration only permits preemergence application to field corn. The postemergence application period is requested to allow application to corn plants up to 11 inches in height. In addition to the amended registration, ARP has requested an increase in the corn forage tolerance from 1.0 ppm to 2.6 ppm.

Currently, the following tolerances have been established for the preemergence Section 3 registration on field corn:

target crop:	field corn fodder	1.5 ppm
	field corn forage	1.0 ppm
	field corn grain	0.05 ppm
rotational crops:	sorghum fodder	0.1 ppm
	sorghum forage	0.1 ppm
	sorghum grain	0.02 ppm
	soybean forage	0.7 ppm
	soybean grain	0.1 ppm
	soybean hay	1.0 ppm
	wheat forage	0.5 ppm
	wheat grain	0.02 ppm
	wheat straw	0.1 ppm

RECOMMENDATION

PIRAT has concerns with the proposed action based on dietary and occupational exposure. Until the recommendations outlined below are adopted/rectified, HED cannot recommend that the acetochlor registration be amended to include postemergence use on corn.

1. The current language used in 40 CFR 180.470 implies that registrations exist for sorghum, soybean, and wheat. The tolerances listed under 40 CFR 180.470 for crops other than corn (sorghum, soybean, and wheat) should be moved to a separate subsection (b) under the following heading:

"(b) Indirect or inadvertent tolerances. Tolerances are established for indirect or inadvertent residues of acetochlor in or on the raw agricultural commodities when present therein as a result of the application of acetochlor to growing crops listed in paragraph (a) of this section and other non-food crops as follows:

sorghum, fodder	0.1 ppm
sorghum, forage	0.1 ppm
sorghum, grain	0.02 ppm
soybean, forage	0.7 ppm
soybean, grain	0.1 ppm
soybean, hay	1.0 ppm
wheat, forage	0.5 ppm
wheat, grain	0.02 ppm
wheat, straw	0.1 ppm"

2. PIRAT received two different versions of the acetochlor label with the proposed submission (one pin-punched 11/9/92 and the other pin-punched 4/13/95). The conclusions drawn below should be applied to the more recent of the two label versions (4/13/95). ARP should add the following language to the proposed label (changes are bolded):

"Do not use ACETOCHLOR EC on any crop other than **field corn, silage corn, or popcorn.**"

"If crop treated with ACETOCHLOR EC is lost, **field corn, silage corn, or popcorn** may be replanted immediately. Do not make a second application of ACETOCHLOR EC."

"ROTATIONAL CROPS: Do not rotate to crops other than soybeans, sorghum, wheat, or tobacco. Wheat may be planted 4 months after application. **Soybeans, sorghum, and tobacco may be planted a minimum of 12 months after application.**"

In the PPE section, "waterproof gloves" should be changed to "**chemical-resistant gloves**".

3. The ARP should submit a revised Section F which proposes a corn forage tolerance of 3.0 ppm (from the 2.6 ppm currently proposed).

Note to P.M.:

HED defers to RD to check the status of the safeners and proposed tank mix chemicals.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

- a) Short-Term Dermal Risk. The TES Committee has recently met to discuss acetochlor. For short-term dermal MOE calculations, the TES Committee recommended use of the systemic NOEL of 400 mg/kg/day from the 21 day dermal toxicity study in rabbits (MRID No. 00248620). At the LEL of 1200 mg/kg/day, there were deaths and decreased body weight.
- b) Short-Term Inhalation Risk. For short-term inhalation MOE calculations, the TES Committee recommended that no inhalation MOE is needed for short-term exposure, since the inhalation LC₅₀ is in Toxicity Category IV.
- c) Intermediate and Chronic Risk. Since intermediate and chronic exposure scenarios have not been identified for this use pattern, intermediate and chronic toxicological endpoints were not selected.
- d) Cancer Risk. Use the Q1* approach. Acetochlor has been classified as a Group B2 carcinogen by the HED

Cancer Peer Review Committee based on multiple tumors in both sexes of mice and rats and has a $Q1^*$ of $0.017 \text{ (mg/kg/day)}^{-1}$.

- e) Dermal Penetration. Dermal penetration of 19% has been determined in a rat dermal penetration study [MRID No. 41778303]. This value is used for AADD calculation only (cancer risk).

2. Dietary Endpoint Selection

- a) Acute Risk. For acute dietary risk assessment, the TES Committee recommended use of the NOEL of **150 mg/kg/day**, based on increased resorptions per dam, postimplantation loss, and decreased mean fetal body weight (MRID No. 41592015) at the LEL of 600 mg/kg/day, from the rat developmental study. This risk assessment will evaluate acute dietary risk to pregnant females 13+ and older.
- b) Chronic Risk. The RfD of **0.02 mg/kg/day** was established by the HED RfD Committee based on a one year dog feeding study (MRID No. 41561518) with a NOEL of 2 mg/kg/day and an uncertainty factor of 100 based on increased salivation, alanine amino transferase and triglycerides and decreased blood glucose levels at the LEL of 10 mg/kg/day.
- c) Cancer Risk. Use the $Q1^*$ approach. Acetochlor has been classified as a Group B2 by the HED Cancer Peer Review Committee based on multiple tumors in both sexes of mice and rats and has a $Q1^*$ of $0.017 \text{ (mg/kg/day)}^{-1}$.

Occupational Exposure

- 1. Acute data for this formulation are available to PIRAT. **Provided that the label is revised to require chemical resistant (instead of waterproof) gloves, the work clothing and personal protective equipment (PPE) appearing on the label are in compliance with the Worker Protection Standard (WPS).**
- 2. Acute data for the technical are available. The restricted entry interval (REI) of 12 hours appearing on the label is in compliance with the WPS.
- 3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. The label provided with the submission, Acetochlor EC Herbicide (EPA Reg. No. 66478-2) requires applicators and other handlers to wear: long-sleeved shirts and long pants, waterproof gloves, chemical-resistant footwear plus socks, protective eyewear,

chemical-resistant headgear for overhead exposure, and chemical-resistant apron when cleaning equipment, mixing or loading. PIRAT has conducted its estimates of exposure with workers wearing a single layer of clothing plus gloves.

Dietary Exposure

1. The nature of the residue in corn is adequately understood. The residue of concern is the parent acetochlor, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethylmethylaniline (HEMA) moiety. For rotational crops, the residue of concern is acetochlor and its EMA- and HEMA-producing metabolites. The hydroxymethylethylaniline (HMEA) producing metabolites were not included in the tolerance expression, but are included in the risk assessment calculation (HED Metabolism Committee, 9/15/93).
2. Adequate enforcement methodology (HPLC/electrolytic conductivity) has been submitted for inclusion in PAM II to enforce the tolerance expression (MRID# 434700-01).
3. Residues of acetochlor and its metabolites are not expected to exceed the currently established field corn fodder (1.5 ppm) and grain (0.05 ppm) tolerances as a result of this amended registration. However, the existing field corn forage tolerance of 1.0 ppm will not be adequate. **The ARP should propose a 3.0 ppm tolerance on field corn forage.** No tolerances on processed commodities will need to be established as a result of the proposed amended registration.
4. In the meeting held on 9/15/93, the HED Metabolism Committee concluded that "tolerances for meat, milk, poultry, and eggs are not needed for the proposed [pre-emergence] use on corn". Based on the new higher dietary burden (as noted in Attachment 1), PIRAT concludes that the use still falls under Section 180.6(a)(3), with "no reasonable expectation of finite residues" in ruminant and poultry commodities.
5. Dietary exposure estimates (DRES) for acetochlor are summarized in Attachment 2. PIRAT found an error in the original DRES run. The DRES entries for soybean products were inadvertently entered as 0.2 ppm (rather than 0.15 ppm). The DRES run included with this review uses the correct values, and reduces the previous estimates for chronic and cancer risks.
 - a) Chronic Dietary Risk. The existing acetochlor tolerances (including the increased corn forage tolerance of 3.0 ppm) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to <1%

of the ADI for the US general population (48 states) and 1.6% of the ADI for the highest population subgroup (non-nursing infants, < 1 year old).

- b) Acute Dietary Risk. For the population subgroup of concern, females 13+, the calculated Margin Of Exposure (MOE) value is 500,000.
- c) Dietary Cancer Risk. The existing acetochlor tolerances (including the increased corn forage tolerance of 3.0 ppm) result in a cancer risk of 1.9×10^{-6} for the U.S. general population (48 states). This risk estimate is less than that calculated when acetochlor was first registered (2.2×10^{-6}).
- d) Anticipated Residues. Since the existing acetochlor tolerances plus proposed tolerance use do not result in TMRCs that exceed the RfD for the US general population or any of the 22 subgroups analyzed, there is no need for anticipated residue assessment refinement.

DETAILED CONSIDERATIONS

EXPOSURE ASSESSMENT

OCCUPATIONAL EXPOSURE

Table 1. Occupational Exposure Assumptions	
PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database, Version 1.1 (PHED) unit of exposure values from Best Available Surrogate Exposure Table (BASET, 2/28/96)	Mixer/Loader: Dermal exposure (all liquids, > 10 lb ai, open mixing, single layer clothing plus gloves) = 64.00 μg ai/lb handled; Inhalation exposure = 0.64 μg ai/lb handled. Dermal and inhalation Tox endpoints are not the same.
	Applicator: Dermal exposure (groundboom, open cab, single layer clothing plus gloves) = 14.0 μg ai/lb applied; Inhalation exposure = 0.70 μg ai/lb handled.
Work clothing & PPE	Single layer clothing plus gloves.
Percent absorption	Dermal = 100% for ADD (based on a dermal toxicity study), 19% for AADD (based on oral toxicity study); Inhalation = 100% (default value).
Application type	Ground equipment.
Maximum Application rate	3.0 lb ai/A
Minimum finish spray	Ground: 10 gal/A
Maximum Applications per year	1
Acres treated/day (Y. NG,BEAD)	Ground: 108 acres
Average Farm Size	Based on 1992 Ag Census, Iowa average for corn, 172 acres.
Worker Weight	70 kg (based on Tox endpoint).
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2

Table 2. Occupational Exposure and Risk Assessment ^a					
Worker	ADD ^b Dermal (ug/kg/day)	ADD ^c Inhalation (ug/kg/day)	AADD ^d (ug/kg/day)	Short- term Dermal MOE ^e	Cancer risk ^f
Ground Mixer/Loader	296.2	3.0	0.5	1,400	4.2×10^{-6}
Ground Applicator	64.8	3.2	0.1	6,200	8.5×10^{-7}

^a MOEs are expressed at two significant figures.

^b Average Daily Dose (ADD) = PHED unit exposure x % absorption (100% for dermal and inhalation) x application rate x acres treated/day ÷ kg body weight.

^c Since no short-term inhalation endpoint was identified, the short-term MOE will not be calculated.

^d Average Annual Daily Dose (AADD) = ADD (dermal (19% absorption) + inhalation (100% absorption)) x number of days required to treat field one time x number of treatments/season ÷ 365 days/year.

^e Short-term dermal occupational exposure MOE = NOEL/ADD (where NOEL = 400 mg/kg/day).

^f Cancer Risk = AADD x [Q*1] 0.017 (mg/kg/day)⁻¹ x 35/70

DIETARY EXPOSURE

Residue Data

Residue data that were provided by the ARP to support the proposed action were tabulated and put into DER format by Dynamac Corporation. The review has undergone secondary review in PIRAT and is consistent with CBTS/CBRS policies. The review is included as Attachment 1.

Table 3. Residue Consideration Summary Table		
PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Acetochlor	Acetochlor
FORMULATION	Acetochlor EC	Acetochlor EC
CROP	corn	corn
TYPE APPLICATION	ground	ground
# APPLICATIONS	1	1
TIMING	early postemergence (up to 11 inches tall)	early postemergence
RATE/APPLICATION	3 lbs ai/A	3 lbs ai/A
RATE/YEAR or SEASON	3 lbs ai/A/season	3 lbs ai/A/season
MAXIMUM RESIDUE	N/A	forage: 2.52 ppm fodder (stover): 0.22 ppm grain: 0.014 ppm
RESTRICTIONS	minimum of 10 gal/A, maximum of 50 gal/A no aerial application	
RESIDUE DATA SOURCE	N/A	MRID# 436164-01 and 436164-02
PERFORMING LAB	N/A	Zeneca ABC Laboratories (for Monsanto samples)
CODEX		

Attachment 1: Dynamac review of MRID# 436164-01 and 436164-02.

Attachment 2: DRES report

cc (with Attachments): Herndon (PIRAT), B. Steinwand (DRES), PP#5F4505 (CHEM).

cc (without Attachments): Dykstra (PIRAT), Lewis (PIRAT), PIRAT file, S. Dapson (TOX), Caswell #003B, OREB, PP#3F2966 (CHEM), PP#1F4011 (CHEM), RF (CHEM)

RDI:PIRAT 6/25/96.

7509C:RCAB:PIRAT:CM2:Rm804C:305-6362:6/24/96.

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Attachment 1

**ACETOCHLOR
PP#5F4505
(CBTS No. 15492; DP Barcode D214735)**

Data Evaluation Record

April 17, 1996

Contract No. 68-D4-0010

**Submitted to:
U.S. Environmental Protection Agency
Arlington, VA**

**Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268**

DATA EVALUATION RECORD

PETITION NO.: PP#5F4505

DP BARCODE(S): D214735

CBTS NOS.: 15492

STUDY TYPES: Magnitude of the Residue in/on Field Corn Forage, Fodder, and Grain [Guideline Reference No. 171-4(k)].

STUDY SPONSOR: The Acetochlor Registration Partnership (ARP), c/o Zeneca Ag Products (Wilmington, DE)

MRID NOS.:
43616401 French, D.; Crook, S.; Veal, P.; Bathke, P.; and Boother, P. Magnitude of Residues in Field Corn Following Postemergence Application (USA 1993). Study No. ACET-93-MR-03. Report No. RJ1735B. Unpublished Study Submitted by Acetochlor Registration Partnership, c/o Zeneca Ag Products (Wilmington, DE). 178 p. Study Completed on 12/22/94.
43616402 Allan, J. Acetochlor Metabolite Residues in Field Corn Commodities Following Early Postemergent Applications of Acetochlor. Laboratory Project Nos. MSL-13414 (Monsanto), 41383 (ABC Labs), 93-27-R-2 (Stewart Ag.). Unpublished Study Submitted by Acetochlor Registration Partnership, c/o Zeneca Ag Products (Wilmington, DE). 319 p. Study Completed on 6/94.

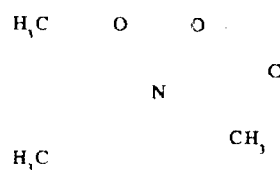
PERFORMING LABORATORIES: Field: Stewart Agricultural Research Services, Inc. (Macon, MO).
Analytical: Residue Chemistry Section of Zeneca Agrochemicals (Jealott's Hill Research Station, Bracknell, Berkshire, UK), and ABC Laboratories (Columbia, MO).

TEST MATERIAL APPLIED TO CROP: MRID 43616401: Acetochlor plus the safeners dichlormid (R-25788), or R-29148.
MRID 43616402: Acetochlor plus the safeners MON 4660, MON 13988, and MON 13900.

EPA REG. NOS.: 66478-2 (7.5 lb/gal EC; Product Name = Acetochlor EC Herbicide)

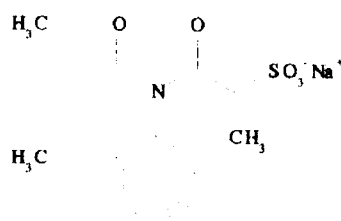
**RESIDUES
MEASURED:**

Acetochlor (2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide)



Acetochlor metabolite class containing the ethyl methyl aniline moiety (EMA);

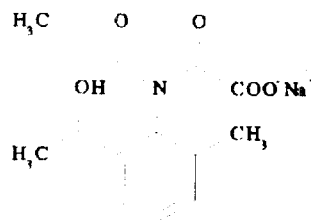
EMA-producing reference standard: Ethanesulfonic acid, 2[(2-ethyl-6-methylphenyl)ethoxymethyl]amino]-2-oxo, sodium salt



Acetochlor metabolite class containing the hydroxyethyl aniline moiety (HEMA);

HEMA-producing reference substance: Acetic acid.

[(ethoxymethyl)[2-(1-hydroxyethyl)-6-methylphenyl]amino]-oxo, sodium salt



DETAILED CONSIDERATIONSMagnitude of the Residue in/on Field Corn Forage, Stover (Fodder), and Grain

In support of a petition, PP#5F4505, to expand the use of acetochlor end-use products to include postemergence application to corn, the Acetochlor Registration Partnership, comprised of Monsanto Chemical Company and Zeneca Corporation (formerly ICI Americas, Inc.), submitted two volumes of field corn residue data (1994; MRIDs 43616401 and 43616402). Data from these submissions are presented in this Data Evaluation Record (DER). Separate data presentations are made for each study because of differences in the residue analytical methodologies.

Established tolerances: Tolerances have been established for the residues of acetochlor [2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide] and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl aniline (HEMA) moiety, to be analyzed as acetochlor, and expressed as acetochlor equivalents in/on field corn forage (1.0 ppm), fodder (1.5 ppm), and grain (0.05 ppm) [40 CFR §180.470]. Rotational crop tolerances for various commodities of sorghum, soybean, and wheat have also been established under 40 CFR §180.470 at levels ranging from 0.02 ppm to 1.0 ppm.

The HED Metabolism Committee, in a meeting held 9/15/93, concluded that the tolerance expression for corn and rotational crops should be expressed in terms of acetochlor and its EMA- and HEMA-producing metabolites. It was determined that HMEA-producing metabolites, while not appearing in the tolerance expression, would be included in risk assessment calculations; see summary memorandum of M. Flood, 9/17/93. The acetochlor tolerances for field corn forage, fodder, and grain were established through PP#3F2966/PP#1F4011 on the basis of residue data reflecting preplant incorporation or preemergence application of an emulsifiable concentrate (EC) formulation.

Proposed tolerances: Section F of PP#5F4505 proposes the establishment of an increased tolerance for residues of acetochlor and its metabolites containing the EMA and HEMA moieties, to be analyzed as acetochlor, EMA, and HEMA, and expressed as acetochlor equivalents in/on field corn forage at 2.6 ppm. The petitioner states that all other established tolerances for acetochlor and its metabolites in/on other raw agricultural commodities should remain unchanged.

Directions for use: Section B of PP#5F4505 includes a specimen label for the 7.5 lb/gal EC formulation (EPA Reg. No. 66478-2; Product Name = Acetochlor EC Herbicide) to describe the currently accepted as well as proposed field corn use patterns.

The 7.5 lb/gal EC formulation is presently registered for use on corn (field corn, silage corn, and popcorn) for either a surface application after planting (preemergence) or shallowly incorporated application prior to planting (preplant incorporated) to blend the herbicide into the upper 1 to 2 inches of soil. Use rates can vary up to 3 lb ai/A, the highest rates being

used in soils having high (>10%) organic matter. Application may be made in a minimum spray volume of 10 gallons per acre using broadcast boom ground equipment; aerial applications and application through sprinkler irrigation systems are prohibited. Tank mixing of the acetochlor EC formulation with other registered herbicides, and use of spray adjuvants are allowed. The maximum use rate permitted for this EC formulation is 3 lbs ai/A. The label specifies that only corn, soybeans, sorghum, tobacco, or wheat may be used as rotational crops, and wheat may be planted at a 4-month plantback interval.

The 7.5 lb/gal EC formulation is proposed for a single early postemergence application (when plants are up to 11 inches tall) to corn (field corn, silage corn, and popcorn) at a maximum rate of 3 lb ai/A. Application may be made in a minimum spray volume of 10 gallons per acre using broadcast boom ground equipment; aerial applications and application through sprinkler irrigation systems are prohibited. Tank mixing of the acetochlor EC formulation with other registered herbicides, and use of spray adjuvants are allowed. The maximum use rate proposed for this EC formulation is 3 lb ai/A. The specimen labels does not specify preharvest intervals for forage, fodder, and grain. No changes in the currently established rotational crop restrictions are being proposed.

Discussion of the data - (1994; MRID 43616401): Eight field trials were conducted during the 1993 growing season in IA, IL, IN, MN, NE, OH, TX, and WI depicting the magnitude of acetochlor residues of concern in/on the commodities of field corn. Each trial consisted of one control plot and four treated plots. Each treated plot received one postemergence application of either the EC or Mcap formulation of acetochlor at 3.0 lb ai/A using ground equipment in ~16-21 gallons of water per acre when the corn plants had reached a height of between 5 and 9 inches. The test substance was mixed with safeners [dichlormid (R-25788) or R-29148]. At each location, two of the treated plots were sprayed with the combination of acetochlor:R-25788 (6:1, v:v), and two were sprayed with acetochlor:R-29148 (18:1, v:v). For each acetochlor:safener mixture, one plot was treated with the EC formulation, and the other was treated with the Mcap formulation.

Samples of corn forage, grain (kernel + cobs), and stover (fodder) were collected at the appropriate growth stages, 12-31 days posttreatment for forage and 104-131 days posttreatment for grain and stover (fodder). Following collection, samples were shipped under frozen storage conditions to Zeneca Ag Products Western Research Center (Richmond, CA) where sample preparation was conducted. Samples of forage, fodder, and grain (consisting of both kernels and cobs) were chopped in dry ice to produce a completely homogenous sample. Subsamples of each prepared sample were transported frozen to Zeneca Agrochemicals Jealott's Hill Research Station (Berkshire, UK) for residue analysis. All samples were stored frozen (<-15 C) at the analytical laboratory prior to actual analysis. The maximum storage interval between harvest and analysis was ~13 months.

Residues in/on treated and untreated corn commodities were determined using Method 244/01 for the analysis of acetochlor and dichlormid, and Method 184/04 for the analysis of the EMA and HEMA class metabolites. Descriptions along with validation data for this method are

presented in "Residue Analytical Methods" section. The results of the corn field trials from this submission are presented in Table 1. The table presents residue data for acetochlor and its EMA and HEMA class metabolites as well as for the safener dichlormid. The petitioner stated that analysis of samples treated with the combination of acetochlor and safener R-29148 is ongoing and will be submitted when completed. Treated samples were analyzed for EMA and HEMA residues in duplicate; the residue value reported in Table 1 for each sample represents the higher value of the duplicate analyses. Each residue value presented in Table 1 was corrected by the petitioner for the "mean external recovery generated in each analytical batch". For purposes of data presentation in this DER, no efforts were made to uncorrect these residue values since the actual mean recoveries used by the petitioner were not provided. No raw data were provided for acetochlor/dichlormid analyses and minimal raw data were provided for EMA/HEMA analyses (results for individual analyses corrected for method recovery). Apparent residues of acetochlor, EMA, HEMA, and dichlormid each were below the detection limit in/on eight untreated samples each of forage, stover (fodder), and grain.

Table 1 Residues of acetochlor and its EMA and HEMA class metabolites, and dichlormid in/on field corn commodities following a single postemergence application of the EC or Mcap formulation of acetochlor at 3.0 lb ai/A mixed with the safener dichlormid (R-25788; MRID 43616401).

Formulation	Trial Site	Residues in Ppm ^{a,b}				
		Acetochlor	EMA	HEMA	Combined EMA + HEMA ^c	Dichlormid
Field Corn Forage (harvested 12-31 days posttreatment)						
Mcap	IA	<0.01	0.05	<0.02	<0.07	<0.01
	IL	<0.01	0.15	0.02	0.17	<0.01
	IN	<0.01	0.17	0.04	0.21	<0.10
	MN	<0.01	0.58	0.09	0.67	<0.01
	NE	0.02	1.6	0.05	1.65	<0.01
	OH	<0.01	0.17	0.05	0.22	<0.01
	TX	<0.01	0.46	0.06	0.52	<0.01
	WI	<0.01	1.4	0.05	1.45	<0.01
EC	IA	<0.01	0.07	<0.02	<0.09	<0.01
	IL	<0.01	0.15	<0.02	<0.17	<0.01
	IN	<0.01	0.14	0.03	0.17	<0.01
	MN	<0.01	1.1	0.08	1.18	<0.01
	NE	<0.01	0.95	0.03	0.98	<0.01
	OH	<0.01	0.14	0.03	0.17	<0.01
	TX	<0.01	0.28	0.03	0.31	<0.01
	WI	<0.01	1.9	0.07	1.97	<0.01
Field Corn Grain (harvested 104-131 days posttreatment)						
Mcap	IA	<0.01	<0.02	<0.02	<0.04	<0.01
	IL	<0.01	<0.02	<0.02	<0.04	<0.01
	IN	<0.01	<0.02	<0.02	<0.04	<0.01
	MN	<0.01	<0.02	<0.02	<0.04	<0.01
	NE	<0.01	<0.02	<0.02	<0.04	<0.01
	OH	<0.01	<0.02	<0.02	<0.04	<0.01
	TX	<0.01	<0.02	<0.02	<0.04	<0.01
	WI	<0.01	<0.02	<0.02	<0.04	<0.01
EC	IA	<0.01	<0.02	<0.02	<0.04	<0.01
	IL	<0.01	<0.02	<0.02	<0.04	<0.01
	IN	<0.01	<0.02	<0.02	<0.04	<0.01
	MN	<0.01	<0.02	<0.02	<0.04	<0.01
	NE	<0.01	<0.02	<0.02	<0.04	<0.01
	OH	<0.01	<0.02	<0.02	<0.04	<0.01
	TX	<0.01	<0.02	<0.02	<0.04	<0.01
	WI	<0.01	<0.02	<0.02	<0.04	<0.01

(continued, footnotes follow)

Table 1 (continued)

Formulation	Trial Site	Residues in Ppm ^{a,b}				
		Acetochlor	EMA	HEMA	Combined EMA + HEMA ^c	Dichlormid
Field Corn Stover (Fodder) (harvested 104-131 days posttreatment)						
Mcap	IA	<0.01	0.03	<0.02	<0.05	<0.01
	IL	<0.01	0.04	<0.02	<0.06	<0.01
	IN	<0.01	0.05	<0.02	<0.07	<0.01
	MN	<0.01	0.07	<0.02	<0.09	<0.01
	NE	<0.01	0.03	<0.02	<0.05	<0.01
	OH	<0.01	<0.02	<0.02	<0.04	<0.01
	TX	<0.01	0.16	0.06	0.22	<0.01
	WI	<0.01	0.03	<0.02	<0.05	<0.01
EC	IA	<0.01	0.04	<0.02	<0.06	<0.01
	IL	<0.01	0.03	<0.02	<0.05	<0.01
	IN	<0.01	0.04	0.02	0.06	<0.01
	MN	<0.01	0.07	<0.02	<0.09	<0.01
	NE	<0.01	0.02	<0.02	<0.04	<0.01
	OH	<0.01	<0.02	<0.02	<0.04	<0.01
	TX	<0.01	0.10	0.04	0.14	<0.01
	WI	<0.01	0.05	0.03	0.08	<0.01

^a Each residue value was corrected by the petitioner for the "mean external recovery generated in each analytical batch." No efforts were made to uncorrect residues since the actual mean recoveries used by the petitioner were not provided.

^b Acetochlor and dichlormid results were obtained from a single analysis. EMA and HEMA results are the expressed as acetochlor equivalents, and are the higher value of duplicate analyses.

^c Because analysis for EMA-producing compounds would include residues of acetochlor, combined residues include only results for EMA and HEMA analyses.

Discussion of the data - (1994; MRID 43616402): Eight field trials were conducted during the 1993 growing season in IA, IL, IN, MN, MO, NE, SD, and TX, depicting the magnitude of acetochlor residues of concern in/on the commodities of field corn. Each trial consisted of the following: one untreated control plot (treatment 1); one plot treated with a 7 lb/gal acetochlor EC formulation (MON 8407) plus the safener MON 4660 at a ratio of 7.0:0.7 lb/gal (treatment 2); one plot treated with the 7.5 lb/gal acetochlor EC formulation (MON 8435) plus the safener MON 13900 (treatment 3); and one plot treated with a 42.5% acetochlor Mcap formulation (MON 8478) plus the safener MON 13900 at a ratio of 4.0:0.13 lb/gal (treatment 4). Each treated plot received one postemergence broadcast application of the acetochlor formulation at 3.0 lb ai/A using ground equipment in ~10-20 gallons of water per acre when the corn plants had reached a height of between 6 and 11 inches. Adequate

information pertaining to test plots, agronomic practices, and atmospheric and soil conditions during the study periods was provided.

Samples of corn forage, grain, and stover (fodder) were collected at the appropriate growth stages, 12-36 days posttreatment for forage, and 106-141 days posttreatment for grain and stover (fodder). Following collection, samples were immediately shipped via refrigerated truck to Monsanto (Chesterfield, MO) where sample preparation was conducted. Samples were chopped in dry ice to a medium to fine consistency. Subsamples of each prepared sample were transported frozen to ABC Laboratories (Columbia, MO) for residue analysis. All samples were stored frozen (-20 C) at the analytical laboratory prior to actual analysis. The maximum storage intervals prior to residue analysis of commodities collected from the respective field trials were ~9 months for forage, ~5 months for grain, and ~6 months for stover fodder.

Residues in/on treated and untreated corn commodities were determined using Monsanto Method RES-074-93-0 which is identical to the current enforcement method. The method is based on the hydrolysis of acetochlor and its metabolites into the two common chemophores, EMA and HEMA. The sum of the two analytes is reported as total ppm acetochlor equivalents. Descriptions along with validation data for this method are presented in "Residue Analytical Methods" section. The results of the corn field trials from this submission are presented in Table 2; only the results of acetochlor (EMA + HEMA) analyses were reported in the submission. Residue values presented in Table 2 were not corrected for concurrent method recovery.

Apparent residues of EMA and HEMA were below the detection limits in/on forage (6 samples), stover (fodder) (8 samples), and grain (8 samples). One untreated forage sample collected in NE bore detectable apparent residues of EMA at 0.0108 ppm (less than the 0.015-ppm limit of quantitation). One additional forage sample collected in MO bore apparent residues of EMA at 0.0763 ppm and HEMA at 0.0285 ppm; the presence of detectable residues was attributed to mislabeling of treated vs. untreated sample.

Table 2. Residues of HEMA- and EMA-yielding metabolites in/on field corn commodities following a single postemergence application of the EC or Mcap formulation of acetochlor at 3.0 lb ai/A mixed with safeners MON 4660, MON 13988, or MON 13900. (MRID 43616402).

Formulation and Treatment Combination	Trial Site	Replicate No. ^a	Uncorrected Residues of Acetochlor Equivalents In Ppm ^b		
			HEMA	EMA	Total ^c
Field Corn Forage (harvested 12-36 days posttreatment)					
7 lb/gal EC formulation (MON 8407) plus the safener MON 4660 (Treatment 2)	IA	1	0.0162	0.0819	0.098
		2	0.0160	0.0883	0.104
	IL	1	0.0373	0.1430	0.180
		2	0.0442	0.1580	0.202
	IN	1	0.0246	0.1600	0.185
		2	0.0251	0.1560	0.181
	MN	1	0.1020	1.7000	1.802
		2	0.0608	0.4790	0.540
	MO	1	0.0216	0.0754	0.097
		2	0.0220	0.0767	0.099
	NE	1	0.0622	1.4150	1.477
		2	0.0599	1.2590	1.319
	SD	1	[0.0118]	0.1100	0.122
		2	[0.0138]	0.1430	0.157
	TX	1	0.0180	0.1910	0.209
		2	0.0192	0.1270	0.146
7.5 lb/gal EC formulation (MON 8435) plus the safener MON 13900 (Treatment 3)	IA	1	[0.0148]	0.0825	0.097
		2	[0.0159]	0.0863	0.102
	IL	1	0.0236	0.0738	0.097
		2	0.0105	0.0252	0.036
	IN	1	0.0207	0.1730	0.194
		2	0.0208	0.1580	0.179
	MN	1	0.1770	2.3430	2.520
		2	0.1230	2.2840	2.407
	MO	1	0.0219	0.0740	0.096
		2	0.0261	0.0833	0.109
	NE	1	0.0359	0.5850	0.621
		2	0.0544	1.1220	1.176
	SD	1	[0.0158]	0.1180	0.134
		2	0.0174	0.1320	0.149
	TX	1	[0.0125]	0.1130	0.126
		2	[0.0100]	0.0731	0.083

(continued; footnotes follow)

Table 2 (continued)

Formulation and Treatment Combination	Trial Site	Replicate No. ^a	Uncorrected Residues of Acetochlor Equivalents In Ppm ^b		
			HEMA	EMA	Total ^c
42.5% Mcap formulation (MON 8478 plus the safener MON 13900 (Treatment 4))	IA	1	[0.0137]	0.0549	0.069
		2	[0.0126]	0.0530	0.066
	IL	1	0.0191	0.0408	0.060
		2	0.0251	0.0676	0.093
	IN	1	0.0292	0.1260	0.155
		2	0.0221	0.1130	0.135
	MN	1	0.1410	1.5010	1.642
		2	0.0956	0.6580	0.754
	MO	1	0.0265	0.0924	0.119
		2	0.0258	0.0775	0.103
	NE	1	0.0231	0.4200	0.443
		2	0.0244	0.4500	0.474
	SD	1	0.0188	0.1360	0.155
		2	0.0221	0.1460	0.168
	TX	1	[0.0076]	0.0397	0.047
		2	[0.0074]	0.0633	0.071
Field Corn Grain (harvested 106-141 days posttreatment)					
7 lb/gal EC formulation (MON 8407) plus the safener MON 4660 (Treatment 2)	IA	1	<0.0004	<0.002	[<0.002]
		2	[0.0016]	[0.0031]	[0.005]
	IL	1	[0.0069]	[0.0069]	[0.014]
		2	[0.0059]	[0.0059]	[0.012]
	IN	1	[0.0037]	[0.0043]	[0.008]
		2	[0.0027]	[0.0039]	[0.007]
	MN	1	<0.0004	<0.002	[<0.002]
		2	[0.0025]	<0.002	[<0.005]
	MO	1	<0.0004	<0.002	[<0.002]
		2	<0.0004	<0.002	[<0.002]
	NE	1	[0.0025]	<0.002	[<0.005]
		2	[0.0036]	[0.0021]	[0.006]
	SD	1	<0.0004	<0.002	[<0.002]
		2	<0.0004	<0.002	[<0.002]
	TX	1	[0.0036]	<0.002	[<0.006]
		2	[0.0037]	<0.002	[<0.004]

(continued: footnotes follow)

Table 2 (continued)

Formulation and Treatment Combination	Trial Site	Replicate No. ^a	Uncorrected Residues of Acetochlor Equivalents In Ppm ^b		
			HEMA	EMA	Total ^c
7.5 lb/gal EC formulation (MON 8435) plus the safener MON 13900 (Treatment 3)	IA	1	<0.0004	<0.002	[<0.002]
		2	[0.0012]	[0.0035]	[0.005]
	IL	1	[0.0071]	[0.0034]	[0.011]
		2	[0.0065]	[0.0044]	[0.011]
	IN	1	[0.0024]	[0.0051]	[0.007]
		2	[0.0021]	[0.0024]	[0.005]
	MN	1	<0.0004	[0.0024]	[<0.003]
		2	<0.0004	<0.002	[<0.002]
	MO	1	[0.0025]	[0.0021]	[0.005]
		2	[0.0029]	<0.002	[<0.005]
	NE	1	[0.0022]	<0.002	[<0.004]
		2	[0.0019]	<0.002	[<0.004]
	SD	1	<0.0004	<0.002	[<0.002]
		2	[0.0022]	<0.002	[<0.004]
	TX	1	[0.0042]	[0.0025]	[0.007]
		2	[0.0022]	<0.002	[<0.004]
42.5% Mcap formulation (MON 8478) plus the safener MON 13900 (Treatment 4)	IA	1	<0.0004	[0.0033]	[<0.004]
		2	[0.0028]	[0.0048]	[0.008]
	IL	1	NA ^d	NA	NA
		2	NA	NA	NA
	IN	1	[0.0021]	<0.002	[<0.004]
		2	[0.0025]	<0.002	[<0.005]
	MN	1	<0.0004	<0.002	[<0.002]
		2	[0.0018]	<0.002	[<0.004]
	MO	1	[0.0026]	<0.002	[<0.005]
		2	[0.0037]	<0.002	[<0.006]
	NE	1	<0.0004	<0.002	[<0.002]
		2	[0.0023]	<0.002	[<0.004]
	SD	1	<0.0004	<0.002	[<0.002]
		2	[0.0018]	<0.002	[<0.004]
	TX	1	[0.0042]	<0.002	[<0.006]
		2	[0.0042]	[0.0021]	[0.006]

(continued; footnotes follow)

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Table 2 (continued)

Formulation and Treatment Combination	Trial Site	Replicate No. ^a	Uncorrected Residues of Acetochlor Equivalents In Ppm ^b		
			HEMA	EMA	Total ^c
Field Corn Stover (Fodder) (harvested 106-141 days posttreatment)					
7 lb/gal EC formulation (MON 8407) plus the safener MON 4660 (Treatment 2)	IA	1	[0.0118]	0.0332	0.045
		2	[0.0133]	0.0361	0.049
	IL	1	0.0163	0.0407	0.057
		2	[0.0068]	0.0286	0.035
	IN	1	0.0670	0.1160	0.183
		2	0.0229	0.0581	0.081
	MN	1	[0.0058]	0.0528	0.059
		2	[0.0076]	0.0631	0.071
	MO	1	<0.004	[0.0100]	[<0.014]
		2	<0.004	[0.0102]	[<0.014]
	NE	1	[0.0130]	0.0388	0.052
		2	[0.0115]	0.0472	0.059
	SD	1	0.0243	0.0374	0.062
		2	0.0273	0.0494	0.077
	TX	1	0.0605	0.1270	0.188
		2	0.0784	0.1380	0.216
7.5 lb/gal EC formulation (MON 8435) plus the safener MON 13900 (Treatment 3)	IA	1	[0.0132]	0.0439	0.057
		2	[0.0130]	0.0403	0.053
	IL	1	[0.0121]	0.0280	0.040
		2	0.0178	0.0322	0.050
	IN	1	[0.0095]	0.0349	0.044
		2	[0.0144]	0.0452	0.060
	MN	1	[0.0155]	0.1740	0.190
		2	[0.0112]	0.1740	0.185
	MO	1	<0.004	0.0150	<0.019
		2	[0.0041]	0.0164	0.020
	NE	1	[0.0131]	0.0371	0.050
		2	[0.0117]	0.0415	0.053
	SD	1	0.0432	0.0779	0.121
		2	0.0333	0.0605	0.094
	TX	1	0.0526	0.1200	0.173
		2	0.0414	0.1270	0.168

(continued: footnotes follow)

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Table 2 (continued).

Formulation and Treatment Combination	Trial Site	Replicate No. ^a	Uncorrected Residues of Acetochlor Equivalents In Ppm ^b		
			HEMA	EMA	Total ^c
42.5% Mcap formulation (MON 8478) plus the safener MON 13900 (Treatment 4)	IA	1	[0.0096]	0.0230	0.033
		2	[0.0116]	0.0347	0.046
	IL	1	0.0165	0.0466	0.063
		2	[0.0093]	0.0404	0.050
	IN	1	0.0197	0.0470	0.067
		2	0.0160	0.0327	0.049
	MN	1	[0.0080]	0.1450	0.053
		2	[0.0052]	0.0810	0.086
	MO	1	<0.004	[0.0145]	[<0.019]
		2	<0.004	[0.0134]	[<0.017]
	NE	1	[0.0120]	0.0434	0.055
		2	[0.0072]	0.0287	0.036
	SD	1	0.0358	0.0784	0.114
		2	0.0307	0.0724	0.103
	TX	1	0.0703	0.1460	0.216
		2	0.0792	0.1380	0.217

^a Two field samples were collected from each treated plot.

^b Residue values greater than the limit of detection but less than the limit of quantitation are presented in brackets.

^c Total residues containing no individual components greater than the limit of quantitation are presented in brackets.

^d NA = Not analyzed.

Geographic representation of residue data from the two studies is adequate. The test states of IA(19%), IL(16%), IN(7%), MN(10%), MO(3%), NE(13%), OH(4%), SD(3%), TX(2%), and WI(5%) accounted for 82% of the 1991 U.S. field corn production (1992 *Agricultural Statistics*). The total number of field trials conducted (8 + 8 = 16) is within the current guidance.

Summary of studies: The submitted field trial data are acceptable and adequately depict the proposed postemergence application of the acetochlor EC formulation on field corn. When field corn forage samples were harvested 12-36 days and field corn grain and stover (fodder) samples were harvested 104-141 days following a single postemergence application of the EC or Mcap formulation at 3.0 lb ai/A using ground equipment in ~10-20 gallons of water per acre when the corn plants had reached a height of between 5 and 11 inches, the maximum combined residues of acetochlor and its metabolites containing EMA and HEMA moieties, expressed as acetochlor equivalents, were: 2.52 ppm in/on forage (harvested in MN; MRID 43616402); <0.04 ppm (less than the combined limits of quantitation) in/on grain; and 0.217 ppm in/on stover (fodder) (harvested in TX; MRID 43616402).

These data indicate that the proposed tolerance level of 2.6 ppm for the combined residues of acetochlor and its metabolites containing the EMA and HEMA moieties in/on field corn forage will not be exceeded following application of the EC and Mcap formulation at the maximum proposed use pattern. The present data also suggest that the established tolerance of 0.05 ppm for field corn grain and the established tolerance 1.5 ppm for field corn fodder are supported by the present data.

Residue Analytical Methods

MRID 43616401 - Analyses of field corn commodity samples were conducted by Zeneca Agrochemicals Jealott's Hill Research Station (Berkshire, UK). Samples were analyzed for residues of acetochlor and dichlormid using Method 244/01, a GLC method with nitrogen selective thermionic detection and a detection limit of 0.01 ppm for each compound. Sample analysis for residues of the EMA and HEMA class metabolites was performed using Method 184/04, a GLC method with mass selective detection, and detection limits of 0.01 ppm for both EMA and HEMA (0.02 ppm when expressed as acetochlor equivalents).

A brief summary of Method 244/01 follows. A representative sample was extracted with methanol. After extraction, samples were filtered and the extract was concentrated by evaporating the solvent. The concentrate was transferred to a centrifuge tube, diluted with sodium chloride solution, and partitioned into toluene. The organic fraction was collected and adjusted to a known volume. An aliquot was cleaned up using solid phase amino and silica columns. Residues were eluted using a solution of ethyl acetate:hexane (40:60, v:v), and then adjusted to a known volume. Residues of acetochlor and dichlormid were determined in a single chromatographic run by capillary GLC using a nitrogen selective thermionic detector.

A brief summary of Method 184/04 follows. A representative sample was extracted with acetonitrile:water (50:50, v:v), and the extract was evaporated to dryness. Samples were reconstituted in water:acetone (30:70, v:v), and an aliquot was evaporated to dryness. Saturated sodium hydroxide solution and carbitol were added and the samples were heated under reflux for three hours. Saturated sodium chloride solution was added, followed by partitioning against ethyl acetate. An aliquot of the ethyl acetate fraction was washed with sodium bicarbonate solution and derivatized with heptafluorobutyric anhydride. The heptafluorobutyryl derivatives were analyzed by GLC using mass selective detection.

The petitioner only included summary descriptions of the two methods. Concurrent method validation data for Methods 244/01 and 184/04 were provided. The method recovery data are presented in Tables 3a and 3b. Typical chromatograms as well as example calculations for acetochlor and dichlormid residue determinations were provided. These data suggest that Methods 244/01 and 184/04 are adequate for collecting residue data for acetochlor and its metabolites in/on field corn commodities.

Table 3a. Concurrent method recoveries of acetochlor and dichlormid from untreated samples of field corn commodities fortified with each analyte and analyzed using Method 244/01 (MRID 43616401).

Field Corn Commodity	Fortification Level (ppm)	Number of Samples	% Recovery	
			Acetochlor	Dichlormid
Forage	0.02	3	78-102	86-91
	0.05	3	70-94	72-92
	0.10	4	78-114	84-97
Stover (Fodder)	0.02	4	75-83	72-101
	0.05	3	80-94	83-93
	0.10	4	79-96	72-90
Grain	0.02	3	90-106	73-110
	0.05	3	93-111	71-103
	0.10	2	83, 103	77, 77

Table 3b. Concurrent method recoveries of EMA and HEMA from untreated samples of field corn commodities fortified with each analyte and analyzed using Method 184/04 (MRID 43616401).

Field Corn Commodity	Fortification Level (ppm)	Number of Samples	% Recovery *	
			EMA	HEMA
Forage	0.04	3	72-110	64, 68; 78, 78
	0.05	5	77-109	65; 71-93
	0.10	5	69; 73-114	71-88
Stover (Fodder)	0.04	3	73-79	71-82
	0.05	3	69; 80, 87	75-77
	0.10	3	76-81	71-77
Grain	0.04	4	73-103	78-101
	0.05	4	72-97	70-105
	0.10	4	70-99	69; 90-114

* Recovery values outside the acceptable 70-120% range are listed separately.

MRID 43616402 - Analyses of field corn commodity samples were conducted by ABC Laboratories (Columbia, MO) using Monsanto Method RES-074-93-0 entitled "Regulatory Enforcement Method for the Determination of Acetochlor Residues in Milk, Beef Tissues and Raw Agricultural Commodities". This method is similar to previously reviewed Method MSL-9572 (PP#1G2454, L. Cheng, 8/7/90, and PP#3F2966/PP#1G2454, N. Dodd, 4/29/91). Briefly, corn samples were extracted with 20% water:acetonitrile and concentrated. The extract was hydrolyzed by base and steam distilled into dilute acid. The distillate was made basic and partitioned with methylene chloride to extract EMA and HEMA, the hydrolysis products of acetochlor and its metabolites. These residues were then back extracted from the methylene chloride with an aqueous

methanolic:HCl solution. Additional methanol was added and the sample was allowed to stand for 12 hours. During this time HEMA was converted to MEMA [2-(1-methoxyethyl)-6-methylaniline]. The pH of the solution was adjusted to 5-7 and the analytes were separated and quantitated by reversed-phase HPLC with oxidative coulometric electrochemical detection (HPLC-OCED). The limits of detection, expressed as acetochlor equivalents, were: 0.002 ppm for HEMA and 0.004 ppm for EMA in forage; 0.0004 ppm for HEMA and 0.002 ppm for EMA in grain; and 0.004 ppm for HEMA and 0.007 ppm for EMA in fodder (stover). The limits of quantitation, expressed as acetochlor equivalents, were 0.016 ppm for HEMA and 0.015 ppm for EMA in all commodities. The petitioner included validation data for Monsanto Method RES-074-93-0. These recovery data are presented in Table 3c. Representative chromatograms from the analyses were provided. These data suggest that Monsanto Method RES-074-93-0 is adequate for collecting residue data for acetochlor metabolites in/on field corn commodities.

Table 3c. Recoveries of acetochlor metabolites from untreated samples of field corn commodities fortified with each analyte and analyzed using Monsanto Method RES-074-93-0 (MRID 43616402).

Field Corn Commodity	Fortification Level (ppm)	Number of Samples	% Recovery ^a	
			HEMA	EMA
Concurrent Fortifications ^b				
Forage	0.01-1.0	20	65.6; 70.0-86.3	62.0; 78.2-118; 129
Grain	0.01-0.10	20	72.8-100; 130	73.5-103; 126
Stover (Fodder)	0.01-0.50	20	52.6, 62.9, 69.4; 71.0-116; 129	67.4; 80.9-117; 124, 124, 139, 149
Method Validation				
Forage	0.01-3.0	10	66.9, 67.3, 67.9; 70.9-81.2	81.7-120
Grain	0.01-0.10	4	75.4-98.6	86.2-100
Stover (Fodder)	0.01-0.50	4	71.9-84.0	83.8-104

^a Recovery values outside the acceptable 70-120% range are listed separately.

^b Concurrent fortification results include results from samples of "blind" fortifications of field corn commodities made by the petitioner and sent to the analytical laboratory.

Storage Stability Data

All field corn commodity samples were stored frozen prior to residue analysis. The maximum storage interval prior to residue analysis of commodities collected from the field trials described in MRID 43616401 was ~13 months. The maximum storage intervals prior to residue analysis of commodities collected from the field trials described in MRID 43616402 were ~9 months for forage, ~5 months for grain, and ~6 months for stover (fodder).

No storage stability data were provided with the present submission. However, it is noted that residues of acetochlor *per se* have been found to be stable during frozen storage in/on forage for 155 weeks (~36 months) and in grain and processed commodities for 742 days (~24 months); residues of EMA- and HEMA-producing metabolites were found to be stable during frozen storage in/on grain, forage, and stover (fodder) for over 1500 days (~49 months; PP#3F2966/PP#1F4011, M. Flood, 7/12/93).

Maximum Theoretical Dietary Burden

The maximum theoretical dietary burden of acetochlor residues of concern to beef and dairy cattle is recalculated below in Table 4 as a result of the petitioner's request for a higher tolerance on field corn forage, a major livestock feed item.

Table 4 Calculation of maximum theoretical dietary burden of acetochlor residues of concern to beef and dairy cattle.

Field Corn Feed Item	% Dry Matter	Estimated Tolerance (ppm)	Beef Cattle		Dairy Cattle	
			% in Diet	Dietary Burden (ppm)	% in Diet	Dietary Burden (ppm)
Forage	40	3.0 *	40	3.00	50	3.75
Grain	88	0.05	60	0.03	40	0.02
Stover (fodder)	83	1.5	--	--	10	0.18
Total			100	3.03	100	3.95

- * The estimated tolerance level for field corn forage is 3 ppm. The maximum combined residues of acetochlor and its metabolites containing EMA and HEMA moieties from the current field trials reflecting the maximum proposed use pattern was 2.52 ppm. The petitioner proposes a tolerance level of 2.6 ppm.

Attachment #2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF -->100		
Acetochlor CAS No. 34256-82-1 A.I. CODE: 121601 CFR No.	1yr feeding - dog NOEL= 2.0000 mg/kg 0.00 ppm LEL= 10.0000 mg/kg 0.00 ppm ONCO: B2 (HED/SAP)	Testicular & kidney effects; salivation; change in liver enzymes Evidence of carcinogenicity in rats (nose/liver) & mice (multiple sites).	OPP RfD= 0.020000 EPA RfD= 0.020000		No data gaps.	RfD/PR reviewed 12/07/90 EPA deferred 03/27/91 RfD/PR reviewed 02/06/92 EPA verified 03/26/92 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD		DIFFERENCE AS PERCENT OF RFD		EFFECT ON ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**	CURRENT TMRC*	NEW TMRC**	DIFFERENCE AS PERCENT OF RFD	ARC	ARC	XRFD
U.S. POPULATION - 48 STATES	0.000113	0.000113	0.000113	0.566845	0.000000	0.000111	0.55361	
U.S. POPULATION - SPRING SEASON	0.000109	0.000109	0.000109	0.546125	0.000000	0.000107	0.53265	
U.S. POPULATION - SUMMER SEASON	0.000112	0.000112	0.000112	0.561515	0.000000	0.000109	0.54532	
U.S. POPULATION - FALL SEASON	0.000116	0.000116	0.000116	0.581700	0.000000	0.000113	0.56682	
U.S. POPULATION - WINTER SEASON	0.000114	0.000114	0.000114	0.568630	0.000000	0.000111	0.55542	
NORTHEAST REGION	0.000103	0.000103	0.000103	0.514070	0.000000	0.000102	0.51079	
NORTH CENTRAL REGION	0.000113	0.000113	0.000113	0.564100	0.000000	0.000110	0.55201	
SOUTHERN REGION	0.000116	0.000116	0.000116	0.578605	0.000000	0.000112	0.56027	
WESTERN REGION	0.000122	0.000122	0.000122	0.608610	0.000000	0.000116	0.58246	
HISPANICS	0.000128	0.000128	0.000128	0.639070	0.000000	0.000124	0.61776	
NON-HISPANIC WHITES	0.000112	0.000112	0.000112	0.560580	0.000000	0.000109	0.54692	
NON-HISPANIC BLACKS	0.000112	0.000112	0.000112	0.557840	0.000000	0.000108	0.54151	
NON-HISPANIC OTHERS	0.000107	0.000107	0.000107	0.534740	0.000000	0.000104	0.52041	
NURSING INFANTS (< 1 YEAR OLD)	0.000102	0.000102	0.000102	0.510520	0.000000	0.000087	0.43428	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000396	0.000396	0.000396	1.978285	0.000000	0.000324	1.62218	
FEMALES (13+ YEARS, PREGNANT)	0.000077	0.000077	0.000077	0.387355	0.000000	0.000076	0.38180	
FEMALES 13+ YEARS, NURSING	0.000095	0.000095	0.000095	0.477415	0.000000	0.000093	0.46650	
CHILDREN (1-6 YEARS OLD)	0.000234	0.000234	0.000234	1.168090	0.000000	0.000233	1.16678	
CHILDREN (7-12 YEARS OLD)	0.000175	0.000175	0.000175	0.876445	0.000000	0.000174	0.86953	
MALES (13-19 YEARS OLD)	0.000123	0.000123	0.000123	0.613720	0.000000	0.000122	0.60814	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000100	0.000100	0.000100	0.498105	0.000000	0.000097	0.48750	
MALES (20 YEARS AND OLDER)	0.000087	0.000087	0.000087	0.434515	0.000000	0.000085	0.42318	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000076	0.000076	0.000076	0.378970	0.000000	0.000073	0.36522	

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
			AD1	UF	No data gaps.	RfD/PR reviewed 12/07/90 EPA deferred 03/27/91 RfD/PR reviewed 02/06/92 EPA verified 03/24/92	
Acetochlor Caswell #0038 CAS No. 34256-82-1 A.I. CODE: 121601 CFR No.	1-yr feeding- dog NOEL= 2.0000 mg/kg 0.00 ppm LEL= 10.0000 mg/kg 0.00 ppm ONCO: 82 (HED/SAP)	Testicular & kidney eff- ects; salivation; change in liver enzymes Evidence of carcinogenic- ity in rats (nose/liver) & mice (multiple sites).	OPP RfD= 0.020000 EPA RfD= 0.020000	100			On IRIS.

COMMODITY CONTRIBUTION BY RAC FOR U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMR		%RFD	TMR ONCO RISK	ANTICIPATED RESIDUE (PPM)		ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
			TYPE	(UG/KG/DAY)							
15029AA	SOYBEANS-SPROUTED SEEDS	0.100	P	0.000000	0.000	0.000000000000	0.15000	0.000000	0.000	0.000000000000	
270100A	00 NOT SPECIFIED (NO CONSUMPTION)	0.100	P	0.064431	0.322	0.00000108888	0.15000	0.048323	0.242	0.00000081666	
28023AA	18 PROCESSED OIL	0.100	P	0.000104	0.001	0.000000000176	0.15000	0.000078	0.000	0.000000000132	
28023AB	SOYBEANS-UNSPECIFIED	0.100	P	0.000180	0.001	0.000000000304	0.15000	0.000043	0.000	0.000000000073	
	21 COOKED-NFS						0.15000	0.000020	0.000	0.000000000034	
	23 COOKED-FRESH-BOILED						0.15000	0.000018	0.000	0.000000000030	
	25 COOKED-FRESH-FRIED						0.15000	0.000038	0.000	0.000000000064	
	31 COOKED FRESH OR CANNED						0.15000	0.000017	0.000	0.000000000029	
28023WA	SOYBEANS-FLOUR, FULL FAT	0.100	P	0.000584	0.003	0.000000000987	0.15000	0.000136	0.001	0.000000000230	
	21 COOKED-NFS						0.15000	0.000213	0.001	0.000000000360	
	22 COOKED-FRESH-BAKED						0.15000	0.000089	0.000	0.000000000150	
28023WB	31 COOKED-FRESH OR CANNED	0.100	P	0.000190	0.001	0.000000000321	0.15000	0.000143	0.001	0.000000000242	
28023WC	SOYBEANS-FLOUR, LOW FAT	0.100	P	0.002492	0.012	0.00000004211	0.15000	0.000095	0.000	0.000000000161	
	21 COOKED-NFS						0.15000	0.000123	0.001	0.000000000208	
	22 COOKED-FRESH-BAKED						0.15000	0.000785	0.004	0.00000001327	
	51 COOKED-CANNED						0.15000	0.000471	0.002	0.00000000796	
	53 COOKED-CANNED-BOILED						0.15000	0.000396	0.002	0.00000000669	
CROP GROUP TOTALS FOR LEGUME VEGETABLES:											
24002EA	CORN, GRAIN-ENDOSPERM	0.050	P	0.008270	0.041	0.00000013976	0.05000	0.000031	0.000	0.000000000052	
	10 RAW-FRESH OR NFS						0.05000	0.001089	0.005	0.00000001840	
	21 COOKED-NFS						0.05000	0.006144	0.031	0.00000010383	
	22 COOKED-FRESH-BAKED						0.05000	0.001006	0.005	0.00000001700	
24002FA	23 COOKED-FRESH-BOILED	0.050	P	0.000000	0.000	0.000000000000	0.05000	0.000000	0.000	0.000000000000	
	CORN, GRAIN BRAN						0.05000	0.000284	0.001	0.000000000480	
24002GA	00 NOT SPECIFIED (NO CONSUMPTION)	0.050	P	0.007287	0.036	0.00000012315	0.05000	0.006319	0.032	0.00000010679	
	CORN SUGAR						0.05000	0.000685	0.003	0.00000001158	
	10 RAW-FRESH OR NFS						0.03000	0.000713	0.004	0.00000001205	
24006AA	21 COOKED-NFS	0.020	P	0.000475	0.002	0.000000000803	0.03000	0.000000	0.000	0.000000000000	
	22 COOKED-FRESH-BAKED						0.03000	0.000000	0.000	0.000000000000	
24007AA	SORGHUM (INCLUDING MILO)	0.020	P	0.002812	0.014	0.00000004752	0.03000	0.000000	0.000	0.000000000000	
	00 NOT SPECIFIED (NO CONSUMPTION)										
	WHEAT-ROUGH										
	10 RAW-FRESH OR NFS										

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Acetochlor		1yr feeding- dog		Testicular & kidney eff-		ADI	UF -->100	No data gaps.		RfD/PR reviewed 12/07/90	
Caswell #003B		NOEL= 2.0000 mg/kg		ects; salivation; change		OPP RfD= 0.020000				EPA deferred 03/27/91	
CAS No. 34256-82-1		0.00 ppm		in liver enzymes		EPA RfD= 0.020000				RfD/PR reviewed 02/06/92	
A.I. CODE: 121601		LEL= 10.0000 mg/kg		Evidence of carcinogenic-						EPA verified 03/24/92	
CPR No.		0.00 ppm		ity in rats (nose/liver)							
		ONCO: B2 (HED/SAP)		& mice (multiple sites).		Q*: 0.01690				On IRIS.	

COMMUNITY CONTRIBUTION BY RAC FOR: U.S. POPULATION 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMRC TYPE (UG/KG/DAY)	%RFD	TMRC ONCO RISK	ANTICIPATED RESIDUE (PPM)		ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
						RESIDUE	ARC			
24007GA	WHEAT-GERM	0.020	P	0.000016	0.000	0.03000	0.000269	0.001	0.00000000455	0.000000000000
	10 RAW-FRESH OR NFS					0.03000	0.002576	0.013	0.00000004353	0.000000000000
	22 COOKED-FRESH-BAKED					0.03000	0.001372	0.007	0.00000002319	0.000000000000
24007HA	WHEAT-BRAN	0.020	P	0.000243	0.001	0.03000	0.000000	0.000	0.00000000000	0.000000000000
	10 RAW-FRESH OR NFS					0.03000	0.000024	0.000	0.00000000041	0.000000000000
	21 COOKED-NFS					0.03000	0.000002	0.000	0.00000000003	0.000000000000
	22 COOKED-FRESH-BAKED					0.03000	0.000005	0.000	0.00000000008	0.000000000000
24007WA	WHEAT-FLOUR	0.020	P	0.025145	0.126	0.03000	0.000358	0.002	0.00000000605	0.000000000000
	10 RAW-FRESH OR NFS					0.03000	0.000010	0.000	0.00000000017	0.000000000000
	21 COOKED-NFS					0.03000	0.021054	0.105	0.00000035581	0.000000000000
	22 COOKED-FRESH-BAKED					0.03000	0.013855	0.069	0.00000023415	0.000000000000
270020A	CORN, GRAIN-OIL	0.050	P	0.001140	0.006	0.03000	0.002797	0.014	0.00000004727	0.000000000000
	18 PROCESSED OIL					0.05000	0.001140	0.006	0.00000001927	0.000000000000
CROP GROUP TOTALS FOR CEREAL GRAINS:						0.045388	0.227	0.00000076706	0.299	0.00000100949

GRAND TOTALS FOR U.S. POPULATION 48 STATES

0.113369 0.567 0.00000191594

0.110721

0.554 0.00000187118

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION
 ARC = ANTICIPATED RESIDUE CONTRIBUTION
 RFD = REFERENCE DOSE

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Acetochlor	Caswell #0038	1yr feeding- dog	Testicular & kidney effects; salivation; change in liver enzymes	AD1 UF -->100	No data gaps.	RfD/PR reviewed 12/07/90
	CAS No. 34256-82-1	NOEL= 2.0000 mg/kg		OPP RfD= 0.020000		EPA deferred 03/27/91
	A.I. CODE: 121601	0.00 ppm	Evidence of carcinogenicity in rats (nose/liver) & mice (multiple sites).	EPA RfD= 0.020000		RfD/PR reviewed 02/06/92
	CFR No.	LEL= 10.0000 mg/kg				EPA verified 03/24/92
		0.00 ppm				On IRIS.
		ONCO: B2 (HED/SAP)		Q*: 0.01690		

COMMUNITY CONTRIBUTION BY RAC FOR NON NURSING INFANTS (< 1 YEAR OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
15029AA	SOYBEANS-SPROUTED SEEDS	0.100	P	0.000000	0.000	0.15000	0.000000	0.000
27010DA	00 NOT SPECIFIED (NO CONSUMPTION)							
27010DA	SOYBEANS-OIL	0.100	P	0.135963	0.680	0.15000	0.203945	1.020
28023AA	18 PROCESSED OIL							
28023AA	SOYBEANS-UNSPECIFIED	0.100	P	0.000000	0.000	0.15000	0.000000	0.000
28023AB	21 COOKED-NFS							
28023AB	SOYBEANS-MATURE SEEDS DRY	0.100	P	0.000000	0.000	0.15000	0.000000	0.000
28023AA	10 RAW-FRESH OR NFS							
28023AA	21 COOKED-NFS							
28023AA	23 COOKED-FRESH-BOILED							
28023AA	25 COOKED-FRESH-FRIED							
28023AA	31 COOKED-FRESH OR CANNED							
28023AA	SOYBEANS-FLOUR, FULL FAT	0.100	P	0.003405	0.017	0.15000	0.004927	0.025
28023AA	21 COOKED-NFS							
28023AA	22 COOKED-FRESH-BAKED							
28023AA	31 COOKED-FRESH OR CANNED							
28023AB	SOYBEANS-FLOUR, LOW FAT	0.100	P	0.000000	0.000	0.15000	0.000027	0.000
28023AB	21 COOKED-NFS							
28023AB	SOYBEANS-FLOUR, DEFATTED	0.100	P	0.023715	0.119	0.15000	0.000152	0.001
28023AC	SOYBEANS-FLOUR, DEFATTED							
28023AC	10 RAW-FRESH OR NFS							
28023AC	21 COOKED-NFS							
28023AC	22 COOKED-FRESH-BAKED							
28023AC	31 COOKED-FRESH OR CANNED							
28023AC	SOYBEANS-FLOUR, LOW FAT	0.100	P	0.000000	0.000	0.15000	0.000000	0.000
28023AC	21 COOKED-NFS							
28023AC	22 COOKED-FRESH-BAKED							
28023AC	51 COOKED-CANNED							
28023AC	53 COOKED-CANNED-BOILED							
GROUP TOTALS FOR LEGUME VEGETABLES:					0.815	0.244624		1.223

24002EA	CORN, GRAIN-ENDOSPERM	0.050	P	0.014124	0.071	0.05000	0.000000	0.000
24002EA	10 RAW-FRESH OR NFS							
24002EA	21 COOKED-NFS							
24002EA	22 COOKED-FRESH-BAKED							
24002EA	23 COOKED-FRESH-BOILED							
24002EA	CORN, GRAIN-BRAN	0.050	P	0.000000	0.000	0.05000	0.003054	0.015
24002EA	00 NOT SPECIFIED (NO CONSUMPTION)							
24002EA	CORN SUGAR	0.050	P	0.034127	0.171	0.05000	0.000153	0.011
24002EA	10 RAW-FRESH OR NFS							
24002EA	21 COOKED-NFS							
24002EA	22 COOKED-FRESH-BAKED							
24006AA	SORGHUM (INCLUDING HILO)	0.020	P	0.000000	0.000	0.05000	0.000000	0.000
24006AA	00 NOT SPECIFIED (NO CONSUMPTION)							
24007AA	WHEAT-ROUGH	0.020	P	0.002446	0.012	0.05000	0.000000	0.000
24007AA	10 RAW-FRESH OR NFS							

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Acetochlor	Caswell #0038	1yr feeding- dog	2.0000 mg/kg	Testicular & kidney eff-	ADL UF -->100	OPF RfD= 0.020000	No data gaps.			RfD/PR reviewed 12/07/90	
	CAS No. 34256-82-1	NOEL=	0.00 ppm	ects; salivation; change		EPA RfD= 0.020000				EPA deferred 03/27/91	
	A.I. CODE: 121601	LEL=	10.0000 mg/kg	in liver enzymes						RfD/PR reviewed 02/06/92	
	CFR No.		0.00 ppm	Evidence of carcinogenic-						EPA verified 03/24/92	
		ONCO: B2 (HED/SAP)		ity in rats (nose/liver)						On IRIS.	

COMMUNITY CONTRIBUTION BY RACI FOR NON-NURSING INFANTS (< 1 YEAR OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)		TMRG TYPE (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)		ARC (UG/KG/DAY)	%RFD
24007GA	WHEAT-GERM	0.020	P	0.000009	0.000	0.03000	0.000250	0.000250	0.001
	21 COOKED-FRESH-BAKED					0.03000	0.000835	0.000835	0.004
	22 COOKED-FRESH-BOILED					0.03000	0.002584	0.002584	0.013
24007HA	WHEAT-BRAN	0.020	P	0.000020	0.000	0.03000	0.000000	0.000000	0.000
	10 RAW-FRESH OR NFS					0.03000	0.000013	0.000013	0.000
24007WA	WHEAT-FLOUR	0.020	P	0.018161	0.091	0.03000	0.000000	0.000000	0.000
	21 COOKED-FRESH-BAKED					0.03000	0.000000	0.000000	0.000
	22 COOKED-FRESH-BAKED					0.03000	0.000031	0.000031	0.000
270020A	CORN, GRAIN-OIL	0.050	P	0.000605	0.003	0.03000	0.000000	0.000000	0.000
	18 PROCESSED GIL					0.03000	0.020145	0.020145	0.101
						0.03000	0.005765	0.005765	0.029
						0.03000	0.001332	0.001332	0.007
						0.05000	0.000605	0.000605	0.003
CROP GROUP TOTALS FOR CEREAL GRAINS:					0.347	0.079811			0.399

GRAND TOTALS FOR NON-NURSING INFANTS (< 1 YEAR OLD)

0.324435

1.163

0.232575

1.163

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED
 TMRG=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION
 ARC = ANTICIPATED RESIDUE CONTRIBUTION
 RFD = REFERENCE DOSE

1.622