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United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-98-020 December 1998

Reregistration Eligibility Decision (RED)

Alachlor

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case alachlor. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional generic data on alachlor to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the date of your receipt of this letter. The second set of required responses is due 8 months from the date of your receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Kathryn Boyle at (703) 305-6304.

Sincerely yours,

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

Enclosures

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SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Citation of Data and Data Matrix**. Complete and sign EPA forms 8570-34 and 8570-35 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

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REREGISTRATION ELIGIBILITY DECISION

Alachlor

LIST A

CASE 0063

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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ALACHLOR REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEC	Lowest Observed Effect Concentration
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product

GLOSSARY OF TERMS AND ABBREVIATIONS

MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TWMC	Time Weighted Mean Concentration
WP	Wettable Powder
WPS	Worker Protection Standard

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EXECUTIVE SUMMARY

This Reregistration Eligibility Decision Document (RED) addresses the reregistration eligibility of the pesticide alachlor, 2-chloro-N-(2,6-diethylphenyl)-N-(methoxymethyl)acetamide. Alachlor is a herbicide used for weed control on corn, soybeans, sorghum, peanuts, and beans. There are liquid, dry flowable, microencapsulated, and granular formulations. The timing of applications is preplant, pre-emergent, at-plant for corn and soybeans, post-transplant, post-emergent, and at ground crack for peanuts only. Alachlor is applied by ground, aerial, and chemigation equipment. It can also be mixed with dry bulk fertilizer.

Alachlor was first registered in 1969 as a selective herbicide for control of broadleaf weeds and grasses. Alachlor is produced by the Monsanto Company in the US.

EPA has completed its reregistration eligibility decision for the pesticide alachlor and determined that all uses, when labeled and used as specified in this document, are eligible for reregistration. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. This decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all Reregistration Eligibility Decisions (REDs) signed subsequent to August 3, 1996, are accordingly being evaluated under the new standards imposed by FQPA.

Reregistration Eligibility

The Agency has concluded under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore all products are eligible for reregistration. The Agency has accepted a risk mitigation measure, proposed by the technical registrant Monsanto, requiring application rate reductions. To assure protection of ground water as a resource, Monsanto has offered to classify alachlor as a Restricted Use Pesticide for ground water concerns. Certain ecological data, residue chemistry data, and exposure data are required to confirm the Agency's risk assessment and conclusions.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from pesticides and other compounds with a common mechanism of toxicity. FQPA further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

FQPA requires that the Agency consider the cumulative effects of alachlor and other chemicals that have a common mechanism of toxicity. The Agency first must determine if a common mechanism of toxicity exists for a group of chemicals. If so, the Agency must decide on the appropriate methodology for combining exposures, and then, after reviewing use information/patterns, determine which of the exposures/scenarios for which chemicals are to be combined, (i.e., cumulative exposure does occur.)

Alachlor is structurally similar to four other pesticides: acetochlor, butachlor, propachlor, and metolachlor. The Agency has not yet completed its assessment of whether or not these chemicals actually have a common mechanism of toxicity. However, a presentation was made to the FIFRA Scientific Advisory Panel (SAP) in March 1997 in which six chloroacetanilide chemicals were presented as a case study. In this case study, several groupings of the chemicals were possible:

I.acetochlor, alachlor and butachlor - based on structure activity relationships (SAR) consideration of common reactive intermediates

II.acetochlor, alachlor, and butachlor - based on statistically significant increases in nasal tumors (metolachlor nasal tumors were not statistically significant)

- acetochlor, alachlor, and butachlor - based on thyroid follicular cell tumors
- acetochlor, alachlor, propachlor, and butachlor - based on stomach tumors or lesions
- acetochlor, alachlor, and butachlor - based on kidney effects
- acetochlor, alachlor, propachlor, butachlor, and dimethamide - based on liver effects
- dimethamide, metolachlor, and propachlor - based on liver tumors

At this time, no determination on the appropriate grouping to use in the assessment has been made. The Agency is in the process of responding to comments resulting from the SAP. For alachlor, neither the appropriate methodology for combining exposures nor the exposures to combine has been determined. However, the Agency has just released a guidance document describing the approach that EPA will use for identifying mechanisms of toxicity and categorizing pesticide chemicals that have a common mechanism of toxicity. Additionally, the single chemical/multi-pathway assessments of each of the chemicals must be completed before the Agency could perform the multi-chemical/multi-pathway assessment. Metolachlor was a 1995 RED. Acetochlor was registered in the early 1990s. Both chemicals would need updated risk assessments. Propachlor is also a 1998 RED. As a result, the Alachlor RED can only go forward at this time as a single chemical/multi-pathway assessment.

The Agency has reassessed all alachlor food and feed related tolerances under the standards of FQPA and determined that, based on available information, there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to alachlor residues. The only type of exposures evaluated were dietary (food and drinking water) exposures, since non-occupational exposures (primarily residential) are unlikely to occur with alachlor use.

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Human Health Effects

Alachlor has been evaluated for carcinogenic activity in rats and mice. In accordance with the 1996 EPA proposed Guidelines for Carcinogen Risk Assessment, alachlor was classified as "likely" to be a human carcinogen at high doses, but " not likely" at low doses. Based on numerous studies submitted by the registrant that were reviewed by Agency scientists, as well as an external peer review panel, it was agreed that a margin of exposure (MOE) approach (indicative of a non-linear dose response) would be appropriate for evaluating carcinogenic risk in a human health risk assessment.

The scientific validity of the MOE approach has been documented by various review panels, such as the FIFRA Scientific Advisory Panel, and the Cancer Review Committee. However, the policy implications, methodology, and appropriateness of using an MOE approach in regulatory decision making have not yet been fully developed by the Agency. Perhaps, the most critical of the decision criteria to develop are those for determining the appropriate regulatory level. While informed by the science, this determination is ultimately a risk management decision. Once this methodology has been developed, then the available chemical-specific data would be used to determine whether or not the MOEs identified in the risk assessment constitute acceptable risks.

For now, the regulatory decision for alachlor will be based on both the Q_1^* approach and the MOE approach for the evaluation of carcinogenic potential. These are not directly comparable approaches. The Q_1^* approach is indicative of a linear approach and reflects the assumption that any exposure to alachlor could cause cancer. The MOE approach is indicative of a non-linear approach and reflects the assumption that there is an exposure dose below which tumor formation is not likely to occur. Thus, the risk numbers do not translate from one approach to the other. Each approach must be considered separately.

The alachlor database for pre-and post-natal effects is complete based on current requirements. The Agency has reviewed two developmental toxicity studies: one in rats, and one in rabbits. Developmental studies are designed to identify possible adverse effects on the developing organism during pre-natal development which may result from the mother's exposure to the pesticide. For alachlor, there is also a multi-generation rat reproduction study. A reproduction study is designed to provide general information concerning the effects of a test substance on mating behavior, conception, parturition, lactation, weaning, and growth and development of the offspring.

In both of the developmental toxicity studies, the NOELs for developmental effects are the same as the NOELs for maternal effects. Generally, the Agency would be particularly concerned when developmental effects are seen at doses lower than those which cause maternal effects, i.e. a situation in which the mother is not impacted, but the developing organism would be impacted. For alachlor, there is no evidence of a unique sensitivity to the developing organism from pre-natal exposure. In the reproductive toxicity study, the reproductive NOEL is higher than the systemic NOEL, indicating that the parents would be impacted before the offspring. No special sensitivity for infants or children is indicated. Thus, review by Agency scientists indicates no evidence of increased

susceptibility of rats or rabbits to in utero and /or early postnatal exposure to alachlor.

Based on this conclusion, as well as the available information on exposure to residues of alachlor in food and water, the Agency has concluded that the additional safety factor, as required by FQPA for the protection of infants and children, can be removed. Therefore, this safety factor need not be applied to the alachlor risk assessment.

The toxicological effects of a pesticide can vary with different exposure durations and routes. For example, an individual may be exposed throughout their lifetime to pesticide residues in the food and water consumed, but a farm worker could also be exposed for several days or a month to a pesticide by the dermal and/or inhalation routes of exposure. The Agency considers the entire toxicity database and, based on the effects seen for different durations and routes of exposure, determines which risk assessments are necessary to insure that the public is adequately protected from any pesticide exposure.

The alachlor reregistration eligibility review considered the following assessments to be appropriate:

Assessment	Exposure Route	NOEL[1] for Use in Estimating Risk
Acute	Dietary (food and water)	Not required - no evidence of significant toxicity from a one day or single event exposure by the oral route
Chronic (non-carcinogenic)	Dietary (food and water)	RfD[2,3] = 0.01 mg/kg/day
Short-Term Occupational	Dermal + Inhalation	NOEL = 150 mg/kg/day Use of dermal absorption factor (0.24) required.[4]
Intermediate-Term	Dermal + Inhalation	NOEL = 50 mg/kg/day Use of dermal absorption factor not required since NOEL is from a dermal study.[4]
MOE Approach[5] Carcinogenic	Dietary (food and water)	NOEL = 0.5 mg/kg/day (nasal) NOEL = 14 mg/kg/day (stomach)
MOE Approach Carcinogenic Occupational	Dermal + Inhalation	Not appropriate - Exposure assessment does not indicate that use is long-term and continuous.
Q_1^* Approach[6] Carcinogenic	Dietary (food and water)	$Q_1^* = 0.08$ (mg/kg/day)$^{-1}$

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Assessment	Exposure Route	NOEL[1] for Use in Estimating Risk
Residential	Dermal + Inhalation	Not appropriate - The Agency has not identified any alachlor products that are intended for home use, or uses in/around schools, parks or other public areas.

1 A NOEL (no observed effect level) is the dose at which no effects were observed in the test animals.
2 The chronic Reference Dose (RfD) is the traditionally selected endpoint for chronic dietary risk. The RfD represents the quantity of a substance which if absorbed on a daily basis over a lifetime, is not expected to pose significant risk of adverse health effects.
3 Acceptable risk is less than 100% of the RfD.
4 Acceptable risk results in a MOE that is greater than 100.
5 Acceptable risk has not been determined.
6 Acceptable risk is 1×10^{-6}, or lower.

Dietary Risk (Food Only)

People may be exposed to small amounts of alachlor through the consumption of food containing residues of alachlor. Tolerances are pesticide residue levels that should not be exceeded in or on a raw agricultural commodity in the channels of interstate commerce when the pesticide is applied according to label directions. Tolerances have been established (see 40 CFR 180.249) for residues of alachlor in/on a variety of food and feed commodities:

- beans, which includes dry beans, lima beans, forage and fodder;
- corn, fresh sweet, and forage, fodder, and grain;
- eggs;
- milk;
- peanuts, forage, hay, and hulls;
- sorghum, fodder, forage, and grain;
- soybeans, forage, and hay;
- meat and meat byproducts of cattle, goats, hogs, poultry and horses.

Sufficient data are available to determine the adequacy of most established alachlor tolerances. However, some tolerances need to be revoked, and some need to be increased. The reassessed tolerances for alachlor will range from 0.02 to 10 ppm.

EPA has assessed the chronic (non-carcinogenic) dietary risk posed by alachlor. Using refinements to the dietary assessment process and considering all food uses recommended through reregistration, the Anticipated Residue Concentration (ARC) for the overall U.S. population represents less than 1% of the chronic Reference Dose (RfD), the amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, non-nursing infants less than one year old, has an ARC which also represents less than 1% of the chronic RfD. This low fraction of the allowable RfD is considered to be an acceptable dietary risk.

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EPA has assessed the carcinogenic dietary risk posed by alachlor by both the Q_1^* approach and the MOE approach. Both approaches are discussed below in the Aggregate Dietary Exposure Discussion.

Dietary Risk (Drinking Water Only)

People may be exposed to small amounts of alachlor through the consumption of water containing residues of alachlor. Alachlor is regulated under the SDWA (Safe Drinking Water Act). The MCL (Maximum Contaminant Level) for alachlor is 2 ppb. An MCL is the maximum permissible level of a contaminant in drinking water that is delivered to any user of a public water supply system. For alachlor, there is extensive monitoring data for both ground and surface water.

EPA has assessed the chronic (non-carcinogenic) drinking water risk posed by alachlor. Using the monitoring data for alachlor only and Agency assumptions on the amount of water consumed, the estimated exposure represents less than 1% of the chronic Reference Dose (RfD), for adult males, adult females, and children (1 - 6 years) sub-population groups. The Agency considers this to be an acceptable risk due to consumption of drinking water containing small amounts of alachlor.

EPA has assessed the carcinogenic drinking water risk posed by alachlor, using monitoring data and Agency assumptions on the amount of water consumed, for both the Q_1^* approach and the MOE approach. Both approaches are discussed below in the Aggregate Dietary Exposure Discussion.

Aggregate Dietary Risk (Food and Drinking Water)

FQPA requires that the Agency consider aggregate risk, that is, exposure from all food, water, and non-occupational, non-dietary exposures. For alachlor, the aggregate exposure is for food and water only. The highest chronic risk was 4% of the chronic RfD which represents the sub-population child (1 - 6 years). This was calculated considering both food and water containing residues of alachlor as well as consumption of water containing residues of the alachlor ESA degradate. The Agency considers this to be an acceptable risk.

The aggregate carcinogenic risk using the Q_1^* approach considers exposures from both food and water. For adult males and adult females carcinogenic risks range from 7.8×10^{-7} to 1.4×10^{-6}. These risks are consistent with the carcinogenic level (1×10^{-6}) that the Agency considers to be negligible.

The aggregate carcinogenic MOEs (food and drinking water) for adult males and adult females vary from 29,000 to 1,400,000. At this time, the Agency is not making any conclusions regarding the adequacy of these calculated MOEs for carcinogenic dietary risk. This is due to the fact that the Agency has not yet made a final decision as to the appropriate uncertainty factors which would be adequately protective of a carcinogenic endpoint regulated using a non-linear approach. However, given that the cancer risk using the Q_1^* approach is acceptable and that the magnitude of

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the calculated MOEs is quite large, the Agency believes that the dietary cancer risk from the use of alachlor is not of concern.

A comparison of the two approaches is given in the following Table:

Comparison of Carcinogenic Dietary Assessments				
Source of Water used in Assessment	Exposure (food and water)	MOE (nasal tumors)	(MOE) (stomach tumors)	Q_1^*
Adult Male				
NAWWS[1] (ground water)	0.0000127	39,000	1,100,000	1.0×10^{-6}
USGS[2] (reservoir data)	0.0000132	38,000	1,100,000	1.1×10^{-6}
ARP[3] (surface water)	0.0000098	51,000	1,400,000	7.8×10^{-7}
Adult Female				
NAWWS (ground water)	0.0000166	30,000	840,000	1.3×10^{-6}
USGS (reservoir)	0.0000173	29,000	810,000	1.4×10^{-6}
ARP (surface water)	0.0000133	38,000	1,100,000	1.1×10^{-6}

1 Data is from the National Alachlor Well Water Survey
2 Data is from the United States Geological Survey
3 Data is from the Acetochlor Registration Partnership

Occupational Risk

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to alachlor during normal use of granular, liquid, and dry flowable formulations. No protective equipment is required for the granular formulations. For worker protection, the Agency will require the use of additional protective equipment (chemical resistant gloves, apron, and chemical resistant shoes) when handling liquid and dry flowable formulations for workers supporting groundboom applications. For workers supporting aerial applications, closed (mechanical transfer) systems will be required for liquid formulations. Monsanto will be required to develop water soluble packaging for dry flowable formulations for aerial applications. Closed (mechanical transfer) systems will be

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required for the dry bulk fertilizer impregnation process.

The levels of protection required were based on the intermediate-term (one week to several months) exposure scenario. The exposure assessment indicated that use of alachlor is an intermittent exposure. The MOE methodology is consistent with a non-linear mechanism which requires continuous exposure. Due to the existence of an exposure pattern that is intermittent (not long-term and continuous), it is not appropriate to perform a carcinogenic MOE risk assessment for the occupational scenario.

Unlike the MOE approach to carcinogenic risk assessment, the Q_1^* approach assumes that any exposure could result in tumor formation. Thus, this type of assessment could be performed for an intermittent exposure. However, the scientific validity of the MOE approach for carcinogenic risk assessment of alachlor has been documented. Alachlor was classified as "likely" to be a carcinogen at high doses, but "not likely" at low doses. It is only the policy on determining an appropriate regulatory level that has not been fully developed by the Agency. Since, performing a carcinogenic MOE risk assessment for the occupational scenario is not appropriate, a Q_1^* carcinogenic occupational assessment for comparison purposes is not necessary.

The potential for post-application worker exposure is negligible, provided the Restricted Entry Interval (REI) of 12 hours is observed. This is due to the timing of applications. Alachlor is applied to the soil and/or soil incorporated pre-plant, and pre-emergent. Thus the application of alachlor to emerging plants, well before the plants are mature, mitigates the potential for post-application exposure.

Environmental Assessment

The Environmental Fate Assessment for alachlor shows that:

- Alachlor has a low affinity to adsorb to soils and is expected to be highly mobile.
- Alachlor is moderately persistent and dissipates primarily by aerobic soil metabolism processes with a half-life of 2-3 weeks.
- The major acid degradates of alachlor are very mobile and appear to be persistent.
- Field dissipation studies confirm this fate profile (half-life of 6-11 days; leaching through 42-48 inches in one of the studies).

The Water Resources Assessment concludes that:

- Alachlor is highly mobile and moderately persistent. These two characteristics are generally observed in chemicals that reach ground water and surface water.
- Alachlor presents a clear hazard to groundwater quality. Reliable monitoring studies have demonstrated that alachlor, even when used according to the label instructions, results in significant groundwater contamination. Alachlor use also results in groundwater in the use areas being contaminated with degradation products, which are also very mobile and persistent,
- Monitoring studies show that alachlor levels in surface water result in effects on aquatic plants

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and indirectly on aquatic animals.

- Available information indicates that (surface) drinking water supply systems will usually comply with the SDWA.

The available toxicity data for alachlor indicate that alachlor is:

- Slightly to practically non-toxic to birds on an acute oral basis (LD_{50} of 1500 mg/kg).
- Slightly toxic to mammals, based on a rat study (LD_{50} of 930 mg/kg).
- Slightly toxic to honey bees (LD_{50} >36 µg/bee).
- Slightly to moderately toxic on an acute basis to freshwater fish (LC_{50} 1-33 ppm).
- Highly to moderately toxic to freshwater fish on a chronic basis (NOEC≥0.1 ppm, LOEC≥0.2 ppm).
- Moderately toxic to saltwater fish (3.9 ppm), moderately toxic to saltwater mysid (2.4 ppm) and moderately toxic to shellfish (1.6 ppm).
- Highly toxic to aquatic plants (based on a single species tested: NOEL=0.35 ppb, LOEL=0.69 ppb, EC_{50}=1.64ppb).

Therefore, a potential risk to nontarget terrestrial and aquatic plants, and endangered plant species exists. Additionally, the available information on the major alachlor degradates indicates that the degradates appear to be less toxic to aquatic organisms than the parent.

An evaluation of the risk to nontarget organisms from the use of alachlor products, combining toxicity data with potential exposure, indicates that:

- Alachlor poses a potential risk to terrestrial animals on a chronic basis. Additional information are required to confirm this assessment.
- The granular formulations and high use rate pose the greatest risk to nontarget organisms.
- Alachlor levels observed in surface water monitoring studies could result in extensive adverse effects on aquatic plants.
- Aquatic animals are not at acute risk due to exposure to alachlor, but chronic effects may be observed under certain circumstances.

The Agency has significant concerns about the impact alachlor and its degradates may have on groundwater quality. Consideration of environmental chemistry and fate properties indicates that alachlor and a number of alachlor degradates will leach to ground water. An extensive body of groundwater monitoring information has been reviewed which confirms that alachlor and alachlor degradates do in fact contaminate groundwater.

To mitigate these concerns, the Agency will:

- Classify alachlor as a Restricted Use Pesticide (RUP) for ground water concerns
- Add labeling language requiring a 50 ft setback of mixing and loading activities from wells, rivers, or lakes unless such activity is protected by an impervious pad.
- After promulgation of the Ground Water and Pesticides Management Plan Rule, require use in accordance with an approved State or Tribal Management Plan

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Product Reregistration

Before reregistering the products containing alachlor, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this decision document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

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I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. As a result, EPA has embarked on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process includes a more in depth analysis of the new safety standard and how it should be applied to both food and non-food use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. In addition, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of alachlor including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes alachlor, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for alachlor. Section V discusses the reregistration requirements for alachlor. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

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II. CASE OVERVIEW

a. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Alachlor
- **Chemical Name:** 2-chloro-N-(2,6-diethylphenyl)-N-(methoxymethyl)acetamide
- **Chemical Family:** Acetanilide
- **CAS Registry Number:** 15972-60-8
- **OPP Chemical Code:** 090501
- **Empirical Formula:** $C_{14}H_{20}NO_2Cl$
- **Trade and Other Names:** Lasso, Alanex
- **Basic Manufacturer:** Monsanto Chemical Company

b. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of alachlor is in Appendix A.

Type of Pesticide: Herbicide

Mode of Action: Chloroacetamides are known to inhibit biosynthesis of fatty acids, lipids, protein, isoprenoids, flavonoids, and gibberellins.

Use Sites:

TERRESTRIAL FOOD+FEED CROP

Crops Grown for Oil: Soybeans

Grain Crops: Corn (Field), Sorghum

Groups of Agricultural Crops Which Cross Established Crop Groupings: Corn (unspecified), Peanuts (unspecified), Soybeans (unspecified)

Seed and Pod Vegetables: Beans (Dried-Type), Beans (Mung), Beans (Succulent, Lima), Soybeans (Edible)

Specialized Field Crops: Corn (Pop)

TERRESTRIAL FEED CROP

Forage Grasses: Corn

Forage Legumes and Other Nongrass Forage Crops: Soybeans

TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Ornamental Woody Shrubs and Vines

Target Pests for Single Active Ingredient Products:

Barnyardgrass, Crabgrass, Cupgrass (woolly), Foxtail (giant, green, robust, purple, yellow, robust white), Goosegrass, Johnsongrass, Millet, Panicum (browntop, fall, Texas), Rice (red), Sandbur, Grassbur, Shattercane (wildcane), Signalgrass (broadleaf), Red Sprangletop, Witchgrass, Florida Beggarweed, Carpetweed, Cocklebur, Coffeeweed, Copperleaf, Galinsoga, Groundcherry (annual), Groundcherry (cutleaf), Jimsonweed, Kochia, Lambsquarters, Morningglory (tall, pitted, ivyleaf, entireleaf, smallflower), Mustard, Nightshade (black, hairy), Pigweed, Carelessweed, Purslane, Florida Pusley, Common Ragweed, Giant Ragweed, Sicklepod, Smartweed, Bristly Starbur, Common Sunflower, Velvetleaf, Buttonweed, Waterhemp, Yellow Nutsedge, Amaranths, Milkweed, Russian Thistle, Canada Thistle, Horseweed, Fleabane, Prickly Lettuce, Hophornbeam copperleaf, Burcucumber, Yellow Nutgrass, Texasweed, Mexicanweed, Spotted Spurge, Quackgrass, Wild Poinsettia, Brachiaria, Smooth Brome, Downy Brome, Orchardgrass, Fescue, Perennial Ryegrass, Wirestem Muhly, Wheat, Corn, Annual Bluegrass, Kentucky Bluegrass, Sorghum, Alfalfa, Hemp Sesbania, Red Clover, White Clover, Venice Mallow, Sida (prickly, spiny), Teaweed, Ladysthumb, Curly Dock, Witchweed, Redweed, Common Mullein, Marestail, Eastern Black Nightshade, Puncturevine.

Formulation Types Registered:
Technical Grade Active Ingredient

End Use Products
- Emulsifiable Concentrate
- Flowable Concentrate
- Granular
- Microencapsulated
- Soluble Concentrate/Liquid

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Multiple Active Ingredient Products Contain:

- 036101 (Trifluralin)
- 080803 (Atrazine)
- 103601 (Glyphosate-salt)
- 128848 (Imazaquin)
- 080803 + 129043 (Atrazine + Dicamba)

Method and Rates of Application:

Method and Rate - see Appendix A

Equipment - Aircraft; Boom sprayer; Center pivot irrigation; Granule applicator; Ground; Pneumatic (compressed air) applicator; Sprayer; Spreader

Type of Treatment - Band treatment; Chemigation; Conservation tillage; Directed spray; Soil broadcast treatment; Soil incorporated treatment; Soil treatment; Spray

Timing - At planting; Early preplant; Ground-crack; Postemergence; Postplant; Posttransplant; Preemergence; Preplant

c. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of alachlor. These estimates are derived from a variety of published and proprietary sources, as well as USDA and State statistics that are available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Table 1 below summarizes the pesticide's use by site.

Table 1: Percent of Various U.S. Crops Treated Annually with Alachlor, 1993 - 1995

Site/1	Acres Grown /2 (X 000)	Acres Treated (X 000)/3	Percent Crop Treated	Pounds AI Applied (X 000)	Major Region or State
Beans, Dry	1,826	150 - 170	<10	270 - 330	Nationwide
Beans, Succulent	44	5 - 15	10 - 35	15 - 25	CA and ID
Corn, Sweet	763	235 - 250	30 - 35	400 - 500	Nationwide

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Table 1: Percent of Various U.S. Crops Treated Annually with Alachlor, 1993 - 1995

Site/1	Acres Grown /2 (X 000)	Acres Treated (X 000)/3	Percent Crop Treated	Pounds AI Applied (X 000)	Major Region or State
Corn, Field	77,235	15,000 - 20,000	20 - 25	20,000 - 30,000	Nationwide
Ornamentals	597	15 - 20	<5	20 - 25	Southeast
Peanuts	1,688	20 - 30	<5	100 - 150	Southeast
Sorghum	10,944	1,050 - 1,450	10 - 15	1,500 - 2,500	Nationwide
Soybeans	60,418	4,000 - 6,000	5 - 10	7,000 - 11,000	Nationwide
Sunflowers	2,837	20 - 30	<1 - 1	20 - 40	SD and NE
Totals		20,495 - 27,965		29,325 - 44,570	

/1 - Site identification based on REFS.
/2 - Acres grown based on USDA, Agricultural Census, and state statistics.
/3 - Acres treated represents the number of acres treated times the number of applications.

d. Data Requirements

Data requested in the 1984 Registration Standard for alachlor include studies on product chemistry, environmental fate, toxicology and residue chemistry. Pursuant to FIFRA, Data Call-In Notices (DCIs) were issued on June 9, 1986, (required the submission of residue chemistry data), June 18, 1986, (required the submission of use and exposure data pertaining to the ground and surface water studies), August 28, 1991, (required the submission of ecological effects, residue chemistry and environmental fate studies), and October 13, 1995, (required the submission of exposure data). These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

e. Regulatory History

Alachlor was registered in 1969 as a selective herbicide for control of broadleaf weeds and grasses. In the US, technical alachlor alachlor is produced by Monsanto Company. There are 12 active products and one 24(c) registration. Monsanto has ten active products and American Cyanamid has two active products.

A Registration Standard was issued for alachlor on November 20, 1984. The Registration Standard stated that (1) alachlor was classified as an oncogen and therefore subject to the Agency's requirement that it be considered for Special Review, (2) that the Agency would not approve any new uses for alachlor during the period of the Special Review, and (3) that alachlor appeared to leach through the soil and had been found in groundwater. Monsanto voluntarily removed the use of

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alachlor on potatoes. Several label restrictions were required to mitigate risk from alachlor. These restrictions included: the use of protective clothing, a tumor hazard warning statement, a water contamination warning statement, prohibition of aerial application, and handling instructions to reduce applicator exposure. A special information and training program available to all users of alachlor was required.

The Registration Standard required additional data on the leaching and mobility of alachlor to examine the potential of alachlor to contaminate ground and surface water. A monitoring study of ground and surface water was required. Additional studies were also required in the areas of toxicology, product chemistry, and residue chemistry.

Alachlor has been the subject of previous Agency regulatory action. On January 9, 1985, the Agency published a Notice of Initiation of Special Review of Registrations of Pesticide Products Containing Alachlor (Federal Register, Volume 50, No. 1115) and issued the Alachlor Position Document (PD-1) the document detailing the basis for the Special Review. The Special Review was initiated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) because pesticide products containing alachlor met or exceeded the Agency's then applicable oncogenicity criteria at 40 CFR 162.11 (a)(3). Specifically EPA determined that exposure to pesticide products containing alachlor resulted in the increased incidence of tumors at multiple sites in two species of laboratory animals (mice and rats). Subsequently, the risk criteria in 40 CFR 162.11 were superceded by revised criteria set forth in 40 CFR 154.7 (a) (2). The Agency determined that alachlor exceeded the revised criteria for oncogenicity, which is now referred to as carcinogenicity, as well.

Following the review of public comments and additional information received in response to the Notice of Initiation of Special Review and the Alachlor PD-1, EPA issued a Notice of Preliminary Determination on October 8, 1986 (Federal Register, Volume 51, No. 36106). In this notice the Agency announced its proposed decision to allow the continued use of alachlor products subject to modifications of the terms and conditions of registration. This notice also announced the availability of the Alachlor Technical Support Document (TSD) which detailed the basis for the Agency`s Preliminary Determination. The TSD was a detailed discussion of the risk and benefit data considered by EPA. These documents were distributed in accordance with Sections 8 and 25 of FIFRA and sent to all registrants and applicants for registrations of alachlor products.

In the Preliminary Notice the Agency **proposed** to reclassify alachlor as a restricted use pesticide, to require the use of a closed mixing/loading system whenever alachlor was applied to 300 acres or more, to allow aerial applications of alachlor but prohibit the use of human flaggers, and to retain the tumor warning on labels. In addition, pursuant to 40 CFR 162.17, EPA notified producers of all alachlor products registered solely for intrastate sale and distribution, that they were required to submit complete applications for registration. In response to the Preliminary Notice, the registrant provided additional residue data that indicated that residues in lima beans and dry beans were lower than previously estimated. The registrant also agreed to remove green peas from the labeling.

Following review of comments and additional information received in response to the

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Preliminary Notice, EPA issued a notice entitled "Alachlor; Notice of Intent to Cancel Registrations, Conclusion of Special Review on December 31, 1987 (Federal Register, Volume 52, No. 49480). This notice, known as the Alachlor Position Document 4 (PD-4) concluded the Special Review, and stated that EPA would cancel the registrations and deny applications for registration of products containing alachlor that did not comply with the terms and conditions of registration set forth in the PD-4. The PD-4 stated that tolerances would be rewritten once all residue data required by the Registration Standard were received and evaluated. The PD-4 required the following label amendments; Restricted Use due to Oncogenicity, a tumor hazard warning, and use of mechanical transfer systems by mixer/loaders and/or applicators who treat 300 acres or more annually. Human flaggers were prohibited during aerial application. Labeling bearing required changes was submitted and accepted in early 1988.

The Notice of Final Determination stated that the available data were adequate for demonstrating alachlor's potential to contaminate ground water. However, the available data were considered to be inadequate for a risk assessment considering the inadequate representation of alachlor's use in terms of geographic area and associated hydrogeologic conditions. Thus, this issue was deferred pending completion of the National Alachlor Well Water Survey (NAWWS). As discussed in this RED, the Agency has received and reviewed the NAWWS data. It was one of the studies relied on in determining quantitative drinking water risks. The other commitment made in the PD-4 was "to revisit the risk and benefits of alachlor on a crop-by-crop basis." Since the dietary risks, considering both food and water, for chronic and carcinogenic risks are not of concern, the Agency will not perform a risk/benefit analysis.

In 1996 the Food Quality Protection Act of 1996 (FQPA) was signed into law. Since FQPA requires the Agency to consider the potential for cumulative effects from alachlor and other compounds with a common mechanism of toxicity, Monsanto has submitted its assessment of the common mechanism of alachlor with other pesticides. Additionally, based on the results of the Agency's Cancer Peer Review, Monsanto petitioned for removal of the Restricted Use classification of alachlor.

III. SCIENCE ASSESSMENT

a. Physical Chemistry Assessment

Technical alachlor is a colorless to white crystalline solid with a melting point of 39.5-41.5 ^{o}C and a specific gravity of 1.133 g/mL at 25 ^{o}C. At 25 ^{o}C alachlor is soluble in water at 242 ppm. Alachlor is soluble in ether, acetone, benzene, alcohol, and ethyl acetate, and is slightly soluble in hexane. The following figure shows the chemical structure of alachlor.

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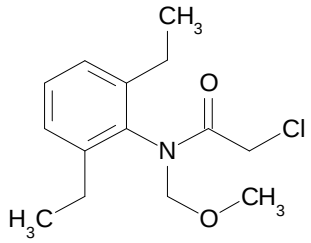

Empirical Formula:	$C_{14}H_{20}NO_2Cl$
Molecular Weight:	269.77
CAS Registry No.:	15972-60-8
Shaughnessy No.:	090501

b. Human Health Assessment

1. Toxicology Assessment

Toxicology data are used to assess the hazards to humans and domestic animals. The data are derived from a variety of acute, subchronic, and chronic toxicity tests; developmental/reproductive tests; and tests to assess mutagenicity and pesticide metabolism. Reregistration eligibility decisions require that the Agency have sufficient information to select the appropriate end-points for performing a human health risk assessment. This requires a toxicological database that is not only complete, but of acceptable quality.

The toxicological data base on alachlor is adequate and will support reregistration eligibility. (See Table 2)

Table 2: Alachlor Toxicological Database

Guideline	Study Type	MRID No.	Required?	Satisfied?
OPPTS GLN 870.1100 (formerly 81-1)	Acute oral toxicity - rat	00139383	yes	yes
OPPTS GLN 870.1200 (formerly 81-2)	Acute dermal toxicity - rabbit	00139384	yes	yes

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Table 2: Alachlor Toxicological Database				
Guideline	Study Type	MRID No.	Required?	Satisfied?
OPPTS GLN 870.1300 (formerly 81-3)	Acute inhalation toxicity - rat	00109561	yes	yes
OPPTS GLN 870.2400 (formerly 81-4)	Primary eye irritation - rabbit	00139385	yes	yes
OPPTS GLN 870.2500 (formerly 81-5)	Primary dermal irritation - rabbit	00139386	yes	yes
OPPTS GLN 870.2600 (formerly 81-6)	Dermal sensitization- guinea pig	00161728	yes	yes
OPPTS GLN 870.3100 (formerly 82-1a)	Subchronic oral toxicity - rat	00023658	yes	no (satisfied by 83-1a)
OPPTS GLN 870.3150 (formerly 82-1b)	Subchronic oral toxicity - dog	00087479	yes	yes
OPPTS GLN 870.3200 (formerly 82-2)	21-day dermal toxicity - rabbit	00147328	yes	yes
OPPTS GLN 870.4100 870.4200 870.4300 (formerly 83-1a, 83-2a, 83-5)	Chronic oral toxicity/ carcinogenicity - rat or Combined chronic toxicity/ carcinogenicity	00091050, 00139021, 00141060	yes	yes
OPPTS GLN 870.4100 (formerly 83-1b)	Chronic oral toxicity - dog	00148923	yes	yes
OPPTS GLN 870.4200 (formerly 83-2b)	Carcinogenicity - mouse	00075709, 43507601	yes	yes

Table 2: Alachlor Toxicological Database				
Guideline	Study Type	MRID No.	Required?	Satisfied?
OPPTS GLN 870.3700 (formerly 83-3a)	Teratology - rat Prenatal developmental toxicity	00043645	yes	yes
OPPTS GLN 870.3700 (formerly 83-3b)	Teratology - rabbit Prenatal developmental toxicity	40579402	yes	yes
OPPTS GLN 870.3800 (formerly 83-4)	Multi-generation reproduction - rat Reproduction and fertility effects	00075062	yes	yes
OPPTS GLN 870.5300 870.5385 870.5500 870.5550 870.5575 (formerly 84-2, 84-4)	Mutagenicity - various assays	00109563, 00141061, 00141062, 00149821	yes	yes
OPPTS GLN 870.7485 (formerly 85-1)	General metabolism - rat Metabolism and Pharmacokinetics	00132045	yes	yes
OPPTS GLN 870.7600 (formerly 85-3)	dermal penetration (absorption)	00149403, 00149404, 00149405	yes	yes

a. Acute Toxicity

Data from acute toxicity studies serve as the basis for labeling and packaging requirements. Acute toxicity studies with alachlor indicate low toxicity. Table 3 below summarizes the available information on the acute toxicity of alachlor.

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Table 3: Acute Toxicity of Alachlor				
GLN No.	Study Type (%a.i.)	MRID No.	Results	Toxicity Category
870.1100	Acute Oral (92.8%)	00139383	LD50 = 930 mg/kg	III
870.1200	Acute Dermal (90.0%)	00139384	LD50 = 13.3 g/kg	IV
870.1300	Acute Inhalation (95.3%)	00109561	LC50 > 1.04 mg/L (4 hours)	III
870.2400	Primary Eye Irritation (92.8%)	00139385	No significant irritation	IV
870.2500	Primary Skin Irritation (92.8%)	00139386	No significant irritation	IV
870.2600	Dermal Sensitization (94.5%)	00161728	Sensitizer	N/A

The oral LD_{50} for alachlor in a rat study was 930 (810-1050) mg/kg (MRID No. 00139383). Clinical signs observed after oral dosing included ataxia, muscle tremors, hyperactivity, lethargy, dyspnea, and convulsions. The LC_{50} for rat inhalation was 1.04 mg/L for 4 hours. Clinical signs were related to eye and nasal irritation (MRID No. 00109561).

Alachlor has been shown to be a skin sensitizer in guinea pigs (MRID No. 00161728). Alachlor was also a skin sensitizer in a repeated insult patch test in humans (MRID No. 00023611, 00023612).

b. Subchronic Toxicity

In an IBT (Industrial Biotest) subchronic toxicity study (MRID No. 00023658), male and female Charles River albino rats from Charles River Breeding Laboratories, Inc., North Wilmington, MA received 0, 20, 200, or 2000 ppm CP50144 technical alachlor which is 0, 1.5, 15, or 146 mg/kg/day for the control, low, mid and high dose groups, respectively by standard conversion factors for 90 days. Systemic toxicity was noted in the high dose animals as decreased body weights and body weight gains, decreased food consumption and efficiency, increased absolute and relative spleen weights, increased relative liver weights, increased relative to body weight kidney weights, and decreased relative gonad weights (testis and ovaries). The systemic toxicity NOEL (No Observed Effect Level) is 15 mg/kg/day. The systemic toxicity LOEL (Lowest Observed Effect Level) is 146 mg/kg/day based on decreased body weights, body weight gains, reduced food consumption,

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increased spleen, liver and kidney weights, and decreased gonad weights. This study is classified as unacceptable since it is an invalidated IBT study. Guideline requirements are not satisfied. However, this study was not repeated since an adequate chronic toxicity study was performed by the registrant.

In a subchronic feeding study, Beagle dogs were administered doses of 0, 5, 25, 50, or 75 mg/kg/day of alachlor (93.3% a.i.; Lot No. MTLT 1128X) in capsules for six months. Systemic toxicity was noted as an increase in liver weights at the lowest dose tested (LDT; 5 mg/kg/day) and above in males, and at 25 mg/kg/day and above in females. An increase in the incidence of gross pathological observations (discoloration of the liver and biliary hyperplasia) in the liver were noted at 25 mg/kg/day and above in both sexes. Dose related body weight gain decrement, reduction in total serum protein levels, globulin levels, increase in Serum AP (alkaline phosphatase), LDH (lactate dehydrogenase) and occasionally SGPT (serum glutamic-pyruvic transaminase) activities in both sexes were noted at 25 mg/kg/day and above. Increased incidence of emaciation and mortality were noted at 50 mg/kg/day and above. The systemic toxicity NOEL could not be determined, but would be less than 5 mg/kg/day (LDT). The systemic toxicity LOEL is equal to or less than 5 mg/kg/day based on increased liver weight (MRID No. 00087479).

In a 21-day dermal toxicity study, alachlor (EC MCB/C9; Lot# MDLL0407B, 45.3% a.i. and Lot# MDLL0429B, 45.2% a.i.) was administered to New Zealand white rabbits at dose levels of 0, 50, 300, or 1000 mg/kg. Repeated exposure resulted in skin damage ranging from dermal irritation to corrosion. The observations occurred in a dose-related manner. Systemic toxicity was noted as an increase in polymorphonuclear leukocytes which may have resulted from the presence of the chronic inflammatory reaction in the dermis. There was also a significant ($p < 0.01$) decrease in body weight in both sexes at the high dose. There was also regenerative anemia, with an elevated white blood cell count, and platelet counts, and a decreased albumin/globulin ratio. Also, there was evidence of liver glycogen depletion at the high dose. Three animals in the mid dose and 6 animals in the high dose died or were sacrificed *in extremis*. The cause of death may be related to bacterial pneumonia due to bacteria entering through damaged skin.

The systemic toxicity NOEL is 50 mg/kg/day. The systemic toxicity LOEL is 300 mg/kg/day based on hematological and clinical chemistry changes. The dermal toxicity NOEL could not be determined, but would be less than 50 mg/kg/day. The dermal toxicity LOEL is equal to or less than 50 mg/kg/day due to skin damage (MRID No. 00147328).

c. Chronic Toxicity and Carcinogenicity

In a one-year study in beagle dogs, alachlor technical (94.1% a.i.; Lot# MULT 0417B) was given by capsule at doses of 0 (control), 1.0, 3.0, or 10 mg/kg/day. Systemic toxicity was noted at the 3 mg/kg/day dose as hemosiderosis in the kidney of one male dog and in the spleen of another male dog; and at the high dose as hemosiderosis and hemolytic anemia in the liver of males (3/6). The systemic toxicity NOEL is 1 mg/kg/day. The systemic toxicity LOEL is 3 mg/kg/day based upon signs of hemosiderosis and hemolytic anemia (MRID No. 00148923).

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In a two-year feeding study, Long-Evans rats received doses of 0, 100, 300, or 1000 ppm (approximately 0 (control), 14, 42, or 126 mg/kg/day) technical alachlor in the diet for approximately 117 weeks in males (812 to 813 days) and 106 weeks in females (741 to 744 days). It should be noted that the test substance used for the first 11 months of the study was stabilized with 0.5% epichlorohydrin (Lot # XHI-167, 92.6% a.i.), while the test substance used for the remaining 16 months of the study was stabilized with epoxidized soybean oil (Lot # MHK-6, 92.19% a.i.). Epichlorohydrin is carcinogenic for male Wistar rats and Sprague-Dawley rats: when given in drinking water epichlorohydrin has been found to cause forestomach tumors (squamous cell papillomas and carcinomas) in male Wistar rats (Konishi et al. Gann 71:922-923, 1980). By the inhalation route epichlorohydrin has been found to cause squamous carcinomas of the nasal cavity (Laskin, et al. J. Natl. Cancer Inst. 65:751-755, 1980). The effect of epichlorohydrin on tumor formation in this study is not known.

Systemic toxicity was noted at 14 mg/kg/day and above as ocular lesions in the form of uveal degeneration syndrome, and as increased thyroid weights in both sexes; and as increased liver weight in the high dose groups. These observations were correlated with degenerative liver changes at all dose levels. There were decreased body weights in the mid and high dose males and the high dose females during the second year of the study. Statistical evaluation of mortality indicated an increasing trend for male and female rats with increasing doses. Male rats had an increased incidence of nasal respiratory epithelium adenomas, and adenomas and/or adenocarcinomas combined at 42 and 126 mg/kg/day ($p < 0.01$ and significant trends). Also, there was increased incidence in malignant mixed gastric tumors and gastric adenocarcinomas and/or malignant mixed gastric tumors combined at 126 mg/kg ($p < 0.01$ and significant trends). There were increased incidences in thyroid follicular cell adenomas and adenomas and/or carcinomas combined at 126 mg/kg ($p < 0.01$ and significant trends). There were increased incidences in the 126 mg/kg/day dose group for stomach osteosarcomas, and thyroid follicular cell carcinomas (both at $p < 0.05$). There were increased incidences of brain oligodendrogliomas of the hypothalamus, stomach osteosarcomas, and thyroid follicular cell carcinomas (all at $p < 0.01$) and significant trends. For female rats there was increased incidence of nasal turbinate adenomas, and adenomas and/or adenocarcinomas combined at 42 ($p < 0.05$) and 126 ($p < 0.01$) mg/kg/day and significant trends for these tumor types. There was also an increased incidence of malignant mixed gastric tumors, and gastric adenocarcinomas and/or malignant mixed gastric tumors combined ($p < 0.01$) at 126 mg/kg/day, as well as significant trends for these tumor types. Also, increased incidence at 14 and 126 mg/kg/day of mammary gland adenofibromas, adenofibromas and/or fibroadenomas combined, and adenofibromas, fibroadenomas, and papillary adenocarcinomas combined ($p < 0.05$). There were significant increasing trends in liver adenomas, stomach osteosarcomas, and thyroid follicular cell adenomas and/or adenocarcinomas combined (all at $p < 0.01$). Of all the tumors listed above, the increasing trend observed in brain oligodendrogliomas of the hypothalamus, and the significant trend in brain ependymomas and ependymomas and/or malignant ependymomas combined in male rats and the significant pair-wise comparisons for mammary gland adenofibromas, adenofibromas and/or fibroadenomas combined, and adenofibromas, fibroadenomas, and papillary adenocarcinomas combined and liver adenomas in female rats were considered to have occurred at excessively toxic doses, and only the tumors of the nasal epithelium, stomach, and thyroid were treatment related and are the basis for considering

alachlor to be carcinogenic in the rat. The systemic toxicity NOEL could not be determined but would be less than 14 mg/kg/day. The systemic toxicity LOEL is equal to or less than 14 mg/kg/day based on ocular lesions (uveal degeneration syndrome) and hepatic toxicity (MRID No. 00091050).

In a second long-term study, Long-Evans rats were fed doses of 0, 0.5, 2.5 or 15 mg/kg/day technical alachlor (94.13%; Lot# MULT 0417B; stabilized with 1.28% epoxidized soybean oil) for 110 weeks (25 to 26 months). Systemic toxicity was noted at 15 mg/kg/day, highest dose tested (HDT), as molting of the retinal pigmentation (uveal degeneration syndrome), increased mortality rate (significant increasing trend) in females (no effect in males) and abnormal disseminated foci in male livers. Male rats had increased incidence of nasal respiratory epithelium adenomas at 15 mg/kg/day ($p < 0.01$ with significant trend). Female rats had an increased incidence of adrenal benign pheochromocytomas and nasal respiratory epithelium adenomas at the 15 mg/kg/day dose level ($p < 0.05$ and $p < 0.01$, respectively and significant trend). There was also increased incidence of thymus malignant lymphosarcomas at the 15 mg/kg/day dose level ($p < 0.05$); however, only the tumors of the nasal epithelium were treatment related and are the basis for considering alachlor to be carcinogenic in the rat. The systemic toxicity NOEL is 2.5 mg/kg/day and the systemic toxicity LOEL is 15 mg/kg/day, based on molting of retinal pigmentation and increased mortality in females, with abnormal disseminated foci of the liver in males (MRID No. 00139021).

In a special two-year study, technical alachlor (94.13% a.i.; Lot# MULT-0417B; stabilized with 1.28% epoxidized soybean oil) was administered in the diet at 126 mg/kg/day to Long-Evans rats for two years to assess ocular effects of the compound (uveal degeneration syndrome). It was observed that females were more sensitive than males, and that once the uveal degeneration syndrome was observed, it was irreversible (a group exposed to alachlor for the first 5 to 6 months). The nasal, thyroid and gastric tumors observed in earlier investigations were observed. The nasal tumors were noted at the end of the study (2 years) in the group that was exposed to alachlor for the first 5 to 6 months (MRID No. 00141060).

In a carcinogenicity study, technical (alachlor; Lot# XHI-167, 92.6% a.i.; Lot# MHK-6, 92.19% a.i.) stabilized with epichlorohydrin at the start of the study (for 11 months) and then with a lot stabilized with epoxidozed soybean oil was given to CD-1 albino mice in the diet for 18 months at doses of 0 (control), 26, 78 or 260 mg/kg/day. Systemic toxicity was noted in the mid and high dose groups as increased liver weights, increased kidney weight in the mid and high dose males, and in the high dose females as reduced survival (statistical evaluation of mortality showed no significant incremental changes with increasing doses of alachlor in male mice while female mice showed a significant increasing trend in mortality with increasing doses of alachlor) and body weight gains (10%), males were not similarly affected. Thyroid follicular atrophy was noted in the mid and high dose males and the high dose females. There was an increase in water consumption in the high dose groups. Males had a significant increasing trend in bronchioalveolar adenomas at $p < 0.05$. There were no significant differences in the pair-wise comparisons of the male dosed groups with the controls. Female mice had significant increasing trends, in addition to significant differences in the pair-wise comparisons of the 260 mg/kg/day dose group with the controls, for bronchioalveolar adenomas and adenomas and/or carcinomas combined, all at $p < 0.01$ (MRID No. 00075709).

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In a second carcinogenicity study, CD-1 albino mice (60 animals/sex/dose) from Charles River Laboratory (Portage MI) received 0 (control), 100, 400 or 1600 ppm (male: 0, 16.64, 65.42, or 262.40 mg/kg/day; and female: 0, 23.73, 90.34, or 399.22 mg/kg/day respectively, calculated directly from food consumption data) of alachlor (94.64% a.i.; Lot# MUS-9107-3181-T) in the diet for 18 months. Ten animals/ sex/ dose were sacrificed at 12 months. Systemic toxicity was noted in high dose males as lower body weight gains for the period ending on day 91; high dose males and females with lower body weight gains for the period ending on day 372 and high dose females with lower body weight gains to the end of the study. There were no decreases in food consumption, rather there were increases in high dose females. No treatment related effects on food efficiency were noted in the treated males; however, the high dose females had a dose related decrease in food efficiency at 12 and 18 months.

Gross pathological observations included (at 18 months) a mass/nodule of the liver as noted in 6/41, 7/40, 10/41, and 10/41 in males and 1/40, 0/42, 1/36, and 3/40 in females for the control, low, mid and high dose groups, respectively; a mass/nodule of the lung in 3/41, 9/40, 10/41, and 12/41 in males and 1/40, 2/42, 9/36, and 6/40 in females for the control, low, mid and high dose groups, respectively. There was a statistically significant increase in absolute liver weights of the low and high dose females and liver weights relative to brain weights in high dose females at 12 months. Also, there was an increase in relative liver weights in high dose females at 18 months. The high dose males showed a statistically significant increase in absolute and relative liver weights at 18 months. There was a statistically significant decrease in kidney weights relative to body weights in high dose females at 12 months and a decrease in absolute kidney weight in high dose females at 18 months. The males at 18 months had a significant increase in absolute kidney weights in all dose groups, increased kidney weights relative to body weights in the low and high dose groups and increased kidney weights relative to brain weight in the mid and high dose groups.

Non-neoplastic observations included slight increases in tubular epithelium hyperplasia/regeneration in the kidney(s) of high dose males, an increase in centrilobular hepatocellular hypertrophy in mid and high dose males along with an increase in high dose females of fibrous osteodystrophy of the sternum. Neoplastic observations included an increase in bronchoalveolar adenomas in all treated groups in males (7, 18, 27, and 22%, for the control, low, mid and high dose groups, respectively) and females (5, 14, 10, and 17% for the control, low, mid and high dose groups, respectively), statistical significance was achieved in mid dose males. The combined incidence of bronchoalveolar adenomas/carcinomas was increased in all treated groups in males (7, 18, 32, and 22% for the control, low, mid and high dose groups, respectively). Only the mid dose males were statistically significantly different from the controls.

These data indicate that CD-1 mice showed evidence of bronchoalveolar adenomas (mostly) and/or carcinomas in the lung, but the data were considered to be inconclusive in terms of the relationship to alachlor treatment especially when both mouse carcinogenicity studies are considered together. The systemic toxicity NOEL for males is 16.64 mg/kg/day and the systemic toxicity LOEL for males is 65.42 mg/kg/day based on an increase in centrilobular hepatocellular hypertrophy in mid and high dose males. The systemic toxicity NOEL for females is 90.34 mg/kg/day and the systemic

toxicity LOEL for females is 399.22 mg/kg/day based on body weight gain decrements and an increase in fibrous osteodystrophy of the sternum. (MRID No. 43507601).

d. Developmental Toxicity

Developmental studies are designed to identify possible adverse effects on the developing organism which may result from the mother's exposure to the pesticide during pre-natal development.

In a developmental toxicity (teratology) study, Charles River rats were given 0 (control), 50, 150 or 400 mg/kg/day of alachlor (92.19% a.i.; Lot# MHK-6) by gavage on gestation days 6 through 19, inclusive. Maternal systemic toxicity was noted at the high dose as maternal deaths, and increased incidence of soft stools, red matter around the nose and mouth and anogenital staining and reduced body weight gains. Developmental toxicity was noted at the high dose as a slight increase in the mean number of early and late resorptions with related increased post-implantation loss and a slight reduction in the mean number of viable fetuses. The maternal toxicity NOEL is 150 mg/kg/day. The maternal toxicity LOEL is 400 mg/kg/day based on increased mortality, increased incidence of clinical signs and reduced body weight gains. The developmental toxicity NOEL is 150 mg/kg/day. The developmental toxicity LOEL is 400 mg/kg/day based on increased resorptions and decreased litter size (MRID No. 00043645).

In a developmental toxicity study, New Zealand white rabbits received doses of 0 (control), 50, 100 or 150 mg/kg/day alachlor (94.7% a.i., Lot# 51486-C) by gavage on days 7 through 19, inclusive. Maternal systemic toxicity was noted at the high dose as decreased body weight gain during the dosing period followed by a rebound in body weight gain during the period following dosing. No developmental toxicity was noted in the parameters measured. The maternal toxicity NOEL is 100 mg/kg/day. The maternal toxicity LOEL is 150 mg/kg/day based upon a reduction in body weight gains. The developmental toxicity NOEL is equal to or greater than 150 mg/kg/day (highest dose tested) and the developmental toxicity LOEL is greater than 150 mg/kg/day (MRID No. 40579402).

e. Reproductive Toxicity

A reproduction study is designed to provide general information concerning the effects of a test substance on mating behavior, conception, parturition, lactation, weaning, and growth and development of the offspring.

In a three-generation reproduction study, Sprague Dawley CD rats received either 0 (control), 3, 10, or 30 mg/kg/day technical alachlor (92.6% a.i.; Lot# XHI-167) in the diet. Parental/ Offspring systemic toxicity was noted at the high dose in the form of discoloration of the kidney and reduced kidney weights (especially in F_2 parents and F_{3b} pups). Histopathology revealed chronic nephritis in the high dose males. The high dose females of each parental generation and the F_{3b} females had lower ovary weights (this decrease was maximal (17%) and significant in the F_o generation, and was also associated with 17% decrease in the ovaries to body weight ratio). No microscopic changes were

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reported in the ovaries and no effect was noted on reproductive parameters. The parental/offspring systemic toxicity NOEL is 10 mg/kg/day. The parental/offspring systemic toxicity LOEL is 30 mg/kg/day based on kidney effects. Since there were no effects on reproductive parameters, the reproductive toxicity NOEL is equal to or greater than 30 mg/kg/day (HDT). The reproductive toxicity LOEL is greater than 30 mg/kg/day. (MRID No. 00075062).

f. Mutagenicity

Alachlor

A reverse mutation assay in five strains of Salmonella typhimurium (TA1535, TA100, TA1537, TA1538, and TA98) using 10 to 5000 μg/plate with and without S9 metabolic activation was negative (MRID No. 00109563).

An E. coli WP2 hcr reverse mutation assay using 10 to 5000 μg/plate with and without S9 metabolic activation was negative (MRID No. 00109563).

A rec assay with Bacillus subtilis (H17 and M45) using 20 to 2000 μg/disk was negative (MRID No. 00109563).

Alachlor was positive in an in vivo/in vitro unscheduled DNA synthesis (UDS) assay at 1000 mg/kg, a dose approximating the LD_{50} in rats. Doses tested were 50, 200, and 1000 mg/kg with evaluations at 2 and 12 hours (MRID No. 00141061).

An assay of structural chromosomal aberrations (e.g., in vivo cytogenetics in rat bone marrow) was negative. Single doses of 0, 100, 300, or 1000 mg/kg with sacrifice times of 6, 12, 24, and 48 hours (MRID No. 00141062).

A CHO (Chinese hamster ovaries) HGPRT mammalian cell forward mutation test was negative. Dose levels tested were 15 to 150 μg/ml without S9 metabolic activation and 15 to 330 μg/ml with S9 metabolic activation (MRID No. 00148921).

Alachlor was negative in an Ames Salmonella typhimurium mammalian microsome plate incorporation assay, conducted in the absence of S9 and with S9 prepared from uninduced rat, mouse, or monkey nasal turbinates, at concentrations ranging from 50 to 5000 μg/plate. Tester strains TA98, TA100, TA1535, and TA1537 were used (MRID No. 42651301).

Alachlor was positive for inducing UDS in hepatocytes recovered from male Fischer-344 rats at 12 hours after oral gavage administration of 1000 mg/kg. (It is noted that the dose at which a positive response was observed **approximates the LD_{50}** of alachlor in rats.) The average number of net nuclear grains counts were increased by >5 compared with the controls, with > 10% of the cells in repair (increased net nuclear grains counts over control were obtained with 2/5 animals, and increases of >5 net grains were observed with 3/5 animals. Similarly, a comparison of the individual

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data from treated animals and the vehicle control group showed that hepatocytes recovered from 3 of 5 animals were positive for UDS, cells from one animal showed a borderline positive response, and liver cells from the remaining animal was negative. These data are suggestive of a genotoxic response. There was no indication of UDS activity at 12 hours after oral gavage administration of lower doses (50, 200, or 500 mg/kg) or at 2 hours following gavage with 1000 mg/kg (MRID No. 42651302).

Alachlor was negative in a micronucleus assay in Long-Evans rats conducted with a single intraperitoneal injection of 150, 300, or 600 mg/kg and 24-, 48-, and 72-hour sacrifice times. Two males and one female receiving the high dose died, and clinical signs of toxicity were observed in males at all doses and in mid- and high-dose females. A separate experiment in the same study with radiolabeled alachlor provided evidence that the test material reached the target organ, bone marrow, when administered intraperitoneally. (MRID No. 42651303).

In a mouse micronucleus assay (MRID No. 44032103), groups of 10-15 male CD-1 mice received single oral gavage administrations of 250, 500 or 1000 mg/kg alachlor (>99%). The test material was delivered to the animals in corn oil. Animals were sacrificed at 24 and 48 hours post-administration; bone marrow cells were harvested and 2000 polychromatic erythrocytes per male were examined for the incidence of micronucleated polychromatic erythrocytes (MPEs). Death and other clinical signs (i.e., piloerection and/or decreased defecation) were observed at the highest dose tested. Cytotoxicity for the target organ was not observed at any dose. The positive control induced the expected high yield of MPEs in the treated males. There was, however, no evidence that alachlor induced a clastogenic or aneugenic effect at any dose or sacrifice time. The study contained major guideline deficiencies (i.e, use of a single sex, only 5 males/dose/sampling time and no 72-hour post-treatment sacrifice). However, the study is classified as acceptable for the following reasons:

- Previous studies have shown that alachlor is not active in the mouse bone marrow micronucleus assay.
- Adequate justification for the use of males only was provided.
- Variations within and among treatment groups were minimal; hence, the findings with the smaller than recommended sample size are considered valid.
- The uniformly negative response in conjunction with the absence of an effect on cell cycling suggest that sampling cells 72 hours after compound administration would not have altered the outcome of the study.

Based on these considerations, the Agency concluded that the study satisfied the requirements for 84-2 for in vivo cytogenetic mutagenicity data.

Metabolites of Alachlor

Urine from alachlor treated rats was tested in an Ames Salmonella assay using strains TA98, TA100, TA1535, and TA1537 in the presence and absence of arochlor 1254-induced mammalian activation system and/or ß-glucuronidase/sulfatase and dose levels of 0.005 to 0.5 ml/plate. There

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was a weak mutagenic response in strain TA98 in the presence of ß-glucuronidase. A weak mutagenic response was also observed in strain TA1537 in the presence of both ß-glucuronidase and metabolic activation (MRID No. 00155389, 00155392).

Bile from alachlor treated Long-Evans rats tested in an Ames Salmonella assay using strains TA98, TA100, TA1535, and TA1537 in the presence and absence of arochlor 1254-induced liver homogenate (S-9) or ß-glucuronidase at dose levels of 0.01 to 0.20 ml/plate was negative under all conditions (MRID No. 00155389, 00155393).

Ames Salmonella assays with **synthesized** metabolites of alachlor using strains TA98, TA100, TA1535, and TA1537 at dose levels of 0.004 to 10.00 mg/plate both with and without S9 metabolic activation showed that of five metabolites tested (t-hydroxysulfone [CP101394; rat, mouse, goat, hen, rotation crops metabolite], *sec*- amide p-hydroxy methylsulfone [CP51214; rat metabolite], t-sulfinyllacetic acid [CP108267; corn metabolite], t-oxanilic acid [CP108064; soil, water, soybean metabolite], and t-sulfonic acid [CP108065; corn, soil, soybeans, water metabolite]), only the t-hydroxysulfone metabolite was observed to be mutagenic (strain TA100 at 3 and 10 mg/plate in the presence and absence of metabolic activation). (MRID No. 00151394, 00151395, 00151396, 00151397, 00151398, 001513999)

In Ames Salmonella assays with **synthesized** metabolites of alachlor (CP97230 and CP101384 [s-hydroxysulfone]) using strains TA98, and TA100 at dose levels of 0.01 to 10.00 mg/plate both with and without S9 metabolic activation only the s-hydroxysulfone metabolite was observed to be weakly mutagenic (strain TA100 at 1, 3 and 10 mg/plate in the presence and absence of metabolic activation). The responses that were less than a 2-fold increase indicating a positive response. (MRID No. 00155389, 00155391).

Two alachlor metabolites, 2'6'-diethyl-2-methyl thioacetanilide (DMTA) and 2'6'-Diethylaniline (DEA), were tested (MRID No. 42651301) in an Ames Salmonella typhimurium mammalian microsome plate incorporation assay in the absence of S9 and with S9 prepared from uninduced rat, mouse, or monkey nasal turbinates. Tester strains TA98, TA100, TA1535, and TA1537 were used. DMTA was positive in strain TA1535 in three independent Salmonella typhimurium mammalian microsome plate incorporation assays, conducted with S9 prepared from mouse nasal turbinates. In addition, there was a tendency for increased numbers of revertants of TA1535 to occur following exposure to higher dose levels (1500 and/or 5000 μg/plate) of DMTA. This was also observed in one of two assays conducted with rat nasal turbinate S9. Although only marginal increases were observed, the increases were reproducible and statistically significant. There was no response in tester strains TA98, TA100 or TA1537 with the nonactivated test material or in the presence of S9 prepared from mouse, rat, or monkey nasal turbinates. However, it should be noted that DMTA is not a stable product of alachlor metabolism.

DEA was positive in strains TA1535 and TA100 in at least two independent Salmonella typhimurium/mammalian microsome plate incorporation assays, conducted with S9 prepared from mouse nasal turbinates. The nonactivated test material and the test material activated with rat nasal

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turbinate S9 were also positive in strain TA100. Although only marginal increases were observed, they were reproducible and statistically significant. There was no consistent response in tester strains TA98 and TA1537.

g. Metabolism

Metabolism studies in Sprague Dawley rats found that an oral dose of 7 or 700 mg/kg of alachlor was mainly eliminated in urine and feces, and that 89% of the dose was eliminated in 10 days (minimal alachlor was found in the expired CO_2). The elimination was considered to be biphasic; the initial rapid phase had a half life of 0.2 to 10.6 hours, which then slowed to a half life of 5 to 16 days. Fourteen metabolites were identified in urine and 13 in feces. Three of the metabolites were common to both urine and feces. The eliminated metabolites were conjugates of mercapturic acid, glucuronic acid, and sulfate (MRID No. 00132045).

From a metabolism study in Rhesus monkeys, five urinary metabolites were identified after intravenous injection. One of these metabolites, (also found in rat and mouse urine, N-[2-ethyl-6-(1-hydroxyethyl)-phenyl]-N-(methoxymethyl)-2(methylsulfonyl)acetamide), tested positive in the Ames test with Salmonella typhimurium, with and without activation. This metabolite was an HEEA metabolite not previously identified in the monkey.

Of the metabolites found in the above two metabolism studies, only two urinary metabolites were common to both the rat and monkey (secondary and tertiary mercapturic acid conjugates). Side chain hydroxylation and sulfate conjugation metabolites were not found in monkey urine as they were in rats (MRID No. 40000901).

Another metabolism study was conducted on male and female Long Evans rats (MRID 42651306, 42852107, 42651308, 42852108). This study consisted of seven groups of rats. Both oral dosing studies using corn oil as the vehicle and intravenous administration studies using propylene glycol as the vehicle were performed. Together these seven studies satisfy GLN 85-1. The study is considered to be the definitive study for understanding how the rat metabolizes alachlor.

Oral administration of alachlor was studied using female Long-Evans Crl:CD(LE)BR rats six to nine weeks of age in five dose groups. Groups 1, 2, and 3 each consisted of 33 rats. Each group received single oral doses of radiolabeled alachlor (uniformly labeled in the phenyl ring with 14-C, and enriched with 13-C at the C-2 carbon) at target doses of 7 (Group 1), 70 (Group 2), or 700 (Group 3) mg/kg. Group 4 consisted of 21 rats which received 15 consecutive daily doses of radiolabeled alachlor at 700 mg/kg/day. Group 5 consisted of 6 rats which received a single oral dose of radiolabeled alachlor at 700 mg/kg for the purpose of obtaining plasma samples at 2, 4, and 6 hours post-dosing. Long Evans rats (5/sex/dose) were used to study the disposition and metabolism of alachlor following intravenous administration at 7 (Group 6) or 70 (Group 7) mg/kg.

In the oral studies, absorption at the 7 or 70 mg/kg dose levels was essentially complete, with a slight decrease in absorption at the 700 mg/kg dose level. Repeated oral dosing at 700 mg/kg had

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no significant effect on absorption. Residual radioactivity did not exceed 5% of the administered dose at any of the dose levels in this study. On a ug/g basis, the residual radioactivity in the non-glandular stomach was higher than in the glandular stomach except at 4 hours post-dose at the 700 mg/kg dose level. Decreasing the dose decreased the percentage of the dose in the non-glandular stomach but not in the glandular stomach. Nasal turbinates showed a secondary peak of radioactivity at 8 hours post-dose at the 700 or 70 mg/kg dose levels in contrast to other tissues. Excretion of alachlor derived radioactivity was approximately equivalent between urine and feces, with between 30-47% excreted in urine and 41-45% excreted in feces at single oral doses of 7, 70, or 700 mg/kg. Intravenous dosing at 7 or 70 mg/kg resulted in a similar excretion profile. Repeated oral dosing at 700 mg/kg resulted in a slight increase in fecal excretion of radioactivity. In urine, the *sec*- amide hydroxymethyl sulfone metabolite (metabolite F5) of alachlor was the predominant urinary metabolite after oral and intravenous administration, ranging from 2.1-7.4% of the dose. Repeated oral dosing resulted in the appearance of several additional metabolites, but it is not known whether these additional metabolites are unique to repeated oral administration of alachlor. In feces, the tert-amide mercapturic acid and the disulfide appeared to be the major metabolites after single oral doses of alachlor. Increasing the dose appeared to increase the percentage of these 2 metabolites in feces.

In this study, male and female CD-1 mice (10/sex) received a single oral dose of radiolabeled alachlor in corn oil (890 mg/kg for male mice, 819 mg/kg for female mice). Urine and feces were collected daily for up to 7 days post-dose for analysis of excreted radioactivity and for identification of metabolites. In urine, 18.4 ±3.9% and 23.6±4.1% of the dose was excreted in male and female mice, respectively. In feces, 66.5±6.9% and 53.6±3.6% of the dose was excreted in male and female mice, respectively. Total recovery of radioactivity was 85.5±3.7% for male mice, and 79.4±2.7% for female mice. (The low recoveries may be due to the fact that the mice were housed in pairs in units larger than those normally used for a mouse.) Analysis of blood at seven days post-dose showed 0.095±0.016% of the dose in males, and 0.075±0.017% of the dose in females. Half life for urinary elimination was reported as 0.88±0.11 days in males, and 1.18±0.16 days in females. Half-life for fecal elimination was reported as 0.90±0.06 days in males, and 1.11±0.05 days in females. The data in this study show that in contrast to the rat, feces is the major route of excretion for alachlor derived radioactivity in CD-1 mice. The high percentage of fecal excretion could be the result of poor absorption of test chemical or extensive biliary excretion in the mouse.

Pooled urine and fecal samples representing the 0-48 hour collection time for urine and the 0-96 hour collection time for feces, were analyzed for metabolites of alachlor in male and female CD-1 mice. In feces, at least 10 metabolites were isolated (See Table 4). Urinary metabolites are in Table 5.

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Table 4: Metabolites in Mouse Feces		
Metabolite	% of Dose - Male Feces	% of Dose - Female Feces
alachlor	1.8	2.2
tert-amide mercapturic acid	4.1	3.3
disulfide conjugate	0.6	1.0
sec-amide mercapturic acid	0.7	0.6
tert-amide thioacetic acid	1.2	0.9
tert-amide hydroxy sulfone	0.6	0.5
tert-amide dihydroxysulfone	0.0	0.0
benzyl glucuronide	2.1	1.0
tert-amide cysteine conjugate +NCH20-glucuronide	5.0	3.7

Table 5: Urinary Metabolites Characterized in the Mouse		
Metabolite	% of Dose - Male Urine	% of Dose - Female Urine
tert-amide cysteine conjugate	0.1	0.3
NCH2O glucuronic acid	1.9	3.2
cysteine sulfoxide (proposed)	0.2	0.3
sec-amide dihydroxysulfone	0.1	0.2
sec-amide hydroxy sulfoxide	0.1	0.2
sec-amide hydroxy sulfone	0.1	0.2
para-amino sulfate	0.1	0.2

While metabolism of alachlor utilizes the same metabolic pathways in mice as in rats, there are quantitative differences between mice and rats in the metabolite profile present. Mouse feces were found to contain greater amounts of mercapturic acid conjugate and lesser amount of disulfide conjugate than in rat feces. The number of urinary metabolites observed in mouse urine was greater than in rat urine. Mouse urine was found to contain greater amounts of glucuronic acid conjugates and cysteine conjugates than the rat, but a lesser amount of phenolic (hydroxylated) metabolites

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(MRID No. 42651305, 42852106).

h. Special Studies

Monsanto has voluntarily submitted a number of special studies on alachlor which were performed to better understand the mechanisms involved in the toxic responses induced by alachlor, including tumor formation. The following special studies can be categorized in the following groups: in vivo metabolism studies, in vitro metabolism studies, whole body autoradiography (WBA) studies, mutagenicity studies, and cell proliferation/cytotoxicity studies. Some of the submitted data used for cancer peer review consisted of studies conducted with butachlor, a structural analog of alachlor. These special studies do not satisfy any guideline requirements. Further discussion of the conclusions of these studies is in the Dose Response Assessment Section under the Cancer Classification discussion.

In Vivo Metabolism Studies

- Effect of Multiple Oral Dosing on the Metabolism, Distribution, and Elimination of Alachlor in the Long-Evans Rat. (MRID Nos. 42651310, 42852109)

- A Study of the Metabolism and Excretion of Alachlor in Rats Chronically Exposed to Alachlor; Routes and Rates of Elimination. (MRID No. 42651307) Characterization of Metabolites in the Urine and Feces. (MRID No. 42931101)

- Metabolism of Alachlor Methyl Sulfide in Long-Evans Rats. (MRID No. 42651309)

In Vitro Metabolism Studies with Alachlor and Alachlor Metabolites

- A Study of the In Vitro Liver Slice Metabolism of Alachlor in the Male Rat, Mouse, and Monkey. (MRID No. 42651311)

- A Study of the In Vitro Metabolism of Alachlor Using Enzyme Preparations From Selected Rat Tissues. Part I. Preparation of Tissue Homogenates. (MRID No. 42651312)

- In Vitro Metabolism of Alachlor by Rat Liver, Kidney, Lung, Nasal, and Stomach Homogenates. (MRID No. 42852110)

- In Vitro Metabolism of Alachlor by Rat and Mouse Liver and Nasal Enzymes. (MRID No. 42852111)

- Metabolism of Alachlor Methyl Sulfide in Long-Evans Rats. (MRID No. 42651309)

- In Vitro Metabolism Study of Alachlor, Alachlor Secondary Methyl Sulfide, and 2,6-Diethylaniline by Rat and Monkey Nasal Turbinate Part II. (MRID No. 42651314)

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- In Vitro Metabolism of Alachlor, Alachlor Secondary Sulfide, Alachlor Sec-Amide, and 2,6-Diethylaniline by Rat and Human Nasal Turbinates and Liver. (MRID No. 43482301)

- Effects of Alachlor on Tissue Levels of Glutathione in the Rat. (MRID No. 42651318)

- Effect of Alachlor on Glutathione Levels of Cultured Adult Rat Hepatocytes. (MRID No. 43641603) (Note: This study was not conducted according to 40 CFR Part 160, but is a report based on university thesis research conducted at Searle, a Monsanto subsidiary.)

Studies on Alachlor Using Whole Body Autoradiography (WBA)

- Whole Body Autoradiography Studies on 14-C Alachlor in Rats, Mice, and Monkeys. (MRID No. 42852103)

- A Comparative Study of the Distribution and Localization of Alachlor, Metolachlor, and MON 4601 in Rats Using WBA. (MRID No. 42852104)

- A Study of the Distribution and Localization of Alachlor-Methylsulfide in Rats Using WBA. (MRID No. 42651304)

- A Study of the Distribution and Localization of Diethylaniline (DEA) in Rats and Mice Using WBA. (MRID No. 43507401)

- A Study of the Distribution and Localization of Dimethylaniline (DMA) in Rats and Mice Using WBA. (MRID No. 43706001)

- Comparison of the Distribution and Excretion of Radiolabeled Alachlor in the Sprague-Dawley, Fisher 344 and Long-Evans Rat and Golden Syrian Hamster. (MRID No. 42852105)

Mutagenicity Studies with Alachlor

- Determination of CP-50144-Derived Radioactivity in Rat. (MRID No. 43369201)

- Study of the Effects of Alachlor on Cellular Stress Response Genes in Rat Nasal Turbinate Tissue. (MRID No. 43590002)

Cell Proliferation / Cytotoxicity Studies

- Characterization of Covalent Adducts Formed with Nasal Tissue Protein Following Dietary Administration of 14-C Alachlor to Female Long-Evans Rats. (MRID No. 43641604)

- A Study of the Effect of Alachlor and Selected Metabolites on Cytotoxicity Markers in Nasal

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Tissue of the Long-Evans Rat. (MRID No. 43641602)

- Gastric Tumor Initiation/Promotion Study of Butachlor in Sprague-Dawley Rats (Monsanto Company, The Agricultural Group, Environmental Health Laboratory for Monsanto Company, Monsanto Study#: ML-92-365, Monsanto EHL Study#: EHL 92142, August 18, 1994, MRID No. 43729502).

- A Study of the Mechanism of Butachlor Induced Carcinogenicity in Female Sprague-Dawley Rats (Monsanto Company, The Agricultural Group, Environmental Health Laboratory for Monsanto Company, Monsanto Study#: EHL-92049, Monsanto Study#: ML-92-146, February 9, 1995, MRID No. 43750801).

- A Study on the Effect of Butachlor on Cell Proliferation in Selected Tissues of the Mouse (Monsanto Company, The Agricultural Group, Environmental Health Laboratory for Monsanto Company, Monsanto Study#: EHL-93064, Monsanto Study#: ML-93-153, August 11, 1994, MRID No. 43729503).

- Effects of Butachlor on Cell Proliferation and Mucosal Thickness in the Gastric Tissue of Female Rhesus Monkeys (American Health Foundation and White Sands Research Center and Environmental Health Laboratory for Monsanto Company, Monsanto Study#: EHL-93064, Monsanto Study#: WS-93-164 and WS-93-165, MRID No. 43729501).

- Gastric Tumor Promotion Study of Alachlor in Long-Evans Rats. Monsanto Company, The Agricultural Group, Environmental Health Laboratory for Monsanto Company, Monsanto Study No. ML-93-137, Monsanto EHL Study# EHL 93049, February 3, 1995. MRID No. 43590001.

The data from these studies were used to draw the following conclusions:

Nasal Tumors

Based upon the available data for alachlor, the following hypothesis has been proposed for the production of tumors in the nasal mucosa: alachlor is metabolized in the rat to the glutathione (mercapturic acid) conjugate, which is excreted through the bile into the gut. In the gut, enteric bacteria metabolize the conjugate to the thiol conjugate, with subsequent S-methylation of the thiol. This product, the methyl sulfide, is re-absorbed into the systemic circulation where conversion to the secondary sulfide occurs. Hydrolysis of the secondary sulfide by arylamidase produces the diethylaniline metabolite of alachlor. Oxidation of the diethylaniline metabolite produces the putative toxic metabolite, diethylbenzoquinone imine (DEBQI). This metabolite binds to cellular protein, resulting in eventual cell death. Ensuing regenerative cell proliferation can then lead to neoplasia through “fixation” of spontaneous mutations.

The registrant presented data in support of their conclusion that the nasal tumors observed

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following alachlor administration are unique to the rat based on differences in disposition of alachlor in the rat versus other species. In vivo studies in Long-Evans rats (MRID No. 42651306, 42651308, 42852107, 42852108) and CD-1 mice (MRID No. 42651305, 42852106) showed that a greater percentage of a given dose of alachlor was eliminated in feces of mice vs rats. In addition, it was shown that mouse urine contained a greater percentage of glucuronide conjugates and cysteine conjugates of alachlor, while rat urine contains a greater amount of phenolic (hydroxylated) metabolites. In addition, rat feces were found to contain greater percentages of mercapturic acid conjugates and sulfone metabolites than mouse feces. These data are supportive of the proposed metabolic pathway for production of the putative toxic intermediate of alachlor in the rat. In addition to the comparative metabolism of alachlor in rats versus mice, the in vivo metabolism of the methyl sulfide metabolite of alachlor in female Long-Evans rats demonstrated the production of 4-amino-3,5-diethylphenylsulfate, a stable end-product indicative of the formation of the quinone imine precursor (MRID No. 42651309).

In vitro studies conducted by the registrant demonstrated the presence of the reactions necessary for production of the DEBQI intermediate. These include glutathione conjugation of alachlor, hydrolysis of the secondary sulfide by arylamidase, and hydroxylation of 2,6-diethylaniline. Further, in vitro studies demonstrated significant species differences in the rates of these reactions. Comparative in vitro metabolism of alachlor by several tissues in the Long-Evans rat (MRID No. 42852110) showed the presence of arylamidase activity in liver and nasal tissue resulting in formation of the 2,6-diethylaniline metabolite. Oxidation of the 2,6-diethylaniline metabolite to 4-amino-3,5-diethylphenol was shown to be approximately 50 times greater in nasal microsomes than in liver microsomes. Rat and mouse liver and nasal tissues were compared for their ability to metabolize alachlor to the proposed DEBQI intermediate (MRID No. 42852111). The velocity of the nasal aryl amidase reaction in rat nasal tissue towards the sec-amide metabolite of alachlor was observed to be 14-20 times higher in rat than in mouse. The velocity of the nasal arylhydroxylase towards diethylaniline in rat nasal tissue was found to be approximately 2-fold higher than in mouse. This study demonstrated that certain key enzymes responsible for production of the proposed toxic intermediate of alachlor are more active in rat nasal mucosa vs mouse nasal mucosa. Liver and nasal cytosolic or microsomal fractions were used from rat and monkey to study metabolism of alachlor to the GSH conjugate, the hydrolysis of alachlor secondary sulfide by arylamidase, and the hydroxylation of 2,6-diethylaniline (MRID No. 42651314). Velocity of rat liver GST was 3.9 times greater than monkey GST towards alachlor. Velocity of rat nasal GST was 114.3 times greater than monkey GST towards alachlor. Velocity of secondary sulfide hydrolysis was equivalent in rat and monkey liver preparations, but was 4 times greater in rat nasal tissue vs monkey nasal tissue. Velocity of DEA hydroxylation in rat liver was 3 times greater than in monkey liver, and 7.6 times greater in rat nasal tissue than in monkey nasal tissue. Thus, the enzymes thought to be responsible for production of the toxic intermediate of alachlor are more active in rat nasal tissue vs monkey nasal tissue.

In MRID No. 43482301, cytosolic and microsomal fractions from rat and human liver and nasal tissue were studied to determine the differential species capability to conjugate alachlor with glutathione, to hydrolyze the secondary methyl sulfide (secondary sulfide), and to hyroxylate the

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2,6-diethylaniline metabolite of alachlor. Velocity of glutathione conjugation in rat liver and nasal tissue was 4.0 and 32.5 times greater than in human liver and nasal tissue, respectively. Velocity of hydrolysis of the secondary sulfide was 5.8 times greater in rat nasal tissue vs human. Velocity of DEA hydroxylation was 7.5 times greater in rat liver vs human, and 129.8 times greater in rat nasal tissue vs human.

Whole body autoradiographic (WBA) studies conducted in rats, mice, and monkeys provided further support for the species specificity of the mechanism of alachlor-induced nasal tumors. In MRID No. 42852103, WBA studies in rats, mice, and monkeys following single oral doses of 7, 70, and 700 mg/kg were conducted. A similar picture of tissue distribution was observed in all species with the exception of blood, in which significant amounts were observed only in the rat at 5 days post-dose, and the nasal turbinates, in which significant accumulation was observed in the rat, less in the mouse, and none in the monkey. Comparative WBA studies on the localization of alachlor, metolachlor, and MON 4601 were conducted in male and female rats after target doses of 7 and 700 mg/kg (MRID No. 42852104). Nasal turbinate localization appeared less for alachlor than for metolachlor and MON 4601 at one day post-dose at the 7 and 700 mg/kg dose. The data in this study indicated a faster clearance of alachlor from the intestinal tract vs metolachlor and MON 4601, and also indicate that metolachlor and MON 4601 undergo biliary excretion and enterohepatic circulation. Whole body autoradiography studies of the localization of the methylsulfide metabolite in rats after oral administration at 0.7 and 7.0 mg/kg (MRID No. 42651304) and localization of the diethylaniline metabolite of alachlor in rats after oral administration of 7 and 70 mg/kg (MRID No. 43507401) showed that for the methyl sulfide metabolite, localization in the nasal turbinate was evident up to 5 days post-dose, while for the diethylaniline metabolite, nasal turbinate localization was evident in the rat but not the mouse. Comparative distribution of alachlor using WBA after oral doses of 7 and 70 mg/kg was examined in Sprague-Dawley, Long-Evans, and Fisher 344 rats as well as in Syrian hamsters (MRID No. 42852105). Nasal localization was evident in all three strains, but was most apparent in the Long-Evans rat. Nasal localization was not evident in the hamster.

Collectively, these WBA studies support the conclusion that the distribution of alachlor derived radioactivity to the nasal turbinates, as well as that of alachlor metabolites thought to be involved in nasal tumor formation, is greater in the rat than in the mouse or monkey. When considered in conjunction with in vitro studies on the activities of enzymes responsible for formation of the DEBQI intermediate, it is evident that not only does alachlor derived radioactivity localize to the rat nasal turbinate tissue to a greater degree than in mice or monkeys, but that the activities of the enzymes involved in the conversion of the secondary sulfide to the DEBQI intermediate are significantly higher in the rat than in the mouse, monkey, or human.

The mechanism of alachlor-induced nasal tumors is considered by the registrant as a non-genotoxic mechanism. This argument is largely based upon the mutagenicity database, in which it is argued that alachlor has no significant genotoxic activity in mammalian systems. Studies examining the effect of alachlor administration on tissue glutathione levels following in vivo administration of oral and intraperitoneal doses of alachlor to Long-Evans rats as well as the effect of alachlor on glutathione levels in cultured hepatocytes have been conducted (MRID Nos. 42651318

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and 43641603). These studies showed depletion of hepatic glutathione followed by recovery after a single i.p. dose of 350 mg/kg or single oral doses of 126 or 350 mg/kg. Alachlor was hepatotoxic at concentrations above 400 μM, and significant glutathione depletion was also observed at concentrations above 300 μM alachlor. While no significant depletion of nasal glutathione levels were observed, the DNA damaging effect of alachlor might be related to depletion of glutathione and subsequent tissue toxicity, and not to a direct mode of action. It is noted that significant hepatoxicity in the form of elevated serum ALT (alanine amino transferase), AST (aspartate amino transferase), and LDH (lactate dehydrogenase) as well as centrilobular cytoplasmic eosinophilia, centrilobular inflammation, and centrilobular hepatocellular degeneration/necrosis was observed at a dose of alachlor (1000 mg/kg) which also caused a weak UDS response. These data are consistent with a non-genotoxic mode of action for alachlor.

With regard to the nasal tissue, two studies addressed the mechanism of nasal turbinate induced tumors. In the first study (MRID No. 43641604), female Long-Evans rats were fed 14-C alachlor in the diet at a targeted dose level of 126 mg/kg/day for a total of 13 days. On days 1, 3, 7, and 13, 3 rats were sacrificed and the covalent binding of alachlor derived radioactivity to nasal protein was determined. The results of this study showed a direct correlation between the total level of alachlor binding to rat nasal proteins and length of treatment. The major adduct was identified as the 3,5-diethylbenzo-quinone-4-imime (DEBQI)-cysteine adduct. Formation of DEBQI in the rat nasal tissue is believed to be required for induction of nasal tumors. In the second study (MRID No. 43641602), the in vitro cytotoxicity of alachlor, DEA, secondary sulfide, and secondary amide were assessed in preparations of rat nasal turbinate as evidenced by leakage of the enzyme acid phosphatase into the culture medium. Concentrations of alachlor and metabolites used were either 1 or 5 mM. Alachlor at both 1 and 5 mM was shown to increase acid phosphatase levels in the culture medium. Neither the secondary sulfide or secondary amide caused an increase in acid phosphatase levels at 1 mM (5 mM concentration not possible due to solubility limitations). DEA was observed to increase acid phosphatase levels at 5 mM in nasal tissue. The cytotoxicity observed with alachlor in nasal tissue is consistent with the cell proliferation response observed in nasal tissue after administration of alachlor, but the entity responsible for the cytotoxic response is not known with certainty.

Gastric Tumors

In response to scientific and regulatory questions raised in Japan, an extensive research program was undertaken to understand the mechanism by which chloroacetanilides induce stomach tumors in rats. The majority of this work was conducted with butachlor in Sprague-Dawley rats. Since butachlor is a close structural analog of alachlor, and the two compounds produce the same glandular stomach tumors, extrapolation of the mechanistic information to alachlor is scientifically justified. To further support this, some bridging data have been developed with alachlor and were previously reported to the Agency. The purposes of these provided data are to: (a) report the results and conclusions of the mechanistic studies conducted with butachlor; and (b) integrate these results with those from the alachlor work to show that the same mechanisms are operative for both herbicides.

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In a gastric tumor initiation/promotion study (MRID No. 43729502) the results showed that butachlor had no initiating potential of its own when used at dose levels which produced gastric tumors in the chronic toxicity study in rats. Butachlor was found to enhance the formation of gastric neoplasms when combined with an initiating agent. This occurs primarily in females and at the dose which induced neoplasms in the chronic rat study. In a study of the mechanism of butachlor induced carcinogenicity in female Sprague-Dawley rats (MRID No. 43750801) the investigators concluded that these data delineated the mechanistic processes involved in the production of the gastric, nasal and thyroid tumors for butachlor. It was suggested that the data provided support for the involvement of non-genotoxic mechanisms that would be threshold sensitive to humans. They also stated that these studies further support the view that the rat tumors induced by butachlor are not relevant to man and that butachlor does not pose a human health risk (not formally reviewed by the Agency). In a study on the effect of butachlor on cell proliferation in selected tissues of the mouse (MRID No. 43729503) the investigators found no consistent increase in cell proliferation in either the fundic or pyloric regions. There was a slight increase in the fundic neck region but not in the base region and there was no evidence of toxicity in the mucosa. In another study on the effects of butachlor on cell proliferation and mucosal thickness in the gastric tissue of female Rhesus monkeys (MRID No. 43729501), according to the investigators there were no relevant changes in cell proliferation in any area of the stomach and no changes in the mucosal thickness in any of the monkeys up to and including 400 mg/kg. The results of this study differ from those studies in the rat, where increases in proliferative activity and reductions in mucosal thickness were observed. The doses used in the monkey are reported to exceed the MTD in the rat by 2 to 4 times.

The registrant conducted an initiation-promotion study with alachlor (MRID No. 43590001) as a follow-up to a stomach tumor initiation/promotion study with butachlor. In this study, 100 male and 100 female Long-Evans rats obtained from Charles River Breeding Laboratory, Portage, MI, 6 weeks of age and weighing 168-219 g for males and 139-176 g for females were administered by oral gavage a single dose of 150 mg/kg of the known gastric tumor initiator N-methyl-N'-nitro-N-nitroso-guanidine (MNNG) to 4 groups of 20 animals per sex. One of these groups was not further treated. Another group received dietary administration of 8000 ppm catechol, and two groups received either 15 or 126 mg/kg/day of alachlor in the diet for 1 year while another group (not MNNG treated) received a single oral dose of DMSO (5 mL/kg) followed by dietary administration of alachlor at a level of 126 mg/kg/day (there was another group of 15 animals per sex obtained near the end of the study to serve as "control" animals for serum gastrin levels, gastric fluid amount, pH, and HCl concentration). The investigators determined, at the end of the study, stomach pH, gastric acid secretion over a 4 hour period in 5-6 of the control and DMSO/Alachlor treated animals. They also obtained blood from 9-10 control and DMSO/Alachlor treated animals for serum gastrin determinations. The stomachs of all animals were examined grossly and microscopically.

Alachlor was found to promote the development of glandular stomach tumors in females and to a lesser extent in males. No effect of treatment was noted in the animals treated with MNNG alone (1 tumor). Alachlor alone produced no tumors in males and 4 tumors in females. MNNG/alachlor treated animals produced tumors in 75% of treated females and 30% of treated males at 126 mg/kg/day. These tumors were neoplasms of the glandular stomach, mostly in the fundus region.

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In the 15 mg/kg/day alachlor + MNNG no tumors were observed in the females. However several tumors were found in males at both doses and in females at the 126 mg/kg/day dose following MNNG. The investigators interpreted this as due to MNNG rather than alachlor, since they occurred at equivalent frequency in the males at both doses, the lower of which had no promotional activity. In a previous butachlor initiation/promotion study, the group treated with MNNG only induced adenomas and adenocarcinomas in the pyloric region. Alachlor administration was noted to produce atrophy of the fundic mucosa in almost every animal at 126 mg/kg/day both with and without the initiator, MNNG. No atrophy was noted in any animal at 15 mg/kg/day alachlor for one year. The high dose alachlor animals of both sexes had reduced amounts of fluid in the stomachs. Stomach pH was numerically increased, and gastric hydrochloric acid secretion was decreased and serum gastrin levels were elevated in high dose animals.

The Agency believes that the data provide evidence that alachlor produces glandular stomach tumors in rats through the same non-genotoxic, non-linear sensitive mechanism as butachlor and that this mechanism may be operative in humans under certain specific pathological states.

Alachlor has been shown to produce glandular stomach tumors in Long-Evans rats at doses considered in excess of an adequate dose for carcinogenicity testing. Butachlor also induced these gastric neoplasms in Sprague-Dawley rats following chronic high dose exposure. In this butachlor bioassay, the occurrence of gastric tumors was restricted solely to the highest dose tested (150 mg/kg/day), a level of exposure which was considered greatly in excess of an adequate dose for carcinogenicity testing. In a butachlor chronic bioassay with F-344 rats, the highest dose was considered adequate for carcinogenicity testing, and no gastric tumors were found. This and other information indicate that chloroacetanilides produce stomach tumors in rats via a non-linear type mechanism.

The Agency evaluated the data submitted by the registrant in support of the threshold (non-linear) type mechanism for induction of gastric tumors by alachlor and concurred with the explanation put forth by the registrant.

Thyroid Tumors

Mechanistic data in support of the thyroid tumors consisted of two studies. In the first, dose levels of 0 or 126 mg/kg/day were used to measure indices of thyroid function (T3, T4, and TSH levels). While the results of this study showed no significant effect of alachlor on T3, T4, or TSH levels, the results pertaining to TSH levels were considered invalid based on the use of human antibodies in the TSH assay.

In the second study (MRID No. 42957201), Long-Evans rats were dosed with alachlor for up to 120 days at dose levels of 0 and 126 mg/kg/day. Separate groups were exposed to control diet or alachlor in the diet for 7, 14, 28, 60, or 120 days, with a separate group exposed to alachlor for 60 days in the diet and then control diet for 60 days. The results of this study showed increased liver weights at all time points, increased activity of uridine 5'-di-phosphoglucuronyl transferase

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(UDPGT), and increased thyroid weights from day 14 throughout the remainder of the study. TSH levels were statistically significantly increased from day 14 on, although the increase at day 120 was not significant. T3 levels were increased over control at 7, 14, 60, and 120 days; T4 levels were decreased at 7 and 28 days and increased at 14 days, returning towards normal at following time points. The dose group which received alachlor for 60 days followed by 60 days of control diet showed relatively unaffected T3, T4 and TSH levels. Thyroid follicular hypertrophy/hyperplasia was also noted in the treated animals mainly in the 28 and 60 day groups, with 1 animal in the 120 day group progressing to nodular hyperplasia.

The results of the above studies suggest that thyroid tumors (which only occur in the male rat), result from induction of hepatic UDPGT, with a consequent decrease in circulating T3 and T4 and a subsequent increase in TSH (the compensatory response resulted in increased T3 levels). This action is known to result in a hyperplastic response of the thyroid. The mechanism of thyroid tumorigenesis observed with alachlor is consistent with the mechanism of thyroid tumorigenesis observed with other chemicals causing a disruption of thyroid hormone balance.

Human Studies

Human Biomonitoring

A biomonitoring study of a pesticide involves following a group of workers during a defined field use of the pesticide. Urine is collected before and after exposure and analyzed for metabolites of the pesticide. From this data one determines the quantity of pesticide absorbed during the defined field exposure. Thus, a biomonitoring study consists of two parts (1) a qualitative and quantitative identification of the metabolites of the pesticide, usually by following radiolabel in a mammalian species, and (2) the field study in human subjects.

In the three submitted biomonitoring studies the internal dosage of alachlor was estimated by analysis of the urinary excretion of alachlor metabolites which contained the DEA and HEEA moieties.

The first biomonitoring study (MRID No. 00150089) was conducted using two formulations of alachlor, the EC (emulsifiable concentrate) and the Mcap (microencapsulated). The study was designed to determine the dosages of alachlor in workers, and to compare the dosages of the two formulations. The study was conducted in Indiana during May 1984. Both the EC and Mcap were applied by shallow incorporation to corn fields at an application rate of 4 lbs a.i./acre. Each formulation was applied by four different individuals. Applicators 1, 3, 5, and 7 applied EC and applicators 2, 4, 6, and 8 applied Mcap. Additionally a control subject was present at the field during the application.

The subjects were Monsanto employees who wore goggles and elbow length rubber gloves during mixing/loading and leather boots, trouser, long sleeve shirts and caps throughout the entire operation. The clothing was in agreement with the protective clothing requirements stated on the

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labels. Each applicator emptied eight 2.5 gallon containers of EC or Mcap into 200 gallon tanks. Water was added from nurse tanks with constant agitation. Immediately following mixing, the worker entered a closed cab and applied the alachlor to 20 acres.

The urine from each worker was collected in a borosilicate glass bottle with teflon cap for 120 hours (5 days) after the alachlor application was completed. The samples were analyzed for metabolites of alachlor containing the DEA and HEEA moieties using GC/MS. Urine samples with non-detectable levels of alachlor metabolites were computed as containing 1.25 ppb (one-half the LOD, limit of detection, of 2.5 ppb). The practice of using one-half of the LOD is a standard analytical procedure for dealing with the analytical LODs for chemical residues.

The highest internal dosage for mixing, loading and applying (of the four replicates) for EC formulation was estimated to be 0.0066 μg/kg/lb ai. The internal dosage for the Mcap was estimated to be 0.027 μg/kg/lb ai.

Another biomonitoring study (MRID No. 00159365) was conducted in May and July 1985 in Missouri. In this study the Mcap and WDG (a water dispersable granular formulation), were evaluated. This study was conducted in a manner similar to that of the May 1984 bio-monitoring study: Monsanto employees wearing clothing in accordance with the label, 4 lbs ai/acre, and 20 acres. Open loading was used, with each subject handling 80 lbs ai. Control urine samples were collected prior to study initiation. Urine was collected for 5 days. The urine samples were also analyzed for alachlor metabolites containing the DEA and HEEA moities, but by HPLC (high performance liquid chromatography).

No measurable levels of the alachlor metabolites containing the HEEA moiety were detected in any urine samples for all study subjects. Measurable levels of DEA metabolites were detected for most of the subjects, primarily within the first 48 hours. The internal dosage of the Mcap was estimated to be 0.0038 μg/kg/ai. The internal dosage of the WDG was estimated to be 0.0059 μg/kg/lb ai.

A third biomonitoring study (MRID No. 00159364) was also performed in May and July 1985. This study was also conducted in the same manner as that of the Mcap and WDG 1985 bio-monitoring study. However, a closed loading system was used to transfer the EC. The internal dosage of the EC was estimated to be 0.0034 μg/kg/lb ai.

For all three studies the Agency has concerns due to the small number of replicates as well as the use of protective clothing and the use of the closed cab. Only 20 acres were treated instead of the 100 to 120 acres that could be expected to be treated and incorporated. Additionally, the scenario is only representative of 4 lb ai/acre. The small number of replicates cannot indicate the range of dosage that would be expected. Due to the protected nature of the applicators (clothing and cab) it was assumed that the dosage estimate is from the lower end of the range. A literature search of ground boom application studies indicated that exposure to the applicators ranged over three orders of magnitude. In the alachlor PD4 two orders of magnitude was chosen by the Agency to

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define the exposure range since mixing and loading is included in the dosage estimates with the estimate from the Monsanto bio-monitoring studies considered to be the low end of the range.

As part of the reregistration process, the first biomonitoring study (May 1984, Indiana) was rereviewed. The review indicated that there is probably a formulation related difference for application of the EC versus the Mcap. For the 4 lb ai/acre scenario, the internal estimated dosages were: EC = 0.0032 μg/kg/lb ai, and Mcap = 0.0126 μg/kg/lb ai. The same internal exposure estimates would be appropriate for mixer/loaders, mixer/loader/applicators, or applicators.

Epidemiology Study of Ocular Health Among Alachlor Manufacturing Workers

During a chronic feeding study (MRID No. 00139021) with alachlor, Long-Evans rats were noted to develop severe ocular lesions at the highest test doses. Therefore, another study in Long-Evans rats was conducted to characterize the progression of the previously observed eye lesions (MRID No. 00141060). It was observed that females were more sensitive than males, and that once the uveal degereration syndrome was observed, it was irreversible.

To determine if human workers might be at risk of developing similar lesions, it was decided to conduct an ophthalmologic study which would focus on a human eye lesion that could be considered equivalent to the initiating eye lesion found in Long-Evans rats. Differences between Long-Evans rat and human eyes were considered to be minor; thus, an equivalence for the purpose of evaluating a potential effect of alachlor exposure among workers could be assumed. The uveal tract consists of the iris, ciliary body, and choroid. Long-Evans rats, like humans, have pigmented eyes and each uveal component has melanin-containing cells. The human equivalent of the initiating lesions, uveal pigment disruption and dispersion, is the clinically described Pigment Dispersion Syndrome (PDS). PDS consists of the loss of pigment from the mid-posterior iris with deposition of the pigment on the cornea, trabecular meshwork, lens, and iris.

The study site was the Muscatine, Iowa plant, which began operation in 1961. At Muscatine, herbicide production began in 1964, with the production of alachlor beginning in 1969. To determine whether there were ocular effects among exposed workers, a group of 135 highly exposed alachlor production workers were examined for the presence of PDS. There was a control group of 84 unexposed co-workers and relatives. All participants were examined by the same ophthalmologist at the University of Iowa. The ophthalmologist was unaware of the exposure status of the individual participants.

Components of the eye exam included slit-lamp biomicroscopy of the anterior chamber and a dilated exam of the lens and fundus with scleral depression as well as the routine functional exam. Intraocular pressure was measured prior to dilation. Only one study participant had eye defects meeting the study criteria of PDS. This person was in the control group. For eye abnormalities other than PDS, prevalence rates were similar for exposed and unexposed study participants.

Thus, no evidence of increased risk of ocular disease was found when workers were compared

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to controls. Only one subject, who was from the control group, had the same defect as reported in the study of Long-Evans rats. (MRID No. 43267501)

Epidemiologic Study of Workers

Monsanto performed an epidemiologic study of workers at an alachlor manufacturing plant in Muscatine, Iowa. The product has been manufactured in this plant since 1969. (MRID No. 43878501). The population studied included 1199 workers employed for 1 year or more between 1961 and December 1993. Both mortality and cancer incidence were assessed in this cohort. Mortality follow-up was by company records, social security number, national death index, credit agency, and state motor vehicle records. Follow-up for vital status was very successful, covering over 99% of the cohort. Death certificates were obtained for all 17 decedents.

Assessment of cancer incidence was conducted using the statewide cancer registry in Iowa which was initiated in 1969. Linking with the registry was by social security number, full name, and birth date. Inexact matches were verified by consulting with employee records and the State Health Registry. Workers who left Iowa (< 1/3 the cohort) did not have cancer incidence assessed but were assumed to be similar to those who remained in state.

Quantitative data were insufficient to estimate actual exposure at the plant. Qualitative estimates (high, medium, and low) were made by industrial hygienists based primarily on work history and the potential for dermal exposure. Alachlor's low vapor pressure and airborne measurements taken at the plant (averaging less than 10 ppb) suggest this route of exposure is not significant. The potential for contaminated water occurred between 1968 and 1975. In 1975 low levels of alachlor were detected in the plant's drinking water. However, when the alachlor first appeared in the drinking water is not known. Exposure characterization took into account the contaminated drinking water. Analysis both included and excluded this possibility due to the uncertainty associated with it. Twenty-six non-whites were excluded from the analysis due to inadequate sample size for statistical analysis. However, it was noted that no cancers occurred in this group where 0.1 cases would have been expected.

No deaths or incidence of cancer were reported for the stomach, thyroid, or nasal cavities, as reported in laboratory rats. The study did not find any evidence of statistically increased incidence or mortality from cancer either overall or by individual cancer site with one exception. The one statistically significant finding was based on two cases of chronic myeloid leukemia where only 0.1 cases would have been expected. The 95 percent confidence interval for the standardized incidence ratio was quite wide, 1.9 to 58.1. Given that this ratio is based on only two cases (one of whom had worked at the plant less than 5 years) and the number of statistical tests performed, this result should probably be considered a chance finding without other supporting evidence.

By completion of this study only 24 cancers and 8 cancer deaths had been reported in the entire cohort. The overall cancer mortality ratio (number of observed/expected cases) was 0.9 with a 95% confidence interval of 0.4 to 1.7. The overall cancer incidence ratio was 1.4 based on 24

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observed and 17.1 expected cases (95% confidence interval 0.9 to 2.1). For those workers categorized as having high exposure to alachlor (68% of the cohort), the cancer incidence ratio was 1.2 (95% confidence interval 0.7 to 2.0). The Agency concludes that while no appreciable hazard has been identified to date, one cannot rule out adverse effects in this cohort until these individuals have been followed-up over the course of a lifetime.

i. ESA Metabolite of Alachlor

The ethane sulfonic acid (ESA) metabolite of alachlor is variously referred to as MON 5775, 2',6'-diethyl-N-methoxymethyl-2-sulfoacetanilide, sodium salt or 2-[2,6-diethylphenyl (methoxymethyl) amino]-2-oxoethane sulfonic acid, sodium salt. The formation of alachlor ESA involves the displacement of a chlorine atom by a sulfonic acid moiety. The metabolic route leading to alachlor ESA is postulated to involve initial glutathione displacement of the chlorine atom, followed by successive degradation of the sulfur conjugated moiety through organic acid and methylsulfone intermediates, to ultimately form the sulfonic acid group as a terminal oxidative degradate. Alachlor ESA has always been isolated from natural matrices and synthetic preparations as a salt. The sodium salt has always been utilized for toxicology studies.

Alachlor ESA was originally identified as a metabolite of alachlor in soil (MRID No. 00134327). The alachlor ESA metabolite was determined to be 15 - 25% of the total applied radioactivity, making it the first or second most prevalent degradate in soil. Alachlor ESA has also been quantified in field soil dissipation studies following alachlor applications (MRID Nos. 42528002, 43774701). Low concentrations were detected, but alachlor ESA was not found to persist or leach below 18 inches.

Alachlor ESA has also been identified as a minor alachlor degradate in a laboratory aqueous sediment metabolism study (MRID No. 43774702). It has also been detected in water samples from Indiana (MRID No. 42479901) and Wisconsin (no MRID, submitted under FIFRA 6(a)(2)). In the Indiana well water samples, alachlor ESA concentrations ranged from <1.0 - 23.0 μg/L, and in Wisconsin they ranged from <1.0 - 26.7 μg/L.

Acute Toxicity

In an acute oral toxicity study in rats, the acute oral LD_{50} of alachlor ESA is greater than 6000 mg/kg. This is toxicity category IV (MRID No. 42701501).

Subchronic Toxicity

In a special 91-day drinking water study, male and female Fischer CDF® F-344 Crl BR VAF/Plus® rats from Charles River Laboratories, Inc. (Raleigh, NC) received either 0, 200, 2000, or 10000 ppm (male: 0 (control), 16, 157, or 896 mg/kg/day; female: 0 (control), 23, 207, or 1108 mg/kg/day) alachlor ESA. Systemic toxicity was observed in high dose male and female rats, with increased incidences of decreased activity with rapid/shallow breathing, few feces and feces small in

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size, dehydration, urine staining, emaciation, hunched posture, rough coat, unkempt appearance, and dark material/stain on pads of forelimb, around eyes, mouth and nose, clear and red ocular discharge, and hair loss around eyes. Slight decreased body weight gains (10%) were also noted in high dose male rats (decreased body weight gains were noted in all treated females; however, no dose response was noted). Several statistically significant hematological effects (decreased hemoglobin, hematocrit, red cells, increased MCH and MCHC) and clinical chemistry alterations (decreased AST, ALT, urea nitrogen, albumin, glucose, increased bilirubin and phosphorous) were observed at the mid and high dose in males and/or females, but were minor, mostly not dose related and were not considered biologically relevant, especially in the **absence** of any organ or tissue pathology at this dose. Eye lesions noted in this study were determined not to be related to treatment or to those lesions seen with the parent compound, alachlor. The clinical observations reported related to the eye are due to ocular abnormalities specific to the F-344 rat. The systemic toxicity NOEL was 2000 ppm (157 mg/kg/day in males and 207 mg/kg/day in females). The systemic toxicity LOEL was 10,000 ppm (896 mg/kg/day in males and 1108 mg/kg/day in females) based on increased incidence of clinical signs of toxicity in males and females, and decreased body weight gains in males (MRID No. 42863701).

Developmental Toxicity

In a prenatal developmental toxicity (teratology) study, female Sprague-Dawley Crl:CD®BR rats from Charles River Breeding Laboratories, Inc., (Portage, Michigan) received 0 (control), 150, 400, or 1000 (limit dose) mg/kg/day alachlor ESA (90.0% a.i.; Lot No.: NPD-9203-3974-T) in corn oil by oral gavage from days 6 through 15 of gestation, inclusive. Actual doses were 0, 135, 360, or 900 mg/kg/day based on 90.0% a.i. No maternal toxicity was noted in any measured parameter at the dose levels tested. The maternal toxicity NOEL is equal to or greater than 900 mg/kg/day and the maternal toxicity LOEL is greater than 900 mg/kg/day. No developmental toxicity was noted in any measured parameter at the dose levels tested. Therefore, the developmental toxicity NOEL is equal to or greater than 900 mg/kg/day, and the developmental toxicity LOEL is greater than 900 mg/kg/day (MRID No. 43908101).

Mutagenicity

In an Ames Salmonella mutagenicity assay, alachlor's ethanesulfonic acid, or ESA metabolite, did not cause increases in the reversion of four S. typhimurium strains (TA98, TA100, TA1535, and TA1537) in either the presence or absence of S9 activation at dose levels of 0.01 to 10.00 mg/plate under the conditions of two independent assays (MRID No. 00151398).

In a mouse micronucleus assay, groups of five male CD-1 mice received single oral gavage administrations of 500, 1000 or 2000 mg/kg alachlor ESA (90.7%). The test material was delivered to the animals in deionized water. Animals were sacrificed at 24 and 48 hours postadministration; bone marrow cells were harvested and 2000 erythrocytes per male were examined for the incidence of micronucleated polychromatic erythrocytes (MPEs). No overt toxicity for the treated animals or cytotoxicity for the target organ was observed up to the currently recommended limit dose (2000 mg/kg). The positive control induced the expected high yield of MPEs in the treated males. There

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was, however, no evidence that the test material induced a clastogenic or aneugenic effect at any dose or sacrifice time (MRID No. 43889403).

Metabolism

In a special metabolism study, two groups of male and female Long-Evans rats (two/sex/group) were administered alachlor ESA at a dose of 70 mg/kg by gavage. Group 1 rats were sacrificed 24 hours after treatment and Group 2 rats at 5 days after treatment. Disposition of alachlor ethane sulfonate was determined by collection of excreta and by whole-body autoradiography. Metabolism was assessed by HPLC analysis of processed urine and feces samples. The major route of excretion for alachlor ESA at 70 mg/kg was the feces, with 71-82% of the administered dose excreted by this route. Excretion was rapid with the majority of radioactivity excreted by 24 hours post-dose. HPLC analysis of urine and feces showed alachlor ESA to be the major component in both urine and feces, with three other components isolated but not identified, each comprising less than 2% of the dose. Autoradiographic data on alachlor ESA derived radioactivity at 14 hours postdose showed the major areas of localization were stomach contents, cecum, intestinal contents and urinary bladder. The data indicate that alachlor's ESA metabolite is poorly absorbed, rapidly excreted, and undergoes minor metabolism. (MRID No. 43889404).

Special Studies

In a special study, the proliferating cell nuclear antigen (PCNA) technique was utilized to determine the effect of treatment with 2000 ppm alachlor ESA (157 mg/kg/day for 91 days) on cell proliferation in the olfactory region at the second palatial ridge (Level III), where alachlor-induced tumors are found. Mean nasal cell proliferation values (number of labeled cells per mm of mucosal length) showed no statistically significant increases in cell proliferation in either the olfactory septum or turbinates of male Fischer 344 rats administered alachlor ESA in drinking water for 91 days. (MRID No. 43889401).

In a special study, glandular stomach tissue from female Fischer 344 rats treated with alachlor ESA in drinking water at a dose of 10,000 ppm for 91 days was evaluated using PCNA for evidence of a proliferative response or changes in mucosal thickness. A significant increase in the percentage of labeled cells in the fundic neck region was observed in treated rats, but there were no significant changes in labelling of the fundic base nor in mucosal thickness (MRID No. 43889402).

Conclusions

Table 6: Comparison of Alachlor and Alachlor ESA

Test	Alachlor	Alachlor ESA
Acute oral LD_{50}	930 mg/kg Toxicity category III	> 6000 mg/kg Toxicity category IV

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Table 6: Comparison of Alachlor and Alachlor ESA		
Test	Alachlor	Alachlor ESA
Subchronic Toxicity (1)	90 day invalidated feeding study	91-day drinking water study males NOEL = 157 mg/kg/day LOEL = 896 mg/kg/day females NOEL = 207 mg/kg/day LOEL = 1108 mg/kg/day
Developmental Toxicity	maternal NOEL = 150 mg/kg/day LOEL = 400 mg/kg/day developmental NOEL = 150 mg/kg/day LOEL = 400 mg/kg/day	maternal NOEL => 900 mg/kg/day LOEL > 900 mg/kg/day developmental NOEL => 900 mg/kg/day LOEL > 900 mg/kg/day
Mutagenicity	weakly mutagenic - tested positive in 2 UDS studies. Other alachlor metabolites also found to be weakly mutagenic	no mutagenic activity in two studies
Metabolism (2)	Absorption was essentially complete with alachlor being present in the blood at 24 hours and 5 days post dose. Alachlor excreted approximately equally between urine and feces.	Alachlor ESA is the major component in both urine and feces. Alachlor ESA is poorly absorbed, rapidly excreted (71-82% in the feces within 24 hours), and undergoes minor metabolism.

(1) The subchronic data available for comparison of alachlor with the ESA metabolite of alachlor are not by the same route of administration (in the diet for alachlor *per se* and in the drinking water for the ESA metabolite of alachlor). Also, the study with alachlor *per se* is an IBT study which was not validated nor repeated; therefore the data may be suspect. It is important to note that the subchronic and chronic toxicity studies with alachlor were conducted with different strains of rats ("Charles River Albino rats" vs Long-Evans rats) than the 91 day drinking water study (Fisher 344 rats); however, the available metabolism data do not show any major differences in the handling of the compounds in the Long-Evans versus the Fisher rats.

(2) The available *in vivo* metabolism data indicate that in comparison to alachlor, the alachlor ESA metabolite is poorly absorbed and metabolized to only a minor degree. The products of alachlor ESA metabolism were not identified. The available autoradiography data indicate that in comparison

to alachlor, its ESA metabolite does not show any significant localization to the nasal cavity, thyroid and glandular stomach (gastric mucosa). The available cell proliferation data indicate that in comparison to alachlor, alachlor ESA does not induce cell proliferation.

Overall, the data provided indicate that alachlor's ESA metabolite has less toxic potential than the parent alachlor.

Metabolism Committee Meeting for Alachlor ESA Metabolite

A Metabolism Committee meeting held 1/18/95 discussed the available toxicity data for the alachlor ethane sulfonic acid (ESA) metabolite.

The Metabolism Committee concluded the following:

- Since alachlor ESA is sulfonated, and highly polar, there is likely to be little absorption via the oral or dermal routes, and even if absorbed, it is expected to be readily excreted.
- Information has been provided by the Registrant which indicates toxicity of the parent is based in part on formation of the quinone imine.
- Formation of the potentially carcinogenic quinone-imine from alachlor ESA is unlikely if the metabolite occurs solely in the sulfonated form in the body, or if minimal cleavage to the unsulfonated form occurs.
- Because of the reasons cited above, alachlor ESA is unlikely to be carcinogenic in a 2-year bioassay.
- Alachlor ESA should, however, continue to be included in non-cancer dietary exposure estimates (for comparison to the RfD).
- Alachlor ESA was non-mutagenic in two studies.

2. Dose Response Assessment

a. Reference Dose

A Reference Dose (RfD) represents the quantity of a substance which if absorbed on a daily basis over a lifetime, is not expected to pose significant risk of adverse health effects.
The RfD for alachlor was first assessed on February 21, 1986. This RfD was subsequently verified by the Agency RfD Work Group on March 11, 1986, and again on March 27, 1991.

At that time the RfD was based on a NOEL of 1 mg/kg/day in a one year chronic dog study (MRID No. 00148923). The LOEL was 3 mg/kg/day based on hemosiderosis and hemolytic anemia. An uncertainty factor (UF) of 100 was used to account for interspecies extrapolation and intraspecies variability. The RfD was calculated to be 0.01 mg/kg/day.

The RfD Committee met on 8/19/93 (actual memo was signed 1/31/94) to discuss and reevaluate the RfD for alachlor. At this meeting, it was recommended that the RfD of 0.01

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mg/kg/day remain unchanged.

b. Dermal Absorption

The requirement for a dermal absorption study in the rat was waived, since data from three Rhesus monkey studies (MRID Nos. 00149403, 00149404, 00149405) were combined to determine the dermal absorption factor.

Three pharmacokinetic studies on Rhesus monkeys were performed: an intravenous route of administration study, dermal application of alachlor emulsifiable concentrate (EC), and a dermal application of alachlor micro-encapsulate formulation (Mcap). In all three studies, the levels of radioactivity were monitored in the blood for 7 days, and urine and feces for 9 to 14 days.

The purpose of the intravenous study was to determine the pharmacokinetics of alachlor distribution and elimination. Two monkeys/sex/dose were given single doses of 0.24 or 2.4 mg/kg/day. Alachlor was rapidly distributed in the blood (whole, plasma, and red blood cells) within the first 15 minutes, and rapidly eliminated in urine primarily within the first 24 hours. Approximately 93.3 percent of the low dose and 99.6 percent of the high dose were eliminated in excreta during the 10-day study period. The majority of this elimination was via the urine (82.1% low dose, and 91.4%, high dose).

In both the EC and the Mcap dermal studies, the formulations were tested undiluted and diluted (1:29 for EC and 1:17 for Mcap) with water, 2 monkeys/sex/formulation or dilution/EC or Mcap. The dosages (EC: 32 $\mu g/cm^2$ and 300 $\mu g/cm^2$; and Mcap 10.8 $\mu g/cm^2$ and 217 $\mu g/cm^2$) were applied to a 40 cm^2 skin area and were left on the skin for 12 hours before removal.

For the EC the rate of alachlor absorption was slow and reached a peak in the blood after 24 hours. The total dermal absorption in the low dose animals (32 $\mu g/cm^2$), estimated from excretion of radiolabel and retention of label in tissues, was 6-7% in males and 12-13% in females, uncorrected. However, calculation of the actual amount of test material absorbed through the skin was complicated by the fact that recovery of radiolabelled test material in this test group was poor, ranging from 21 to 77% of the nominal amount applied. Data were submitted demonstrating that up to 40% of the applied dose could apparently evaporate from skin (under conditions simulated in vitro) and that application error could result in application of up to 20% less than the nominal value. In the face of these uncertainties, values for excretion and absorption were calculated based upon the amount of radiolabel that was recovered. Using these correction factors, absorption was 10-24 % (low dose) in males and 16-20% (low dose) in females.

For the EC, recovery of radiolabel was better in the high dose animals (300 $\mu g/cm^2$), and application of a correction factor had little effect. Absorption was 4-9% in males and 10-11% in females.

It is also possible to estimate a percent dermal absorption by using a ratio of the corrected

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percent radiolabel excreted in urine after dermal application to the average percent radiolabel excreted in urine after intravenous administration, which is 87%. Using this ratio, the dermal absorption estimates for the low dose EC group were 9.2-24.8% for males and 16-21.8% for females. For the high dose EC group, the dermal absorption estimates were 4.7-8.9% for the males and 10.7-11.4% for the females. Thus, similar estimates of dermal absorption were obtained by either method of calculation.

For the Mcap, the total dermal absorption for the low dose (10.8 $\mu g/cm^2$) ranged from 3-23% in males and 6-7% in females. For the high dose (217 $\mu g/cm^2$) the total dermal absorption ranged from 2-4% in males and 3-4% in females. Percent dermal absorptions were also estimated using the ratio specified in the discussion of the EC group. Using this ratio, the dermal absorption estimates for the low dose Mcap group were 3.2-23.4% for males and 6.7-7.1% for females. For the high dose Mcap group, the dermal absorption estimates were 2-3.8% in males, and 2.2-3.9% in females. Again, similar estimates of dermal absorption were obtained by either method of calculation.

c. Cancer Classification

The carcinogenicity of alachlor was first evaluated by the Agency's Cancer Peer Review Committee on March 25, 1986. The information available at the time included two chronic rat studies, a special 2-year rat study for ocular lesions, and an 18 month mouse study, as well as historical control data on the mouse, several in vitro and in vivo mutagenic assays, and metabolism data.

The Committee concluded that the data available for alachlor was sufficient for a classification of B2, probable human carcinogen.

> Alachlor met all but one of the criteria specified for the B2 classification, any of which alone can be sufficient for such a classification. That is, alachlor produced an increased incidence in malignant, or combined malignant and benign, nasal turbinate tumors and (other tumor types) in Long-Evans rats in three different experiments at more than one dose level via dietary administration. Alachlor also produced a statistically significant increase in lung tumors in female CD1 mice at 2 dose levels. In a special experiment with Long-Evans rats, nasal turbinate tumors were observed at the end of the study (2 years), in rats that received alachlor for 5 - 6 months. The tumor incidence was as high as 50% and tumor site was unusual; i.e., not an increase of a normal high background tumor type. Additionally, a metabolite of alachlor was mutagenic in the Ames test at 6 dose levels.

On November 19, 1986, the Scientific Advisory Panel (SAP) upheld the B2 classification concluding that alachlor was a B2 carcinogen since it produced "an unusual type of neoplasm (nasal turbinate tumors) in the rat, coupled with the finding that two metabolites of alachlor are mutagenic."

The Committee reconsidered the classification on April 15, 1987, in light of the conclusions

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of the SAP and the registrant's rebuttal that alachlor should be classified as a C, possible human carcinogen. Upon reconsideration of the available data and review of the registrant's arguments and the SAP's decision, the Committee determined that alachlor's classification as a B2, probable human carcinogen, was appropriate; thus, corroborating the March 25, 1986, decision.

A low dose extrapolation model was applied to the animal data to calculate the cancer potency factor. The Q_1^* was calculated to be 0.08 $(mg/kg/day)^{-1}$. This information was verified and then entered into the Agency's Integrated Risk Information System (IRIS).

As part of the Agency's peer review process, alachlor was reconsidered by the Agency's Carcinogenicity Peer Review Committee on September 27, and October 3, 1995, and January 3, 1996. The registrant, Monsanto, voluntarily provided new data to the Agency consisting of a new mouse carcinogenicity study, additional mutagenicity studies, mechanistic data, special metabolism, pharmacokinetic, and cell proliferation studies in support of a request for re-classification of the carcinogenic potential of alachlor. These new data were reviewed by the Agency with respect to the proposed mechanism(s) for induction of nasal, gastric, and thyroid tumors in the rat. The rat tumors were considered to be the most relevant to alachlor risk assessment. The type of lung tumor in the mouse is a common tumor. Since, in one of the mouse studies, the lung tumors were higher in the males, and in the other mouse study the lung tumors were higher in females, it is possible that this is a random event.

Upon evaluation of all of the submitted data regarding the carcinogenicity potential of alachlor and consideration of the full weight-of-the-evidence, the Committee could not reach a consensus as to the classification of alachlor as a carcinogen. Therefore the Committee recommended to defer the carcinogenicity classification of alachlor and reconsider the classification at a later date, using the new Cancer Assessment Guidelines when such guidelines are in effect. In addition, the Committee recommended not to utilize the linear low dose approach, but to utilize the Margin of Exposure (MOE) methodology for the estimation of human risk. The Committee concluded that the data in support of the mechanism for the nasal turbinates is indicative of a rat specific response. Although the rat and human were recognized to possess the same enzyme(s) involved in production of the putative toxic species from alachlor, it was also recognized that the activity of these enzymes was substantially greater in the rat compared to the human. Thus, the model of rat nasal tumorigenesis may not be relevant for human cancer assessment. Thyroid tumors have been proposed to be the result of induction of hepatic glucuronyl transferase with subsequent decrease in circulating T3 and T4, a subsequent increase in TSH, and eventual hyperplastic response of the thyroid. The mechanistic data for thyroid tumor formation meet the criteria established by the Agency and the use of the MOE approach for human cancer assessment is consistent with Agency policy. The Committee stated that the stomach tumor formation was a direct contact effect, non-genotoxic mechanism which parallels human pathological conditions. These tumors result from an indirect response to change in pH. The use of the MOE approach for human cancer assessment was consistent with Agency policy.

On October 30, 1996, the SAP met to consider the weight-of-evidence for alachlor. The SAP was asked to comment on mode of action data, provided by the registrant, for the tumor types in the

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rat associated with administration of alachlor. The Committee met on February 5, 1997, to discuss and evaluate the weight-of-the-evidence on alachlor with particular reference to its carcinogenic potential and to consider the comments from the SAP. The SAP and the Committee conclusions on the tumors induced by alachlor in the rat are summarized as follows:

> Thyroid tumors: Both the SAP and the Committee agreed that the Agency requirements for demonstrating a hormonal mode of action were met by the registrant and that the tumors were observed only at an excessive dose.
>
> Stomach: Evidence was presented that the carcinomas resulting from alachlor were examined to prove that they were carcinoids, not adenocarcinomas or gastric sarcomas, and that these carcinoids are probably related to the proposed gastrin-induced effect. Based on additional information, the evidence alluded to was based on the butachlor study and that the tumors in the alachlor study are considered to be carcinoids. According to the investigators: The alachlor-induced stomach tumors were evaluated microscopically and histochemically by the same scientists involved in the pathological/mechanistic investigations with butachlor (MRID No. 44032101). They concluded that the tumors were gastric carcinoid, stating that the alachlor-associated gastric tumors are poorly differentiated gastric carcinoids, histologically and histochemically resembling the gastric tumors reported with butachlor exposure. Results of these studies indicate that the pathogenesis and progression of the gastric tumors, and the response of the fundic mucosa, are identical with both alachlor and butachlor. Although the tumor increases were significant only at the highest dose (excessive), it was noted that there was also 1 tumor (vs 0 in controls) at the mid-dose (which was considered to be adequate, not excessive) and this is a rare tumor type.
>
> Nasal tumors: The SAP considered these possibly relevant to humans but only at exposures in excess of anticipated human exposures for pesticide use. The Committee considered these tumors relevant to humans (with a quantitative difference). There also was 1 tumor at the mid-dose (not excessive) and this too is a rare tumor type.

In accordance with the EPA proposed Guidelines for Carcinogen Risk Assessment (April 23, 1996), alachlor was characterized as "likely" to be a human carcinogen at high doses, but "not likely" at low doses, by all routes of exposure. This conclusion was based on increased incidences of malignant and combined benign/malignant multiple tumor types in both sexes of the Long Evans rat, which occurred mainly at higher doses. Based on a consideration of modes of action for these tumors, the Committee agreed that a non-linear margin of exposure (MOE) approach should be used for the purpose of risk assessment. The consensus of the Committee was that MOEs for both the malignant mixed gastric tumors and the nasal adenomas be presented for a risk management decision.

The Committee recognizes that while the response occurs only at higher doses and quantitative differences exist in sensitivity between rats and humans, a similar mechanism for nasal tumor production is present in humans, and therefore its relevance to humans cannot be dismissed. The SAP agrees with this position. The rarity of the nasal tumor type and analysis of the structure

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activity relationships also adds to the Committee's concern. The presence of stomach tumors, which are also considered a rare tumor type, and the lack of a consistent histopathologic response, leads to the conclusion that some hazard potential may exist in humans after intense exposures. Clarification of the similarity or dissimilarity of the relevance of the rat stomach tumors could shed light on this uncertainty. The Committee agrees that the rat stomach tumors are relevant to humans at this time. The Committee agrees with the SAP in that thyroid tumor induction may be relevant to humans, but that the tumors in rats were seen at an excessive dose.

Since these are considered rare tumor types, for purposes of risk assessment, the MOE for the nasal tumors should be determined with 0.5 mg/kg/day as the "point of departure" as no tumor response was seen at this dose level. (Tumors were present at the next highest tested dose level, females at 2.5 mg/kg/day, in the 1983 rat study for nasal tumors). The MOE for the stomach tumors should be determined with 14 mg/kg/day as the "point of departure" as no tumor response was seen at this dose level. (Tumors were present at the next highest tested dose level, females at 42 mg/kg/day, in the 1981 rat study for stomach tumors). While not statistically significant at these next higher dose levels, the Committee considered tumor presence biologically significant due to their rarity in rats. Thyroid tumors were observed only at an excessive dose; therefore, no "point of departure" was determined.

d. Other Toxicological Endpoints

The toxicological effects of a pesticide can vary with different exposure durations. The Agency considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments are necessary to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include "acute", "short-term", "intermediate term", and "chronic" risks. These assessments are defined as follows:

> Acute risk results from a one day or single event consumption of food and water, and reflects toxicity which could be expressed following oral exposure to the pesticide residues. High-end exposure to food and water residues are assumed.
>
> Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from occupational pesticide applications. Since enaction of FQPA, this assessment has been expanded. The assessment will be performed when there are primary dermal and inhalation exposures that result from residential or occupational exposures lasting from 1-7 days. However, the analysis for residential exposures will now address both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In a short term assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this

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occurring in most cases, and because the other assumptions built into the assessment assure adequate protection of public health.

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

An Agency Committee of toxicologists and scientists met three times to select the appropriate endpoints for use in the alachlor risk assessment. The results of the latest meeting of that Committee on May 14, 1996, are presented below.

Acute Dietary Assessment:

As part of the dose-response assessment, the Agency's toxicologists review the available database to determine the endpoints of concern. For alachlor, there is no concern for an acute dietary assessment since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route. Therefore, this assessment for a one day high-end dietary exposure is not required.

Short-Term (1 to 7 days) Occupational Exposure Assessment:

This assessment is required. The NOEL to be used for calculating the MOE (Margin of Exposure) is 150 mg/kg/day from a rat developmental toxicity study (MRID No. 00043645). (The LOEL was 400 mg/kg/day based on maternal hair loss, soft stools, anogenital staining, increased mortality, increased post-implantation loss and a reduced number of live fetuses.) The rat developmental toxicity study was chosen instead of the rabbit development toxicity study since the effects in the rat developmental toxicity study were more indicative of toxicity (clinical signs and body weights) versus those in the rabbit developmental toxicity study (body weights). Since the selected NOEL is from a gavage study, the dermal exposure will need to be adjusted by the dermal absorption factor to convert to oral-equivalents. Since the selected NOEL is from a developmental study, the appropriate population subgroup is females 13+ years old.

For all occupational scenarios, the Agency has no concerns for an MOE in excess of 100 for non-cancer effects when the NOEL used in calculating the MOE is from an animal study.

Intermediate-Term (1 week to several months) Occupational Exposure Assessment:

This assessment is required. The NOEL to be used for calculating the MOE is 50 mg/kg/day from a 21-day dermal toxicity study (MRID No. 00147328). (The LOEL was 300 mg/kg/day based on hematological and clinical chemistry changes.) Since the selected NOEL is from a dermal study,

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the dermal exposure will not need to be adjusted by the dermal absorption factor. The selected NOEL is from a dermal study; therefore, it could be considered inappropriate to use the total dose (combined dermal and inhalation exposure) in the MOE calculation. However, in the case of alachlor, the inhalation component is insignificant when compared to the dermal, so the combined total is essentially a dermal exposure.

For all occupational scenarios, the Agency has no concerns for an MOE in excess of 100 for non-cancer effects when the NOEL used in calculating the MOE is from an animal study.

Long-Term (several months to lifetime) Occupational Exposure Assessment:

As part of the hazard assessment process an endpoint of concern was determined for the chronic occupational assessment. However, during the exposure assessment process, the exposures which would result from the use of alachlor were determined to be of an intermittent nature. The frequency and duration of these exposures do not exhibit a chronic exposure pattern. The exposures do not occur often enough to be considered a chronic exposure, i.e. a continuous exposure that occurs for at least several months. Therefore, performing a long-term occupational assessment is not appropriate.

If a chronic scenario can be identified, then this assessment is required. The NOEL to be used for calculating the MOE is 1 mg/kg/day from a 1-year dog study (MRID No. 00148923). (The LOEL is 3 mg/kg/day based upon signs of hemosiderosis and hemolytic anemia.) Since the selected NOEL is from an oral (capsules) study, the exposure will need to be adjusted by the dermal exposure factor.

For all occupational scenarios, the Agency has no concerns for an MOE in excess of 100 for non-cancer effects when the NOEL used in calculating the MOE is from an animal study.

Residential

Alachlor is a restricted use pesticide; therefore, alachlor can be used only by certified applicators and cannot be purchased or used by the general public. The Agency has not identified any alachlor products that are intended for home use, or uses in/around schools, parks, or other public areas. Therefore, residential assessments are not appropriate.

Inhalation

A separate risk assessment for inhalation exposure will not be performed. The inhalation exposure will be added to the dermal exposure, thus implicitly assuming 100% inhalation exposure.

Percent Dermal Absorption:

A dermal absorption factor of 24% as determined from the three rhesus monkey studies

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(MRID Nos. 00149404, 00149403) will be used to adjust dermal exposures when compared to a NOEL from an oral study.

Chronic Dietary:

The RfD is the traditionally selected endpoint for chronic dietary risk. As previously discussed, the RfD for alachlor was determined to be 0.01 mg/kg/day. The aggregate dietary assessment will consider both food and water. As previously stated, there is no chronic residential assessment to aggregate with the chronic dietary assessment.

Carcinogenic Dietary MOE Approach:

A carcinogenic assessment is required for the dietary and/or drinking water scenario. It is likely that individuals will consume alachlor residues throughout their lifetime in the food and water consumed.

Given that these are rare tumor types, the MOE for the nasal tumor should be determined using 0.5 mg/kg/day as the dose "point of departure". No tumor response was seen at this dose level. Nasal tumors were present at the next highest dose level (2.5 mg/kg/day) in the 1983 rat study for nasal tumors. The MOE for the stomach tumors should be determined using 14 mg/kg/day as the dose "point of departure" as no tumor response was seen at this dose level. Stomach tumors were present at the next highest dose level (42 mg/kg/day) in the 1981 rat study for stomach tumors. Thyroid tumors were observed only at an excessive dose; therefore, no "point of departure" was determined.

Carcinogenic Dietary Q_1^* Approach:

A carcinogenic assessment is required for the dietary and/or drinking water scenario. It is likely that individuals will consume alachlor residues throughout their lifetime in the food and water consumed. The Q_1^* of 0.08 $(mg/kg/day)^{-1}$ will be used for assessing dietary cancer risk, assuming a linear approach.

Carcinogenic Occupational MOE Approach:

The Agency's Cancer Peer Review Committee recommended not to use the linear low dose approach, but to utilize the MOE methodology for estimation of human risk. The MOE methodology is consistent with a non-linear mechanism which requires continuous exposure. Thus, the likelihood of a positive carcinogenic response depends on the duration of the exposure as well as the magnitude of the exposure.

It is not appropriate to calculate a carcinogenic MOE for the occupational scenario, as there are no chronic/long-term exposure scenarios for the application of alachlor. Calculation of a carcinogenic MOE for agricultural workers based on intermittent exposure is not appropriate.

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Carcinogenic Occupational Q_1^* Approach:

Unlike the MOE approach to carcinogenic risk assessment, the Q_1^* approach assumes that any exposure could result in tumor formation. Thus, this type of assessment could be performed for an intermittent exposure. However, the scientific validity of the MOE approach for carcinogenic risk assessment of alachlor has been documented. Alachlor was classified as "likely" to be a carcinogen at high doses, but "not likely" at low doses. It is only the policy on determining an appropriate regulatory level that has not been fully developed by the Agency. Since, performing a carcinogenic MOE risk assessment for the occupational scenario is not appropriate, a Q_1^* carcinogenic occupational assessment for comparison purposes is not necessary.

e. Determination of the FQPA 10X Safety Factor

FQPA directs the Agency to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue in setting and reassessing tolerances. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

In determining what safety factor is appropriate for assessing risks to infants and children, EPA considers all available reliable data and makes a decision using a weight-of-evidence approach. This approach takes into account the completeness and adequacy of both the toxicity (hazard) and exposure databases.

The Agency's FQPA Safety Factor Committee met on March 30, 1998, to evaluate both the hazard and exposure databases for alachlor and determine the removal, retention, or reduction of the FQPA Safety Factor (as required by FQPA), to ensure the protection of infants and children from exposure to alachlor. Based on a weight of the evidence approach, the Committee determined that the 10x Safety Factor for enhanced sensitivity to infants and children (as required by FQPA) should be **removed**. This decision was based on the following information:

Hazard Consideration - Determination of Susceptibility

There is no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to alachlor. In the prenatal developmental toxicity studies in rats and rabbits and the multi-generation reproduction study, effects in the offspring were not observed at levels which resulted in evidence of parental toxicity.

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Hazard Consideration - Adequacy of the Toxicological Database

There are **no data gaps** for the assessment of the effects of alachlor following *in utero* and/or postnatal exposure. Based on the toxicity profile for alachlor, a developmental neurotoxicity study in rats is not required.

Exposure Consideration - Dietary (Food)

The established alachlor tolerances are expressed as "alachlor and its metabolites." The current enforcement method measures alachlor and its metabolites containing the DEA and HEEA moieties. There are several other classes of alachlor metabolites that are not included in the tolerance expression.

Alachlor is a herbicide, generally used pre-emergence or early postemergence. Residues are systemic. Rotational crop tolerances are needed indicating that residues remain in the soil for at least a year after use.

Anticipated residues were used in the alachlor chronic and carcinogenic dietary exposure assessment. Anticipated residues for alachlor were based on the average residues found in field trials where alachlor was used at the maximum typical application rate and weighted for the percent of use at each application timing (i.e., preemergence vs. postemergence). Adequate information on percent of crop treated is available for all crops. Up to 35% of corn and lima beans are treated, and up to 15 % of soybeans. Lesser amounts of other crops are treated (e.g., <5% of peanuts). These percentages are down from 10 years ago (when 62% of peanuts were treated).

Since the dietary exposure assessment is based on field trial data, the anticipated residues are likely to overestimate the dietary exposure because application rates and timing assumed in the dietary exposure analysis are conservative, and residues are likely to degrade after the farm gate where field trial samples are obtained. Crops contributing most highly to the dietary exposure for both adults and children were legumes (beans and soybeans) and milk, followed by corn.

Exposure Consideration - Dietary (Drinking Water)

Estimates of alachlor concentrations in ground water are based on the National Alachlor Well Water Survey (NAWWS). These samples represent approximately 6 million wells from which approximately 20 million people draw their drinking water. Reported values are for alachlor per se. No degradates of alachlor were analyzed in the NAWWS. NAWWS data are considered to be of high quality, and because of the statistical design of the survey, are also considered to be the best available data concerning alachlor per se residues in ground water.

Estimates of alachlor concentrations in surface water are also based on available monitoring data. Additionally, in surface water, there is some monitoring data available for the alachlor ESA degradate. Concentrations are reported as time weighted mean concentrations (TWMC) which

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reflect "amortization" of periods of high and low concentrations. Therefore, annual TWMCs (calculated using at least one year of sampling data) are the most appropriate values to use for estimation of chronic exposure to alachlor in drinking water.

The information available to the Agency, a partial toxicological database, indicates that the alachlor ESA degradate is of lower toxicity than the parent. But, the Agency does not have toxicological databases on all degradates of alachlor. However, based on metabolism studies and knowledge of the chemical structures of the degradates, the Agency does not believe that the toxicity of the degradates would exceed that of alachlor. Therefore, the Agency will assume that structurally similar alachlor degradates are no more or no less toxic than alachlor. The Agency has used the available exposure data on alachlor and alachlor ESA to determine that 4% of the RfD is occupied by food and water (children 1 - 6 years). Even if many of the alachlor degradates were present, it is not likely that the RfD would be exceeded.

Exposure Consideration - Residential (Non-occupational, Non-dietary) Uses

Alachlor is a restricted use pesticide; and therefore, can only be used by certified applicators and cannot be purchased or used by the general public. The Agency has not identified any alachlor products that are intended for residential use.

Decision of the FQPA 10X Safety Factor Committee

Based on their consideration of the above hazard and exposure databases, the Agency's FQPA 10X Safety Factor Committee recommended that the **10x factor** for enhanced sensitivity to infants and children (as required by FQPA) should be **removed.** The rationale for this decision is summarized below:

- # There was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to alachlor. In the prenatal developmental toxicity studies in rats and rabbits and the multi-generation reproduction study, effects in the offspring were not observed at levels which resulted in evidence of parental toxicity.
- # The toxicology data base for alachlor is complete. The toxicity profile does not indicate the need for a developmental neurotoxicity study.
- # The use of generally high quality data together with conservative models in the exposure assessment provided adequate protection for infants and children.
- # Alachlor is not currently registered for any residential uses.

3. Exposure Assessment

a. Dietary Exposure

The residue chemistry database includes information on the pesticide residues found in plants and animals, the levels of the detected pesticide residues, and a description of the analytical methods

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used. Residue chemistry data are used by the Agency to determine the residues of concern and to establish tolerances in food and feed. Tolerances are pesticide residue levels that should not be exceeded in or on a raw agricultural commodity in the channels of interstate commerce when the pesticide is applied according to label directions. Tolerances for residues of alachlor in/on raw plant commodities, and in animal commodities are currently expressed in terms of the combined residues of alachlor and its metabolites (calculated as alachlor) (40 CFR §180.249). These tolerances are set at 0.02-3.0 ppm. No food/feed additive tolerances have been established for alachlor residues of concern.

The residue chemistry database for alachlor is adequate and will support reregistration eligibility.

Nature of the Residue - Plants: OPPTS GLN 860.1300 (formerly 171-4a)

The qualitative nature of the residue in plants is adequately understood. Studies with corn and soybeans indicate that alachlor is readily absorbed from soils and translocated throughout the plant. Very little alachlor is translocated from the foliage. Metabolism involves the displacement of chlorine by oxygen or sulfur nucleophiles, hydroxylation at the 1- position of the ethyl group, and conjugation of the metabolites with sugar. The terminal residues to be regulated are those metabolites which can be hydrolyzed under basic conditions to 2,6-diethylaniline (DEA) and 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA). (MRID Nos. 00026221, 00081314, 00131424).

The alachlor ESA metabolite was identified as one of many alachlor metabolites present in these crops. Since alachlor ESA is converted to diethylaniline (DEA) by the alachlor crop residue methodology, it has been quantified in the crop residue analyses conducted for alachlor and is therefore included in the existing crop tolerances listed at 40 CFR § 180.249.

The chemical structures of representative metabolites are presented in Figure A.

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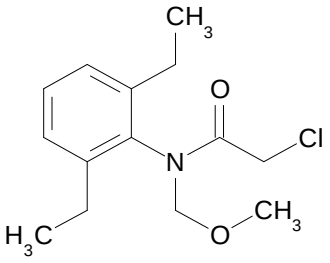
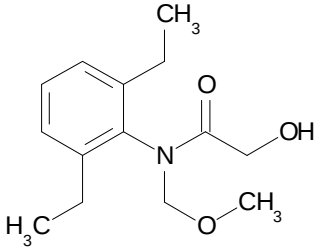
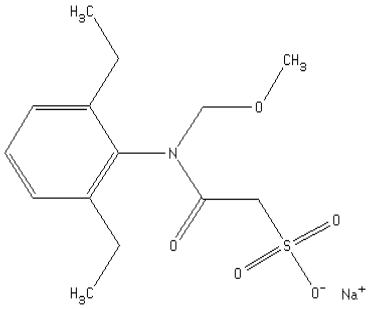
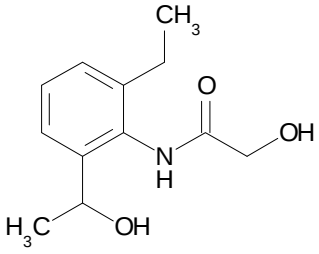
Figure A. The Chemical Structures of Representative Metabolites of Concern of Alachlor.

Common Name Chemical Name	Chemical Structure
alachlor 2-chloro-2',6'-diethyl-N-(methoxy-methyl)acetanilide	
alachlor alcohol metabolite (A-23) N-[(2,6-diethyl)phenyl]-N-methoxymethyl-2-hydroxyacetamide	
alachlor ESA metabolite MON 5775, 2',6'-diethyl-N-methoxymethyl-2-sulfoacet anilide, sodium salt or 2-[2,6-diethylphenyl (methoxymethyl) amino]-2-oxoethane sulfonic acid, sodium salt.	 Alachlor ESA
A-11 N-{[2-ethyl-6-(1-hydroxyethyl)]phenyl}-2-hydroxyacetamide	

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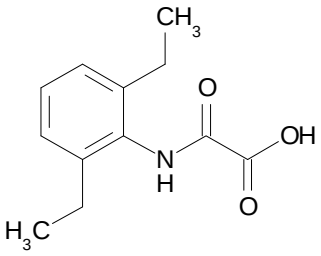
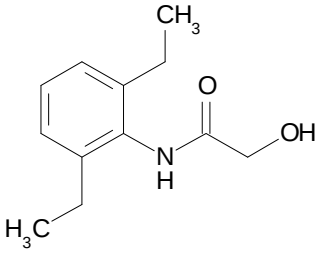
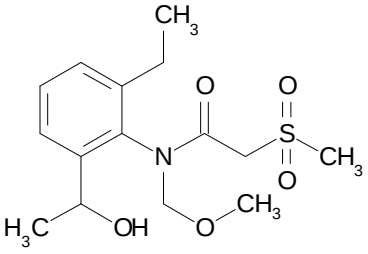
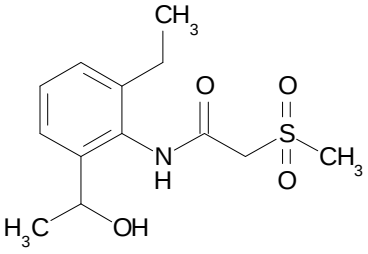
A-18 N-[(2,6-diethyl)phenyl]oxanilic acid	
A-20/AP-7 N-[(2,6-diethyl)phenyl]-2-hydroxyacetamide	
alachlor sulfone metabolite (S-24) N-{[2-ethyl-6-(1-hydroxyethyl)phenyl}-N-methoxymethyl-2-(methyl-sulfone)acetamide	
S-16 N-{[2-ethyl-6-(1-hydroxyethyl)]phenyl}-2-(methyl-sulfone)acetamide	

Nature of the Residue - Livestock: OPPTS GLN 860.1300 (formerly 171-4b)

The qualitative nature of the residue in animals is adequately understood. Studies involving lactating goats and laying hens fed an alachlor alcohol or sulfone metabolite indicate that metabolism of alachlor in hens and ruminants is similar. After displacement of chlorine, metabolites undergo loss of the methoxymethyl group, hydroxylation of the ethyl side-chain(s) usually at the 1- position, and formation of glucuronide conjugates. (MRID Nos. 00137777, 00137778, 00147472, 00147473, 40393901, 40394001, 42594901, 42594902, 42594903, 42594904)

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In animals dosed with technical alachlor, alachlor's ESA metabolite was identified as a metabolite of alachlor in rat, mice, or monkey metabolism studies. (MRID Nos. 00132045, 42852107, 42931101, 42852106, 00154238, 40000901). The initial chlorine displacement step involving glutathione catalyzed by glutathione transferase has been firmly established in these mammals. Methylsulfone and sulfur-conjugated organic acids have been shown to arise from further metabolic conversion of the glutathione adduct in rats and monkeys. Although the initial metabolism of alachlor in mammals is oxidative conversion of the sulfur atom, the metabolic product is not alachlor ESA.

Livestock metabolism studies which included alachlor ESA as one of the dosed components were performed (MRID Nos. 00147472, 00147473). Results from these experiments demonstrated that alachlor ESA was excreted by the animals unchanged, largely via the feces (goats). It did not accumulate in edible tissues.

The residues to be regulated are those metabolites which can be hydrolyzed under basic conditions to 2,6-diethylaniline (DEA) and 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA). See Figure A.

Residue Analytical Methods: OPPTS GLN 860.1340 (formerly 171-4c,d)

Three GLC methods, Methods I(a), I(b), and II, are currently available in the Pesticide Analytical Manual (PAM) Vol. II for the enforcement of tolerances for alachlor residues of concern; however, these methods do not recover 1-HEEA-yielding metabolites. An HPLC method, which determines DEA- and 1-HEEA-yielding metabolites has been validated by the Agency and is considered acceptable for enforcement purposes for plant commodities. The method uses HPLC with oxidative coulometric electrochemical detection of both DEA- and 1-HEEA-producing residues, and was recommended for inclusion in PAM Vol. II as Method III; the limit of detection is 0.01 ppm for each metabolite class. (MRID Nos 00023663, 00093160, 00148285, 00149999, 00152197, 00154237, 00154332, 00155732, 00159793, 00159796, 00162939, 40039901, 40040301, 40040401, 40271801, 40271802, 40529201, 40558001, 40820601, 41916001, 42086001, 42192501, 42286701, 42286702, 42308701, 42349101, 43140001, and PP#9F0740)

Multiresidue Methods: OPPTS GLN 860.1360 (formerly 171-4m)

The FDA Pestrak database (PAM Vol. I, Appendix II, dated 11/90) indicates that alachlor, per se, is completely recovered through Multiresidue Protocols D and E. In addition, multiresidue protocol testing of five alachlor metabolites has been submitted and forwarded to FDA (MRID No. 41949601).

Storage Stability Data: OPPTS GLN 860.1380 (formerly 171-4e)

Adequate storage stability data are available for corn, peanuts, soybeans and their processed commodities, for sorghum, and for animal commodities. Residues of alachlor metabolites are stable

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during frozen storage (<-18 °C) in/on corn forage and fodder, sorghum grain, forage, and fodder, and soybeans for up to 1394 days. Residues of alachlor metabolites are stable during frozen storage in/on sunflower seeds for up to 280 days and in the processed commodities of sunflowers for up to 91 days. These storage stability data can be translated to all crops for which alachlor is currently registered. (MRID Nos. 00149406, 00150090, 00152198, 00152868, 00154237, 40491101, 40628301, 40946901, and 42239501)

Crop Field Trials: OPPTS GLN 860.1500 (formerly 171-4k)

The conclusions regarding the reregistration eligibility of alachlor are based on the use patterns registered by the basic producer, Monsanto Corporation.

Some of the data used in support of existing or proposed tolerances were generated at Craven Laboratories. The Agency determined that it would not rely on Craven data for regulatory decisions, and identified the data that would need to be replaced. However, replacement of the Craven generated magnitude of the residue data were not required for soybeans, provided postemergence and sequential uses on soybeans were removed from all alachlor labels. At this time these use patterns have been deleted from the label.

Data for magnitude of the residue in sorghum grain, forage, and fodder have been evaluated and deemed adequate. Data are available to support the G formulation of alachlor on sweet corn applied preplant incorporated and preemergence at up to 4 lb ai/A. Data are available to support the use of the Mcap/G formulation on sweet corn: preemergence and preplant incorporated and postemergence at 4 lb ai/A. Data have been submitted to support use of the Mcap formulation on corn at 4 lb ai/A preemergence followed by 2 lb/A when used as a sequential application for early postemergence (before the corn is 5" high). The maximum single application rate is 4 lb ai/A.

Additional field residue data are no longer required for beans (dry and succulent), to support pre-emergence uses; for field corn grain, forage, and stover, to support sequential uses of the EC formulation; for sweet corn (K+CWHR) and sweet corn forage and stover to support postemergence and sequential uses of the EC formulation and uses in excess of 4 lb ai/A/season; and for peanuts to support postemergence and sequential uses. Monsanto has elected to delete these uses rather than generate additional residue data at this time. The labels have been changed to reflect these changes.

The proposed tolerances for soybeans and soybean aspirated grain fractions must be revised; higher tolerances are required. Tolerance petitions for bean vines and hay, corn forage and fodder, peanuts, peanut hulls, and sorghum forage are pending. (MRID Nos. 00022988, 00023664, 00023665, 00024526, 00025262, 00026995, 00028556, 00028557, 00028558, 00035389, 00035390, 00035391, 00035395, 00035399, 00068044, 00068045, 00081311, 00147475, 00148285, 00152197, 00152199, 00155732, 00159793, 00159796, 00159936, 41083801, 40039901, 40040301, 40189701, 40271801, 40341201, 40502101, 40511201, 40511301, 40511901, 40662601, 40820601, 41083801, 41862901, 41916301, 42309001, 42313301, 42348901, 42348902, 42349101, 42741601, 42741601, 42929901, 42971701)

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Feeding restrictions have been established for peanut vines and hay, and soybean forage and hay; therefore, the established tolerances for these commodities should be revoked. Note that Monsanto will be submitting data to support sunflower and cotton. Tolerances will need to be established for these commodities.

Processed Food/Feed: OPPTS GLN 1520 (formerly 171-4l)

No food or feed additive tolerances for alachlor are needed on any processed product of any commodity for which alachlor is currently registered. However, all data submitted for magnitude of the residue in processed food/feed have been evaluated and deemed adequate. (MRID Nos. 00148285, 00152197, 00154239, 00154240, 00162937, 00162939, 40040401, 40271802, 40788201, 40947101, 41856301, 41862901, 41916301, 42302001, and PP#0F2313/FAP#1H5612)

Reduction of residue data were submitted for dry beans and peanuts as required by a June 9, 1986, DCI. Residues were determined in canned beans, peanut butter, dry and oil roasted peanuts following commercial processing. A processing factor of 0.2x was determined for canning beans. Processing factors of 0.70x, 0.75x, and 0.83x were determined for peanut butter, dry roasted peanuts, and oil roasted peanuts, respectively. These factors will be used for the determination of anticipated residues for alachlor.

Limited monitoring studies were submitted for peanut butter and infant soy formula. Three major brands of peanut butter were collected in major cities across the US in 1989 in 2 studies. Of the 192 samples collected, 89% had detectable residues of alachlor metabolites. The average residue found was 0.029 ppm alachlor equivalents (with no correction for percent crop treated). In another study, several samples of 2 major brands of soy formula were collected in 9 major cities across the US. No detectable residues of alachlor DEA or HEEA metabolites were found (LOD=0.01 ppm) in any of the 1,398 samples. (MRID Nos. 40330301, 40820601, 40820701, 42158601, 42276701, 42300701, 42309001).

Meat, Milk, Poultry and Eggs: OPPTS GLN 860.1480 (formerly 171-4j)

Data for magnitude of the residue in meat, milk, poultry, and eggs have been evaluated previously; however, the adequacy of the data could not be assessed because at that time the qualitative nature of the residue in animals was not adequately understood. These data were generated from feeding studies in which dairy cattle and poultry were dosed with of a mixture of DEA- and 1-HEEA-yielding metabolites (60% DEA-yielding and 40% 1-HEEA-yielding metabolites) at approximately 4, 12, and 40 ppm. Tissues, milk, and eggs were analyzed for residues of DEA- and 1-HEEA-yielding metabolites and residues were expressed as alachlor equivalents. The maximum residues of DEA-yielding metabolites were 0.9 ppb in milk, 1.0 ppb in fat, 6.2 ppb in kidney, 3.6 ppb in liver, and 0.8 ppb in muscle, and the maximum residues of 1-HEEA-yielding metabolites were 1.6 ppb in milk, 1.5 ppb in fat, 5.4 ppb in kidney, 6.8 ppb in liver, and 1.1 ppb in muscle of dairy cattle fed at approximately 12 ppm (1.7x the maximum expected dietary burden). The maximum residues of DEA-yielding metabolites were 1.0 ppb in eggs, <0.5 ppb (nondetectable) in fat, 1.0 ppb in kidney,

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1.1 ppb in liver, and <0.5 ppb in muscle, and the maximum residues of 1-HEEA-yielding metabolites were 7.8 ppb in eggs, <0.5 ppb in fat, <1.0 ppb (nondetectable) in kidney, <1.0 ppb in liver, and 0.5 ppb in muscle of poultry fed at 4 ppm (approximately 2x the maximum expected dietary burden) (MRID Nos. 00149406, 00150090, 00152198, and 00152868).

These results support the established tolerances of 0.02 ppm for eggs; milk; and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry and sheep. The maximum expected dietary burdens of alachlor residues for cattle and poultry are calculated below; soybean forage and hay, and peanut vines and hay were not included in this calculation since feeding restrictions have been established for these commodities and tolerance revocations have been recommended.

Table 7: Calculated Dietary Burdens

Commodity	Percent in Diet	Percent Dry Matter	Tolerance[1]	ppm (in diet)
Cattle:				
Field corn grain	30	0.88	0.2	0.07
Bean vines	25	0.35	5	3.6
Soybean hulls	25	0.90	5	1.4
Soybean grain dust	20	0.85	10	2.4
Dietary Burden				Total = 7.5
Poultry:				
Soybeans	50	--	1	0.5
Soybean meal	20	--	1	0.2
Soybean grain dust	20	--	10	1.0
Corn Grain	10	--	0.2	0.02
Dietary Burden				Total = 1.8

1 In cases where tolerance proposals are required or pending, appropriate tolerance levels from the Tolerance Reassessment Summary were used.

Water, Fish, and Irrigated Crops: OPPTS GLN 860.1400

Alachlor is not registered for direct use of water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

Food Handling: OPPTS GLN 860.1460

Alachlor is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

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Confined Accumulation in Rotational Crops: OPPTS GLN 860.1850 (formerly 165-1)

All data for confined rotational crops have been evaluated and deemed adequate (MRID Nos. 42395301 and 42395302). Alachlor residues were found to accumulate in all three rotational crops tested. Radishes, lettuce, and wheat were planted 31, 91, 120, or 365 days following the second of two applications of uniformly ring-labeled [^{14}C]-alachlor to sandy loam soil at 4 and 2 lb ai/acre (total 6 lb ai/A). Alachlor per se was not detected in the plants. The major classes of alachlor metabolites found were those containing the DEA and 1-HEEA moities.

Field Accumulation in Rotational Crops: OPPTS GLN 860.1900 (formerly 165-2)

Limited field rotational crop studies have been submitted (MRID No. 43442001). Soybeans and wheat were planted at various plant-back intervals following preemergence application at 4 lb ai/A (1x) and postemergence application at 2 lb ai/A (1x) of a representative 4 lb/gal Mcap formulation to corn. The data indicate that residues of alachlor and its metabolites containing the DEA and HEEA moieties exceed 0.01 ppm (the LOQ) in/on many raw agricultural commodities of soybeans and wheat. Because quantifiable alachlor residues are present in/on rotational crops, rotational crop tolerances need to be established, or the labels may be changed to prohibit rotation to any crop not specified on the label.

Soybeans and wheat can represent legume vegetables and cereal grains. Therefore, data pertaining to field rotational crop studies are still required for a root crop and a leafy crop. Monsanto plans to support cereal grains (except rice), and non-grass animal feeds as rotational crops.

b. Dietary Exposure from Drinking Water

Alachlor is regulated under the SDWA (Safe Drinking Water Act). The MCL (Maximum Contaminant Level) for alachlor is 2 ppb. An MCL is the maximum permissible level of a contaminant in drinking water which is delivered to any user of a public water supply system. Water systems are required to test for regulated chemicals on a quarterly basis. A public water supply is considered in violation of the SDWA when the average of four consecutive monitoring events exceed the MCL or a single event exceeds 4 times the MCL. Cost and the availability of treatment technologies are also considered in promulgating an MCL, as well as the capability of available laboratory facilities of measuring to a common analytical level.

For the purposes of estimating human exposure through drinking water, the Agency has relied on one groundwater study (NAWWS) and two surface water studies (ARP and USGS). (These studies as well as other ground water and surface water studies are discussed in the Environmental Assessment Section of this RED.) The NAWWS study was chosen because it is representative of Midwestern use of alachlor. NAWWS data are considered to be of high quality, and because of the statistical design of the survey are also considered to be the best available data concerning alachlor per se residues in ground water and the population exposed to those residues. The USGS Survey was used because of the detections of alachlor ESA. The ARP is the most recent as well as the most extensive data on alachlor concentrations. The Acetochlor Registration Partnership (ARP) data was collected at drinking water treatment facilities and is therefore finished water. The use of finished

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water in this assessment is appropriate since (1) this is the water that is actually consumed, and (2) generally surface water is treated before consumption. However, it is noted that the primary treatment processes employed by most surface water drinking water supply systems are not expected to be effective in removing alachlor. ARP data was collected for both ground and surface water sites. However, the ARP ground water data has not yet been fully analyzed, and thus cannot be used in this assessment. Additionally, it is believed that alachlor use is decreasing, so the most recent data would reflect this decrease.

Ground Water

Estimates of alachlor concentrations in well or ground water were prepared by the Agency and are based on the National Alachlor Well Water Survey (NAWWS). Monsanto conducted NAWWS to estimate the proportions of private, rural domestic wells with detectable concentrations of alachlor. NAWWS was a complex, statistically designed survey of alachlor occurrences which targeted counties where alachlor was used in 1986. These samples represent approximately 6 million wells from which approximately 20 million people draw their drinking water.

Water samples were collected from 1,430 wells beginning in July 1988, and continuing through May 1989. The samples were analyzed by GC/MS (gas chromatography using a mass selective detector) in SIM (selected ion monitoring) mode. The limit of detection (LOD) for alachlor was 0.03 ppb.

Reported values are for alachlor per se. No degradates of alachlor were analyzed for in the NAWWS. All "Non-detects" (values reported as ND) were averaged in (with the detected residues) using ½ of the LOD, or 0.015 ppb. This is an acceptable procedure for dealing with the analytical limits of detection for chemical residues.

Table 8: NAWWS Data - Residue Levels for Use in Risk Assessment

Alachlor Residue Level Detected in Ground Water (ppb)	Estimate of the Population Exposed	Percentage of the Population Exposed
0.015 (These are non-detects - use ½ the LOD)	19,603,040	99.5
<0.2	63,249	0.32
>= 0.2	35,647	0.18
>2	3,000	0.015

The approximate proportion of the population in the alachlor use area exposed to the various levels of alachlor in ground water is estimated above, using the data from the NAWWS. It was estimated that 19,704,936 people received ground water from wells included in the survey area.

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Surface Water

Approximately 29 million people rely on surface water for their drinking water in the 11 major corn-producing states.

Alachlor can contaminate surface water at the time of application via spray drift or for several weeks postapplication due to run-off. Alachlor surface water concentrations tend to peak in May to early June during the first runoff events following application with rapid decline to approximately pre-application levels by July or August. Concentration of alachlor in surface water depends on numerous factors including the quantity of alachlor used on the drainage area upstream, the infiltration characteristics of the drainage area soils, and the timing, frequency, and intensities of post-application runoff events.

Degradates of alachlor were analyzed in one study, the USGS Reservoir Study. Alachlor per se concentrations are reported as time weighted mean concentrations (TWMCs) which reflect "amortization" of periods of high concentration and of low concentration. A TWMC is calculated as follows: (1) Take the length of time from one measurement to the next and divide by two (For the first and last measurements, the length of time between the first and second was assumed for the first measurement and the time between the last and second to last measurement was assumed for the last measurement); (2) Multiply the measurement by the number of days between each sample event; and (3) Sum those results, then divide by the total number of days during which the measurements occurred. Annual TWMCs (calculated using at least a year's worth of sampling data) are the most appropriate values to use for estimation of chronic exposure to alachlor in drinking water because TWMCs compensate for times of high and low contamination which occur during the year.

USGS Midwestern Reservoir Study

In 1992 and 1993, USGS sampled 76 Midwestern reservoirs. Each reservoir was sampled 4 times each year. The samples were analyzed for both alachlor and alachlor ESA. The LOD for alachlor was 0.05 ppb. The LOD for alachlor ESA was 0.03 ppb. The TWMC for the 2 year period (90th percentile) for alachlor was 0.22 ppb, and for alachlor ESA was 3.00 ppb.

Acetochlor Registration Partnership (ARP) Data (1995-1996)

This is the most recent as well as the most extensive data on alachlor concentrations in surface waters currently available. All of the data were collected at drinking water treatment facilities and is therefore finished (treated) water. Samples were collected at 179 sites in 12 states (Delaware, Illinois, Indiana, Iowa, Kansas, Maryland, Minnesota, Missouri, Nebraska, Ohio, Pennsylvania, and Wisconsin) once every two weeks from April through September for both 1995 and 1996. Two to three additional samples were collected at each site, one or two in the fall and the other in the winter. Unfiltered samples were analyzed for alachlor using GC/MS. The LOD for the study was 0.02 ppb.

A TWMC was estimated by the Agency for each monitoring site in the ARP. These sites were then ranked from highest to lowest. The 90th percentile TWMC for the 2 year period was 0.1

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ppb. Thus, 10% of the monitoring sites have TWMCs greater than 0.1 ppb, and 90% of the monitoring sites have TWMCs less than 0.1 ppb.

Exposure Estimates

Adult Female

The exposure estimate for an adult female (13+ years) is calculated by the following equation:

Exposure = (chemical concentration in µg/L in consumed water) X (10^{-3} mg/µg) ÷ (60 kg body weight) X (2L water consumed/day)

The 2 Liters of water is a default assumption used by the Agency. The 60 kilograms is the Agency's default female body weight.

Adult Male

The exposure estimate for an adult male is calculated by the following equation:

Exposure = (chemical concentration in µg/L in consumed water) X (10^{-3} mg/µg) ÷ (70 kg body weight) X (2L water consumed/day)

The 2 Liters of water is a default assumption used by the Agency. The 70 kilograms is the Agency's default male body weight.

Child (1 - 6 years)

The exposure estimate for a child (1- 6 years) is calculated by the following equation:

Exposure = (chemical concentration in µg/L in consumed water) X (10^{-3} mg/µg) ÷ (10 kg body weight) X (1L water consumed/day)

The 1 Liter of water is a default assumption used by the Agency. The 10 kilograms is a default value for a child's body weight.

The other assumption used is assuming that water from the same source containing the same contaminant level is consumed throughout a 70 year lifetime. Most of the US population moves at some time during their life and does not live in the same area, drinking from the same water source for a 70 year lifetime. It could be considered as either an over-estimation or an under-estimation of risk depending on the contaminant levels in the other sources of drinking water.

Information on detections of the ESA degradate of alachlor was available for only one study - the USGS Reservoir Study. Thus, for all other studies the exposure estimates should be considered

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as under-estimated. The alachlor ESA degradate has been detected in Midwestern reservoirs and streams at concentrations and frequencies that greatly exceed that of alachlor detections.

Table 9: Drinking Water Exposure Estimates - Adult Male		
STUDY	Concentration (ppb)	Exposure (mg/kg/day)
MCL	2	0.0000571
Surface Water		
USGS - Alachlor (reservoir)	0.22	0.0000062
USGS - Alachlor ESA (reservoir)	3.00	0.0000857
ARP Data (1995-1996) (finished water)	0.1	0.0000028
Ground Water		
NAWWS	0.2	0.0000057
NAWWS	0.015	0.0000004

Table 10: Drinking Water Exposure Estimates - Adult Female		
STUDY	Concentration (ppb)	Exposure (mg/kg/day)
MCL	2	0.0000666
Surface Water		
USGS - Alachlor (reservoir)	0.22	0.0000073
USGS - Alachlor ESA (reservoir)	3.00	0.0001
ARP Data (1995-1996) (finished water)	0.1	0.0000033
Ground Water		
NAWWS	0.2	0.0000066
NAWWS	0.015	0.0000005

Table 11: Drinking Water Exposure Estimates - Child (1-6 years)		
STUDY	Concentration (ppb)	Exposure (mg/kg/day)
MCL	2	0.0002
Surface Water		
USGS - Alachlor (reservoir)	0.22	0.000022
USGS - Alachlor ESA (reservoir)	3.00	0.0003
ARP Data (1995-1996) (finished water)	0.1	0.00001

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Ground Water		
NAWWS	0.2	0.00002
NAWWS	0.015	0.0000015

c. Occupational

The Agency has not identified any alachlor products that are intended for home use. Therefore, only an occupational assessment is required.

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators; M/L/As) during use or to persons entering treated sites after application is complete. In the case of alachlor the identification of short-term and intermediate-term endpoints triggers the toxicological criteria and exposure to M/L/As has been identified.

As previously stated, there are no chronic (long-term) occupational exposure scenarios for the application of alachlor. Therefore, a long-term exposure/risk assessment has not been performed. Calculation of a carcinogenic MOE for agricultural workers based on intermittent exposure is not appropriate. Therefore, in this occupational assessment for alachlor, the following scenarios are considered: short-term and intermediate-term.

Use Patterns

Alachlor is a broad spectrum herbicide used on terrestrial food and feed crops and on terrestrial non-food targets. The timing for applications is just prior to, at, or shortly after planting (i.e., preplant, pre-emergent, at planting for corn and soybeans, post-transplant for ornamentals, post-emergent, and at ground-crack for peanuts only).

Agricultural use sites include corn, soybeans, peanuts, grain sorghum (milo), and beans (i.e. dry, lima, red kidney, and mung). Non-food and ornamental uses include applications to ornamental woody shrubs and vines (i.e., junipers and yew). Alachlor is formulated as a liquid (active ingredient 25.2 to 45.1 percent), as a dry flowable (active ingredient 65 percent), as a microencapsulate (active ingredient 41.5 percent) and as a granular (15 percent active ingredient). The maximum application rates range from 4.0 lb ai/acre for corn to 3.0 lb ai/acre for soybean. Several of the application methods involve soil incorporation techniques. Dry bulk fertilizers are impregnated with alachlor at commercial fertilizer or farm chemical dealerships using specially designed, closed systems. In these systems, alachlor and the fertilizers are mixed and blended in a system such as a closed rotary drum container, or similar system. Nozzles situated inside the rotary drum are used to apply the alachlor onto the fertilizer. The fertilizer impregnated with alachlor is then applied using spin-type spreaders, or positive displacement equipment.

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Incident Data

Alachlor is considered a mild irritant according to EPA's "Recognition and Management of Pesticide Poisoning" (Fourth Edition, 1989). No serious cases (deaths or hospitalized cases) have been reported in national surveys of deaths (in the 1960s or 1970s, the last surveys completed) or hospitalization (1971 through 1982). California reported just 3 physician-treated cases in the 12 year period, 1982 through 1993. Two of these three cases involved skin or eye effects and one case was considered a possible systemic poisoning. Thirteen unconfirmed cases have been screened by the Office of Pesticide Program's Incident Data system, most of which reportedly experienced minor dermal effects. No changes in labeling are warranted based on this incident data.

Previous Agency Regulatory Action/ Special Review

At the time of the Special Review of alachlor the Agency used the best available data to estimate worker exposure. Risk estimates for the PD-1 were based on patch data supplied by the registrant which measured exposure to the EC, Mcap, and G formulations. However, in response to the PD-1, the registrant submitted additional data; namely, the previously discussed 1984 and 1985 human biomonitoring data. The Agency reviewed these data. Numerous limitations were identified related to the biomonitoring data, such as: (1) the small number of replicates (4 persons per study) which cannot indicate the range (the expected variability) of exposure to alachlor; (2) study subjects were Monsanto employees; (3) mixer/loaders wore protective goggles, rubber gloves, and rubber overshoes; (4) applicators used enclosed cab tractors exclusively; (5) only 20 acres were treated with alachlor-containing formulations instead of the 80 to 120 acres that could be expected to be treated; (6) some products were soil incorporated; and (7) biological monitoring and passive dosimetry were conducted concurrently on the same individual which may reduce the amount of pesticide reflected in biomonitoring results.

At the time of the PD-4, the biomonitoring data were the best data available, so the Agency used the biomonitoring data to estimate exposure. In fact, the PD-4 stated that the Agency believed that biomonitoring data from well-designed and executed studies, if supported by adequate pharmacokinetic studies, provide a better measure of exposure than patch data. At the time of the PD-4, the Agency used monkey data showing the rate and ratio of excreted alachlor metabolites to interpret the results of the biomonitoring data.

Using the previously submitted patch data from the registrant, and data available in the literature documenting exposure variability, the Agency estimated a range of exposures of two orders of magnitude, with the biomonitoring data representing the low end of the range for exposure to alachlor during mixing/loading and groundboom application. In 1987 the Agency believed the range of exposures defined by the biomonitoring data, the patch data, and the open literature values more accurately reflected applicator exposure estimates than the estimates that were used in the PD-1.

In this risk assessment for the purpose of the re-registration of alachlor, the Agency has used data from PHED as well as the registrant-generated biomonitoring data. As noted previously limitations were identified. Of particular significance were (1) the small number of replicates (4 persons per study), and (7) biological monitoring and passive dosimetry were conducted concurrently

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on the same individual. The small number of replicates lowers the confidence level in the results; however, the higher of the two values (0.0000126 mg/kg/lb ai.) was used in the assessment. The concurrent monitoring is in all probability a small percent of the total amount of alachlor that could be absorbed given the small surface areas of the patches. These data do not meet the Agency's guideline requirements (875.2600), for biological monitoring.

During the 10 year interval since the PD-4, the Pesticide Handlers Exposure Database (PHED; currently Version 1.1) was developed. PHED was developed by Health Canada, the American Crop Protection Association, and EPA, and initially released for public use in 1992. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in the handling or application of pesticides in the field. Use of surrogate or generic data is appropriate since it is generally believed that the formulations and the method of application, not the chemical properties of the pesticide control the amount of dermal and inhalation exposure. Thus, PHED allows exposure and risk assessments to be conducted with a much larger number of observations than available from a single exposure study. The current version of PHED (Version 1.1) contains larger numbers of exposure replicates and a broader spectrum of mixer/loader and applicator scenarios reflecting use of a variety of personal protective equipment. Note that Table 12 rates the data (for number of replicates and quality control parameters) used to estimate exposure for mixing liquids and groundboom application (baseline) as high confidence with the number of replicates varying up to 122.

Generally, biomonitoring data are preferable to passive-dosimetry data. The use of a dermal absorption factor is not necessary for biomonitoring data. Biomonitoring data can give a more accurate estimate of absorbed dose. But, biomonitoring does not determine the source of the exposure (inhalation/dermal; hands/head), and thus, cannot be used to identify what measures, to mitigate exposures, are likely to be the most effective.

Therefore, for the Alachlor Reregistration Eligibility Decision Document, the Agency is using PHED Version 1.1 to assess pesticide handlers exposure to alachlor. However, the results of the biomonitoring study will be used for comparison purposes.

PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in the handling or application of pesticides in the field. The database currently contains data for over 2000 monitored exposure events. Use of surrogate or generic data is appropriate since it is generally believed that the physical parameters of the handling and application process (e.g. the type of formulations, the method of application, and the type of clothing), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than available from a single exposure study.

PHED also contains algorithms that allow the user to complete surrogate task-based exposure assessments beginning with one of the four main data files contained in the system (i.e., mixer/loader, applicator, flagger, and mixer/loader/applicator). Users select data from each file and construct

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exposure scenarios that are representative of the use of the chemical. EPA, in conjunction with the PHED task force, has evaluated all of the data currently in PHED, and developed a surrogate exposure table that contains a series of standard exposure estimates for various scenarios. These standard unit exposure values are the basis for this assessment. The standard exposure values (i.e., the unit exposure values included in the exposure and risk assessment tables) are based on the "best fit" values calculated by PHED. PHED calculates "best fit" exposure values by assessing the distributions of exposures for each body part included in datasets selected for the assessment (e.g., chest or forearm) and then calculating a composite exposure value representing the entire body. PHED categorizes distributions as normal, lognormal, or in an "other" category. Generally, most data contained in PHED are lognormally distributed or fall into the PHED "other" distribution category. If the distribution is lognormal, the geometric mean for the distribution is used in the calculation of the "best fit" exposure value. If the data are an "other" distribution, the median value of the dataset is used in the calculation of the "best fit" exposure value. As a result, the surrogate unit exposure values that serve as the basis for this assessment generally range from the geometric mean to the median of the selected dataset.

The first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, and no chemical-resistant gloves. If, there is a level of concern, then increasing levels of risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to achieve an appropriate margin of exposure (MOE).

Occupational Exposure Scenarios

The Agency has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with alachlor. Based on the use patterns, nine major exposure scenarios were identified for alachlor:

(1a) mixing/loading liquids for aerial and chemigation application;
(1b) mixing/loading liquids for groundboom application;
(2) mixing/loading granulars for drop type tractor drawn application;
(3a) mixing/loading dry flowables for aerial application;
(3b) mixing/loading dry flowables for groundboom application;
(4) aerial application of liquids (fixed-wing);
(5) aerial application of liquids (helicopter);
(6) groundboom application of liquids;
(7) granular drop type tractor drawn application;
(8) mixing/loading and application to dry bulk fertilizer; and,
(9) flaggers.

A summary and description of the caveats and parameters specific to each exposure scenario is shown in Table 12.

Occupational Exposure Tables

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Two types of assessments (short-term and intermediate-term) are required for evaluating occupational risk assessment. The NOEL for estimating short-term risk is from a developmental (oral) toxicity study, which requires the use of a dermal absorption factor (24%), and the average body weight of a female (60 kg) is used in the assessment. The NOEL for estimating intermediate-term risk is from a dermal toxicity study; therefore, no dermal absorption factor is applied. The demonstrated effects from that study are not sex-specific; therefore, the average body weight of humans (70 kg) is used in the assessment.

Table 13 shows the calculations of daily total exposure to alachlor:

- with baseline attire (long-sleeve shirt, long pants, shoes, and socks).

Table 14 shows the calculations of daily total exposure to alachlor:

- with the addition of personal protective equipment (chemical-resistant gloves and double-layer clothing)

Table 15 shows the calculations of daily total exposure to alachlor:

- with the use of engineering controls (closed systems for mixing and loading, closed cabs/cockpits for applications and flagging).

Tables 13, 14, and 15 show the calculations of occupational handler exposure for both the short- and intermediate-term scenario. For the short-term assessment, each table includes a 24% dermal absorption adjustment to the "daily dermal exposure" (column 6). This daily absorbed dermal exposure (column 9) is added to the daily inhalation exposure (column 7) to calculate the daily absorbed total exposure (column 10). This exposure calculation (column 10 in Tables 13, 14, and 15) is used to assess the short-term risk in Table 28. For the intermediate-term assessment, "daily dermal exposure" (column 6) is added to "daily inhalation exposure" (column 7) to calculate the "daily total exposure" (column 8). This exposure calculation (column 8 in Tables 10, 11, and 12 is used to assess the intermediate-term risk in Table 29.

Table 16 is data from the registrant-submitted biomonitoring study.

In Table 14, the level of personal protective equipment (PPE) added (i.e., only chemical-resistant gloves or double-layer body protection plus chemical-resistant gloves) varies among the exposure scenarios based on whether the eventual margins of exposures (MOEs) would be 100 or greater solely with the addition of gloves.

In Table 28, "baseline absorbed total dose" (column 3) is calculated by dividing the value in Table 13 "daily absorbed total exposure" (column 10) by the average female body weight (60 kg). Similarly, in Table 28 "PPE daily total dose" (column (5) is calculated by dividing the value in Table 14 "PPE daily absorbed total exposure" (column 10) by 60 kg. Finally, in Table 28 "Eng. C daily total dose" (column 7) is calculated by dividing the value in Table 15 "Eng. C daily absorbed total exposure" (column 10) by 60 kg.

In Table 29, "baseline total dose" (column 3) is calculated by dividing the value in Table 13 "baseline daily total exposure" (column 8) by the average human body weight (70 kg). Similarly, in Table 29 "PPE daily total dose" (column 5) is calculated by dividing the value in Table 14 "PPE daily

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total exposure" (column 8) by 70 kg. Finally, in Table 29 "Eng. C daily total dose" (column 7) is calculated by dividing the value in Table 15 "Eng. C daily total exposure" (column 8) by 70 kg.

Further explanation of the calculations are in the footnotes.

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Table 12: Exposure Scenario Descriptions for Uses of Alachlor

Exposure Scenario (Number)	Data Source	Daily Acres Treated[a]	Comments[b]
Mixer/Loader Exposure			
Mixing/Loading Liquid (1a and b)	PHED V1.1	80 acres groundboom; 350 acres aerial and chemigation	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates; Inhalation = 85 replicates. High confidence in dermal data; high confidence in inhalation data. **PPE:** "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates. High confidence in dermal and inhalation data. **Engineering Controls:** "Best Available" grades: Dermal and inhalation acceptable grades. Hands = 31 replicates, Dermal = 16 to 22 replicates; Inhalation = 27 replicates. High confidence in dermal and inhalation data. PHED data used for baseline and engineering controls, no Protection Factor (PF) were necessary. Fifty percent PF was used for coveralls (PPE).
Mixing/Loading Granulars (2)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands all grades, dermal and inhalation acceptable grades. Dermal = 29 to 36 replicates; inhalation = 58 replicates; and hands = 10 replicates. Low confidence in dermal data, high confidence in inhalation data. PHED data used for baseline, no PFs were necessary.
Mixing/Loading Dry Flowables (3a and 3b)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands grades A,B, C; dermal and inhalation acceptable grades. Dermal = 16 to 26 replicates; inhalation = 23 replicates; and, hands = 7 replicates. Low confidence in dermal data, high confidence in inhalation data. **PPE:** "Best Available" grades: Hands, dermal and inhalation acceptable grades. Hands = 21 replicates; Dermal = 16 to 26 replicates, inhalation = 23 replicates. High confidence in dermal and inhalation data. PHED data used for baseline, no PFs were necessary. Fifty percent PF was used for coveralls (PPE).
Applicator Exposure			
Aerial equipment--fixed wing enclosed cab (liquids) (4)	PHED V1.1	350 acres	**Engineering Controls:** "Best Available" grades: Hands acceptable grades, dermal and inhalation grades A,B,C. Hands = 34 replicates; Dermal = 24 to 48 replicates; Inhalation = 23 replicates. Medium confidence in dermal and inhalation data. PHED data used for engineering controls, no PFs were necessary.

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Table 12: Exposure Scenario Descriptions for Uses of Alachlor			
Exposure Scenario (Number)	Data Source	Daily Acres Treated[a]	Comments[b]
Aerial equipment--helicopter enclosed cab (liquids) (5)	PHED V1.1	350 acres	**Engineering Controls:** "Best Available" grades: dermal grades A,B,C; inhalation grades "acceptable". Hands = 2 replicates, Dermal = 3 replicates; Inhalation = 3 replicates. Low confidence in dermal and inhalation data. PHED data used for engineering controls, no PFs were necessary.
Groundboom Application (liquids) (6)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 29 replicates; Dermal = 32 to 42 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data. **PPE:** "Best Available" grades: Hands grades ABC and dermal acceptable grades. Hands = 21 replicates Dermal = 32 to 42 replicates Medium confidence in dermal data; high confidence in inhalation data. **Engineering Controls:** "Best Available" grades: Hands, and dermal = ABC grades; Inhalation = acceptable grades. Hands = 16 replicates Dermal = 20 to 31 replicates; Inhalation = 16 replicates. Medium confidence in dermal data; high confidence in inhalation. PHED data used for baseline and engineering controls, no PFs were necessary. Fifty percent PF was added for coveralls for PPE.
Granular Drop Type Tractor Drawn Spreader Application (7)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hand, dermal and inhalation acceptable grades. Dermal = 4 to 5 replicates; hands = 5 replicates; inhalation = 5 replicates. Low confidence in dermal and inhalation data. PHED data was used for baseline, no PFs were necessary.
Mixer/Loader/Applicator			
Mixing/Loading and Application for Dry Bulk Fertilizer (8)	No data	No data	No data
Flaggers			
Flaggers for Aerial Applications (9)	PHED V1.1	350 acres	**Baseline:** "Best Available" grades: Hand, dermal and inhalation acceptable grades. Dermal = 16 to 18; hands = 16; inhalation = 18. High confidence in dermal, hand and inhalation data. PHED data was used for baseline, no PFs were necessary.

a Daily acres treated are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.

b These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. A replicate refers to data acquired during one complete work cycle. "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:
High confidence = grades A and B and 15 or more replicates per body part
Medium confidence = grades A, B, and C and 15 or more replicates per body part
Low confidence = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

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Table 13: Alachlor Exposure Estimates to be Used in Short-Term and Intermediate-Term Risk Assessments - Baseline PHED Values

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	Baseline Daily Total Exposure (mg/day)[f]	Daily Absorbed Dermal Exposure (mg/day)[g]	Baseline Daily Absorbed Total Exposure (mg/day)[h]
Mixer/Loader Exposure									
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	2.9	0.0012	Corn 4.0	350	4,060	1.68	4,061.7	974	976
			Soybeans 3.0		3,045	1.26	3,046.3	731	732
Mixing/Loading Liquids for Groundboom Application (1b)			Corn 4.0	80	928	0.384	928.4	223	223
			Soybeans 3.0		696	0.288	696.3	167	167
Mixing/Loading Granulars for Drop Type Tractor Drawn Spreaders (2)	0.0076	0.0017	Corn 4.0	80	2.4	0.544	2.9	0.58	1.1
			Soybeans 3.0		1.8	0.408	2.2	0.43	0.83
Mixing/Loading Dry Flowables for Aerial Application (3a)	0.07	0.00077	Corn 4.0	350	98	1.08	99.08	24	25
			Soybeans 3.0		73.5	0.81	74.31	18	18
Mixing/Loading Dry Flowables for Groundboom Application (3b)			Corn 4.0	80	22.4	0.25	22.65	5.4	5.6
			Soybeans 3.0		16.8	0.19	16.99	4.0	4.2
Applicator Exposure									
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	See Engineering Controls	See Engineering Controls	Corn 4.0	350	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls
			Soybeans 3.0						
Aerial Application of Liquids - Helicopter Aircraft - Enclosed Cockpit (5)	See Engineering Controls	See Engineering Controls	Corn 4.0	350	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls
			Soybeans 3.0						
Groundboom Application of Liquids - (6)	0.015	0.0007	Corn 4.0	80	4.8	0.224	5.02	1.2	1.4
			Soybeans 3.0		3.6	0.168	3.77	0.86	1.0
Granular Drop Type Tractor Drawn Spreader Application (7)	0.01	0.00022	Corn 4.0	80	3.2	0.07	3.3	0.77	0.84
			Soybeans 3.0		2.4	0.053	2.5	0.58	0.63
Mixer/Loader/Applicator Exposure									
Mixing/Loading and Application of Impregnated Dry Bulk Fertilizer (8)	See text								
Flaggers									

Table 13: Alachlor Exposure Estimates to be Used in Short-Term and Intermediate-Term Risk Assessments - Baseline PHED Values									
Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	Baseline Daily Total Exposure (mg/day)[f]	Daily Absorbed Dermal Exposure (mg/day)[g]	Baseline Daily Absorbed Total Exposure (mg/day)[h]
Flaggers for Aerial Applications (9)	0.01	0.00028	Corn 4.0	350	14.0	0.39	14.39	3.4	3.8
			Soybeans 3.0		10.5	0.29	10.79	2.5	2.8

a Baseline dermal unit exposure represents long pants, long sleeve shirts, no gloves, open mixing/loading, open cabs or cockpits. Note that data on open cockpit aerial applications are not available.
b Baseline inhalation exposure represents no respirator.
c Application rate comes from maximum values found in the alachlor labels EPA Reg Nos. 524-344, 524-403, 524-418, 524-422 and 524-314.
d Daily acres treated are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.
e Daily exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated.
f Total daily exposure (mg/day) = daily dermal exposure (mg/day) + daily inhalation exposure (mg/day). Note that this exposure number is used for the intermediate-term scenario only since the NOEL for calculating the MOE is from a dermal study and the use of the dermal absorption factor is not necessary.
g Daily absorbed dermal exposure (mg/day) = daily dermal exposure (mg/day) * dermal absorption factor (0.24)
h Total absorbed daily exposure (mg/day) = daily absorbed dermal exposure (mg/day) + daily inhalation exposure (mg/day) Note that this exposure is used for the short-term scenario only since the NOEL for calculating the MOE is from an oral study and it was necessary to use the dermal absorption factor.

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Table 14: Alachlor Exposure Estimates to be used in Short-Term and Intermediate-Term Risk Assessments - PHED Personal Protective Equipment (PPE) Values

Exposure Scenario (Scenario #)	PPE Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	PPE Daily Total Exposure (mg/day)[f]	Daily Absorbed Dermal Exposure (mg/day)[g]	PPE Daily Absorbed Total Exposure (mg/day)[h]
Mixer/Loader Exposure									
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	0.043	0.0012	Corn 4.0	350	60.2	1.7	61.9	14.4	16.1
			Soybeans 3.0		45.2	1.3	46.5	10.8	12.1
Mixing/Loading Liquids for Groundboom Application (1b)	0.043	0.0012	Corn 4.0	80	13.8	0.38	14.2	3.3	3.7
			Soybeans 3.0		9.6	0.29	9.9	2.3	2.6
Mixing/Loading Granulars for Drop Type Tractor Drawn Spreaders (2)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Mixing/Loading Dry Flowables for Aerial Application (3a)	0.04	0.00077	Corn 4.0	350	56	1.1	57.1	13.4	14.5
			Soybeans 3.0		42	0.81	42.8	10.1	10.9
Mixing/Loading Dry Flowables for Groundboom Application (3b)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Applicator Exposure									
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	See Engineering Controls	See Engineering Controls	Corn 4.0	350	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls
			Soybeans 3.0						
Aerial Application of Liquids - Helicopter Aircraft - Enclosed Cockpit (5)	See Engineering Controls	See Engineering Controls	Corn 4.0	350	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls
			Soybeans 3.0						
Groundboom Application of Liquids - (6)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Granular Drop Type Tractor Drawn Spreader Application (7)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Mixer/Loader/Applicator Exposure									
Mixing/Loading and Application of Impregnated Dry Bulk Fertilizer (8)	See text								

Table 14: Alachlor Exposure Estimates to be used in Short-Term and Intermediate-Term Risk Assessments - PHED Personal Protective Equipment (PPE) Values

Exposure Scenario (Scenario #)	PPE Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	PPE Daily Total Exposure (mg/day)[f]	Daily Absorbed Dermal Exposure (mg/day)[g]	PPE Daily Absorbed Total Exposure (mg/day)[h]
Flaggers									
Flaggers for Aerial Applications (9)	n/a	n/a	Corn 4.0	350 acres	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a

n/a No longer necessary to carry scenario through analysis as exposure in baseline scenario is sufficiently low to calculate an MOE that will exceed 100

a Scenario 1a and 1b single layer clothing and chemical resistant gloves, open mixing/loading
Scenario 3a: open mixing/loading, double layer of clothing and chemical resistant gloves.
b Baseline inhalation exposure represents no respirator.
c Application rate comes from maximum values found in the alachlor labels EPA Reg Nos. 524-344, 524-403, 524-418, 524-422 and 524-314.
d Daily acres treated are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.
e Daily exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated.
f Total daily exposure (mg/day) = daily dermal exposure (mg/day) + daily inhalation exposure (mg/day). Note that this exposure number is used for the intermediate-term scenario only since the NOEL for calculating the MOE is from a dermal study and the use of the dermal absorption factor is not necessary.
g Daily absorbed dermal exposure (mg/day) = daily dermal exposure (mg/day) * dermal absorption factor (0.24)
h Total absorbed daily exposure (mg/day) = daily absorbed dermal exposure (mg/day) + daily inhalation exposure (mg/day) Note that this exposure is used for the short-term scenario only since the NOEL for calculating the MOE is from an oral study and it was necessary to use the dermal absorption factor.

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Table 15: Alachlor Exposure Estimates to be Used in Short-Term and Intermediate-Term Risk Assessments - Engineering Control (Eng C) PHED Values

Exposure Scenario (Scenario #)	Eng C Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Eng C Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	Eng C Daily Total Exposure (mg/day)[f]	Eng C Daily Absorbed Exposure (mg/day)[g]	Eng C Daily Absorbed Total Exposure (mg/day)[h]
Mixer/Loader Exposure									
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	0.009	0.00008	Corn 4.0	350	9.8	0.11	9.9	2.4	2.5
			Soybeans 3.0		7.4	0.08	7.5	1.8	1.9
Mixing/Loading Liquids for Groundboom Application (1b)			Corn 4.0	80	2.2	0.026	2.2	0.54	0.57
			Soybeans 3.0		1.7	0.02	1.7	0.4	0.42
Mixing/Loading Granulars for Drop Type Tractor Drawn Spreaders (2)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Mixing/Loading Dry Flowables for Aerial Application (3a)	No data	No data	Corn 4.0	350	No data	No data	No data	No data	No data
			Soybeans 3.0		No data	No data	No data	No data	No data
Mixing/Loading Dry Flowables for Groundboom Application (3b)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a
Applicator Exposure									
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	0.005	0.000068	Corn 4.0	350	7	0.095	7.1	1.7	1.8
			Soybeans 3.0		5.3	0.07	5.3	1.3	1.4
Aerial Application of Liquids - Helicopter Aircraft - Enclosed Cockpit (5)	0.0021	0.0000018	Corn 4.0	350	3.0	0.003	3.0	0.7	0.7
			Soybeans 3.0		2.2	0.002	2.2	0.53	0.53
Groundboom Application of Liquids - (6)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a

Table 15: Alachlor Exposure Estimates to be Used in Short-Term and Intermediate-Term Risk Assessments - Engineering Control (Eng C) PHED Values

Exposure Scenario (Scenario #)	Eng C Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (mg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Eng C Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[e]	Eng C Daily Total Exposure (mg/day)[f]	Eng C Daily Absorbed Exposure (mg/day)[g]	Eng C Daily Absorbed Total Exposure (mg/day)[h]
Granular Drop Type Tractor Drawn Spreader Application (7)	n/a	n/a	Corn 4.0	80	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a		
Mixer/Loader/Applicator Exposure									
Mixing/Loading and Application of Impregnated Dry Bulk Fertilizer (8)	See text								
Flaggers									
Flaggers for Aerial Applications (9)	n/a	n/a	Corn 4.0	350 acres	n/a	n/a	n/a	n/a	n/a
			Soybeans 3.0		n/a	n/a	n/a	n/a	n/a

n/a No longer necessary to carry scenario through analysis as exposure in baseline scenario or with addition of PPE is sufficiently low to calculate an MOE that will exceed 100

a Engineering controls dermal unit exposure represents long pants, long sleeve shirts, closed mixing/loading, closed cab tractor.
Scenarios 1a: chemical resistant gloves.
Scenarios 4 and 5: closed cockpit single layer clothing, and no gloves.

b Baseline inhalation exposure represents no respirator.

c Application rate comes from maximum values found in the alachlor labels EPA Reg Nos. 524-344, 524-403, 524-418, 524-422 and 524-314.

d Daily acres treated are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.

e Daily exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated.

f Total daily exposure (mg/day) = daily dermal exposure (mg/day) + daily inhalation exposure (mg/day). Note that this exposure number is used for the intermediate-term scenario only since the NOEL for calculating the MOE is from a dermal study and the use of the dermal absorption factor is not necessary.

g Daily absorbed dermal exposure (mg/day) = daily dermal exposure (mg/day) * dermal absorption factor (0.24)

h Total absorbed daily exposure (mg/day) = daily absorbed dermal exposure (mg/day) + daily inhalation exposure (mg/day) Note that this exposure is used for the short-term scenario only since the NOEL for calculating the MOE is from an oral study and it was necessary to use the dermal absorption factor.

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Table 16: Alachlor Exposure Estimates to be Used in Short-Term and Intermediate-Term Risk Assessments - Values from Registrant-Submitted Biomonitoring Studies

Exposure Scenario (Scenario #)	Biomonitoring Internal Estimated Exposure (mg/kg/lb ai)[a]	Adjusted Biomonitoring Internal Estimated Exposure (mg/kg/lb ai)[b]	Crop and Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Biomonitoring Internal Dose (mg/kg/day)[e]
Mixer/Loader Exposure					
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	0.0000126	n/a	Corn 4.0	350	0.01764
Mixing/Loading Liquids for Groundboom Application (1b)			Corn 4.0	80	0.004032
Mixing/Loading Granulars for Drop Type Tractor Drawn Spreaders (2)	n/a	0.0000000647	Corn 4.0	80	0.0000207
Mixing/Loading Dry Flowables for Aerial Application (3a)	n/a	0.000000316	Corn 4.0	350	0.0004424
Mixing/Loading Dry Flowables for Groundboom Application (3b)	n/a	0.00000032	Corn 4.0	80	0.0001024
Applicator Exposure					
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	This scenario not performed for biomonitoring data				
Aerial Application of Liquids - Helicopter Aircraft - Enclosed Cockpit (5)	This scenario not performed for biomonitoring data				
Groundboom Application of Liquids - (6)	0.0000126	n/a	Corn 4.0	80	0.004032
Granular Drop Type Tractor Drawn Spreader Application (7)	n/a	0.00000767	Corn 4.0	80	0.002454
Mixer/Loader/Applicator Exposure					
Mixing/Loading and Application of Impregnated Dry Bulk Fertilizer (8)	This scenario not performed for biomonitoring data				
Flaggers					
Flaggers for Aerial Applications (9)	This scenario not performed for biomonitoring data				

n/a = not applicable

a Biomonitoring internal estimated exposure represents Monsanto employees who wore long pants, long sleeve shirts, elbow length rubber gloves, caps, goggles, open mixing/loading, no respirator, closed cab tractor.
b The biomonitoring studies were conducted with liquid formulations. Therefore, these internal estimated exposures are not appropriate for use with granular or dry flowable formulations. In an attempt to estimate the internal estimated exposure a ratio of PHED exposure values that have been converted to baseline absorbed total doses were used in a ratio of other formulation/liquid formulation. The alachlor baseline absorbed total doses are from Table 25.

Scenario 2: (0.0000126 mg/kg/lb ai)(0.019/3.7) = 0.0000000647 mg/kg/lb ai
Scenario 3a: (0.0000126 mg/kg/lb ai)(0.41/16.3) = 0.000000316 mg/kg/lb ai
Scenario 3b: (0.0000126 mg/kg/lb ai)(0.094/3.7) = 0.00000032 mg/kg/lb ai
Scenario 7: (0.0000126 mg/kg/lb ai)(0.014/0.023) = 0.00000767 mg/kg/lb ai

c Application rate comes from the application rate of 4 lbs ai used in the Monsanto study.
d Daily acres treated are from EPA estimates of acreage that could be treated in a single day for each exposure scenario of concern.
e Biomonitoring internal dose (mg/kg/day) = Biomonitoring internal estimated exposure (mg/kg/lb ai) * Appl. rate (4 lb ai/A) * Acres Treated/day.

Post Application Exposure

The potential for post-application worker exposure is low, provided the Restricted Entry Interval (12 hours) is observed. This is due to the timing of applications. Alachlor is applied to the soil and/or soil incorporated preplant, pre-emergent, at planting for corn and soybeans, post-transplant for ornamentals, early post-emergent on corn, and at ground-crack for peanuts. This is well before the plants are mature, which mitigates the potential for post-application exposure. Exposure to alachlor during harvesting, even with sweet corn harvesting or seed corn detasseling, is not likely to occur as alachlor is applied primarily preplant and pre-emergent. Therefore, the Agency does not require that any post-application exposure or residue dissipation monitoring data be generated to support the reregistration of alachlor.

4. Risk Characterization

a. Dietary

As previously stated, an acute dietary risk assessment is not required. The RfD of 0.01 mg/kg/day was used for calculating chronic dietary risk. For calculating carcinogenic dietary risk two NOELs (14 mg/kg/day for stomach tumors and 0.5 mg/kg/day for nasal tumors) was used.

The tolerances used in this analysis are listed in Table 78: Tolerance Reassessment. At the time that the dietary assessment was performed, the registrant had expressed interest in supporting rotational crop tolerances for cotton and sunflowers. For this reason these uses were included in the assessment at the tolerance levels that were recently revoked. However, in alachlor petition 8F5000 dated June 25, 1998, Monsanto is requesting to establish tolerances for the direct application of alachlor to cotton and sunflower. This petition is now in review.

The consumption information used in this analysis is derived from USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). Over 30,000 respondents were surveyed over three days as to what foods they ate, with each individual's consumption information being associated with their body weight, sex, age, ethnicity and other sociodemographic information. Individual consumption estimates were weighted to be nationally representative. From these data single day and 3 day average consumption estimates were derived for the U.S. population and select population subgroups. Three day average information is used in the DRES chronic exposure analyses.

The Agency acknowledges that the data from this survey are more than 20 years old. However, at the time that the dietary assessment for alachlor was conducted, the data were the best information available to the Agency.

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High End Chronic Dietary (Food Source) Risk

The DRES chronic exposure analysis assumes tolerance level residues and one hundred percent crop treated to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Selected subgroups are reported in Table 17.

Table 17: Chronic Dietary Analysis (Food Only)

Subgroup	Exposure (mg/kg/day)	%Reference Dose
U.S. population	0.000756	8
Non-nursing Infants (<1 year)	0.003258	33
Children (1-6)	0.001744	17
Children (7-12)	0.001221	12

All other population subgroups were less than 10% of the RfD.

Refined Chronic Dietary (Food Source) Risk

The Dietary Exposure Assessment was refined using anticipated residues (ARs) and percent crop treated (%CT) to give a refined, i.e. more realistic, dietary assessment.

Calculation of Anticipated Residues

Existing FDA monitoring data were not used in calculating alachlor ARs because the data were considered to be of limited usefulness for dietary risk assessment. FDA found no detectable residues of alachlor, per se, in 53,600 samples, but the analyses did not include any of the alachlor metabolites of concern.

The anticipated residues, which are presented below in Table 18, were based on the average residue found in field trials where alachlor was used at the maximum application rate. Additionally a weighting factor was used for the percent of use at each application timing (i.e., preemergence vs. postemergence). For example, 90% of corn is typically treated preemergence at 4 lb ai/A or less with less than 10% treated postemergence (including sequential applications). Results of processing studies were also used to adjust the residue levels found in the raw commodity to account for changes in residue levels due to processing (both commercial and other types of processing). The typical application rates and timing used for the anticipated residue analysis is provided in Table 18 for each crop.

Table 18: Anticipated Residues, Plant Commodities: Calculations and Summary			
Average Residues from Alachlor Uses			
	Avg. Residue	Proc. Factor	Avg. Residue
Corn- 90% of use was preemergence at 4 lb ai/A, 10% of use was postemergence at 4 lb ai/A or sequential applications (4+2 lb ai/A)			
Corn grain	0.011		0.011
Corn meal		0.91[1]	0.010
Corn oil (refined)		0.12[1]	0.0014
Corn starch		0.19[2]	0.0022
Corn forage[7]	0.21		0.21
Corn silage[7]	0.22		0.22
Corn stover[7]	0.12		0.12
Sweet Corn K+CWHR			
preemergence 4 lb ai/A	0.007		0.007
Peanuts-35% of use was preemergence, 75% of use was cracking			
Peanut hulls[7]	0.38		0.38
Peanut nutmeat	0.15		0.15
Peanut meal[7]		1.37[1]	0.21
Peanut oil (refined)		0.06[1]	0.009
Peanut butter		0.70[3]	0.11
Peanuts, dry roasted		0.75[3]	0.11
Peanuts, oil roasted		0.83[3]	0.12
Sorghum preemergence 4 lb ai/A			
Sorghum grain	0.02		0.02
Sorghum forage[7]	0.29		0.29
Sorghum fodder[7]	0.29		0.29
Sorghum stover[7]	0.2		0.20
Soybeans preemergence 4 lb ai/A			
Soybean grain and soybean full fat and low fat flour	0.105		0.11
Soybean grain dust[7]		6.00[4]	0.63
Soybean hulls[7]		1.22[4]	0.13
Soybean toasted meal (feed)[7]		0.88[4]	0.092
Soybean defatted meal (food)		1.30[4]	0.137
Soybean oil (refined)		0.17[4]	0.018
Soybean protein concentrate		0.32[4]	0.034

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Table 18: Anticipated Residues, Plant Commodities: Calculations and Summary			
Average Residues from Alachlor Uses			
	Avg. Residue	Proc. Factor	Avg. Residue
Soybean protein isolate		0.21[4]	0.022
Soybean defatted flour			0.090[5]
Soybean forage[7]	1.36		1.36
Soybean hay[7]	2.61		2.61
Dry Beans preplant incorporated 3 lb ai/A			
Dry beans	0.048	0.20[6]	0.010
Dry lima beans	0.040	0.20[6]	0.008
Bean forage[7]	0.340		0.34
Bean vines[7]	0.396		0.40
Bean hay[7]	0.866		0.87

[1] MRID 00162939
[2] MRID 40788201
[3] MRID 40820601
[4] MRID 00154239, 00154240, 40947101, 41862901 41916301
[5] 4/7 defatted meal + 3/7 protein concentrates and isolates
[6] MRID 40820701
[7] Livestock feed only

In estimating anticipated residues for milk, poultry and eggs, anticipated residues as calculated in Table 18 were used in estimating the dietary burden. (See Table 7 for example of calculation.) Estimated dietary burdens based on these anticipated residues in livestock feeds for cattle, poultry, and swine were determined to be 0.49, 0.20, and 0.27 ppm, respectively. The anticipated residues in livestock commodities were then corrected for the expected recovery in each livestock tissue. Anticipated residue estimates for livestock commodities are listed in Table 19.

Table 19: Anticipated Residues in Livestock Commodities.						
Alachlor Feeding Study Results			Estimated Residues			
	Feeding Level (ppm)	Residue (ppb)	Dietary Burden (ppm)	Residue Measured by Method (ppb)	% Residue of Concern Measured by Method	Total Residue of Concern (ppb)
BEEF						
muscle	4.20	1.20	0.53	0.15	38%	0.40
fat	4.20	1.90	0.53	0.24	70%	0.34

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Table 19: Anticipated Residues in Livestock Commodities.

Alachlor Feeding Study Results			Estimated Residues			
	Feeding Level (ppm)	Residue (ppb)	Dietary Burden (ppm)	Residue Measured by Method (ppb)	% Residue of Concern Measured by Method	Total Residue of Concern (ppb)
liver	4.20	7.80	0.53	0.98	58%	1.70
kidney	4.20	8.70	0.53	1.10	68%	1.61
milk	4.20	1.50	0.69	0.25	40%	0.62
POULTRY						
muscle	12.00	1.00	0.09	0.01	34%	0.02
fat	12.00	1.30	0.09	0.01	75%	0.01
liver	4.00	2.10	0.09	0.05	51%	0.09
eggs	4.00	6.90	0.09	0.16	60%	0.26
SWINE						
muscle	4.00	1.30	0.19	0.06	38%	0.16
fat	4.00	2.60	0.19	0.12	70%	0.18
liver	4.00	4.10	0.19	0.19	58%	0.34
kidney	12.00	7.40	0.19	0.12	68%	0.17

Since the dietary exposure assessment is based on field trial data, the anticipated residues are likely to overestimate the dietary exposure because the application rates and timing assumed in the dietary exposure analysis were at the highest rate on the label, which is not necessarily the typical rate used by the applicator. Additionally, residues are likely to degrade from the time that samples are obtained at the farm gate during transportation, processing and storage, prior to consumption. For the livestock commodities, the following assumptions were used: (1) all alachlor metabolite residues found in the livestock animal metabolism studies are residues of concern and (2) the percentage recovery of the analytical method in livestock commodities is based on the percentage of metabolites recovered in metabolism studies. Alachlor metabolites not identified specifically in the metabolism studies may also respond to the analytical method, so the analytical recovery may be higher than estimated.

Percent Crop Treated Data

Percent crop treated (CT) information are from a three year period 1993 - 1995. The FQPA amendments to Section 408(b)(2)(F) of the FFDCA require that if a tolerance relies on percent crop-treated data, that the Agency make a determination as to the reliability of the data. The percent crop treated estimates used by EPA are derived from Federal and private market survey data. Typically, the Agency considers the range of percent crop treated data from a period of several years, and uses

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the upper end of this range for estimating dietary exposure. In so doing, the Agency is reasonably certain that exposure is not understated for any major population sub-group. Additionally, the DRES (Dietary Risk Evaluation System) used in estimating chronic dietary risk uses regional consumption information to estimate exposure for four population sub-groups that are based on geographical regions of the United States. The Agency will provide for the periodic evaluation of these estimates of percent crop treated, as long as the tolerances for alachlor remain in force.

When a range of percent of crop treated estimates was supplied, the upper end (in bold) was used. One hundred percent CT (default assumption) was used if no information was provided for a crop. This data is now several years old. However, information available to the Agency indicates that alachlor usage has fallen. Thus, these percent crop treated estimates can be considered as slight over-estimates.

Table 20: Percent of Various U.S. Crops Treated Annually with Alachlor

Commodities	Percent Crop Treated	Major Region or State
Beans, Dry	<10	Nationwide
Beans, Succulent	10 - **35**	CA and ID
Corn, Sweet	30 - **35**	Nationwide
Corn, Field	20 - **25**	Nationwide
Peanuts	<5	Southeast
Sorghum	10 - **15**	Nationwide
Soybeans	5 - **10**	Nationwide
Sunflowers	<1 - **1**	SD and NE

Refined dietary exposures and percent RfDs for selected subgroups are reported in Table 21.

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Table 21: Chronic Refined Dietary Analysis (Food Only)		
Subgroup	Exposure (mg/kg/day)	%Reference Dose
U.S. population	0.000011	0.1
Non-nursing Infants (<1 year)	0.000050	0.5
Children (1-6 years)	0.000029	0.3
Children (7-12 years)	0.000019	0.2
Male (20+ years)	0.000007	0.07
Female (13+ years), nursing	0.000010	0.1

All other population subgroups were less than 0.2% of the RfD. Thus, when using anticipated residues and percent crop treated data, all population subgroups are well below the RfD for alachlor. Chronic dietary risk from alachlor from all food uses for which tolerance reassessments have been performed is not of concern.

Dietary Carcinogenic (Food Sources) Risk (MOE Approach)

As stated previously, the Committee recommended using a Margin of Exposure (MOE) approach for estimation of human risk, rather than the linear low dose approach. The NOELs, 0.5 mg/kg/day for nasal tumors and 14 mg/kg/day for stomach tumors, were used for estimating MOEs for adult females and adult males using the chronic exposures in Table 21. It should be noted that alachlor ESA is included in these estimates of exposure, since it is converted in the alachlor crop residue methodology to DEA. Since alachlor ESA is unlikely to be carcinogenic in a 2-year bioassay these residues should not be included in the carcinogenic assessment, but cannot be separated out. Therefore, these exposure estimates are very slight over-estimates.

Carcinogenic MOE = NOEL / exposure

At this time the Agency is not making any recommendations on the level of MOEs to be considered acceptable for dietary risk. However, given the magnitude of the calculated MOEs, dietary cancer risk from all food uses for which tolerance reassessments have been performed is not expected to be of concern. All MOEs in Table 22 have been rounded to two significant figures.

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Table 22: Carcinogenic MOEs		
Population Group	Exposure	MOE
Nasal Tumors (0.5 mg/kg/day)		
Adult Male	0.000007	71,000
Adult Female	0.000010	50,000
Stomach Tumors (14 mg/kg/day)		
Adult Male	0.000007	2,000,000
Adult Female	0.000010	1,400,000

b. Drinking Water

Chronic Drinking Water Risk

Percent RfDs for consumption of drinking water containing residues of alachlor per se were estimated using the RfD for alachlor of 0.01 mg/kg/day for adult males, adult females and child (1 - 6 years). There are no default assumptions for estimating risk for non-nursing infants (< 1 year), although the same assumptions as used for a child (1 -6 years) could be used. Since, the chronic food source risk for both of these sub-population groups was < 1%, the total dietary risk would be similar. All RfDs were rounded to one significant figure.

Table 23: Drinking Water Percent RfDs for Alachlor per se- Adult Male			
STUDY	Concentration (ppb)	Exposure (mg/kg/day)	% RfD
MCL	2	0.0000571	0.6
Surface Water			
USGS - Alachlor (reservoir)	0.22	0.0000062	0.06
ARP Data (1995-1996) (drinking water)	0.1	0.0000028	0.03
Ground Water			
NAWWS	0.2	0.0000057	0.06
NAWWS	0.015	0.0000004	0.004

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Table 24: Drinking Water Percent RfDs for Alachlor per se- Adult Female			
STUDY	Concentration (ppb)	Exposure (mg/kg/day)	% RfD
MCL	2	0.0000666	0.7
Surface Water			
USGS - Alachlor (reservoir)	0.22	0.0000073	0.07
ARP Data (1995-1996) (drinking water)	0.1	0.0000033	0.03
Ground Water			
NAWWS	0.2	0.0000066	0.07
NAWWS	0.015	0.0000005	0.005

Table 25: Drinking Water Percent RfDs for Alachlor per se - Child (1 - 6 years)			
STUDY	Concentration (ppb)	Exposure (mg/kg/day)	% RfD
MCL	2	0.0002	2
Surface Water			
USGS - Alachlor (reservoir)	0.22	0.000022	0.2
ARP Data (1995-1996) (drinking water)	0.1	0.00001	0.1
Ground Water			
NAWWS	0.2	0.00002	0.2
NAWWS	0.015	0.0000015	0.02

All % RfD values are well below 100%. Chronic dietary risk from alachlor from consumption of water containing residues of alachlor per se is not of concern.

No RfD for alachlor ESA has been determined; the toxicological data base is incomplete. Therefore, a default assumption would be to use the parent alachlor RfD for the metabolite. Using the exposures estimated in Tables 6, 7, and 8 and the alachlor RfD of 0.01 mg/kg/day, percent RfDs were estimated to be of 0.9%, 1%, and 3% for adult male, adult female and children (1-6 years), respectively. Another assumption would be to calculate a value for use in a chronic dietary risk assessment using the NOEL from the 91-day alachlor ESA drinking water study. Using the NOEL of 157 mg/kg/day and an uncertainty factor of 1000 (to account for interspecies extrapolation, intraspecies variability and lack of a complete database) a value of 0.16 mg/kg/day was calculated. This gives percent RfDs of 0.05%, 0.06%, and 0.2% for adult male, adult female and children (1-6 years), respectively. Note that both of these approaches indicate little concern for consumption of alachlor ESA in the drinking water.

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Carcinogenic Drinking Water Risk

Carcinogenic MOEs were calculated for adult males and females only. Alachlor ESA is not included in the MOEs since it was determined that alachlor ESA is unlikely to be carcinogenic in a 2-year bioassay. All MOEs were rounded to two significant figures.

Table 26: Drinking Water Carcinogenic MOEs - (Adult Male)

STUDY	Concentration (ppb)	Exposure (mg/kg/day)	MOE[1]	MOE[2]
MCL	2	0.0000571	8,800	250,000
Surface Water				
USGS - Alachlor	0.22	0.0000062	45,000	2,300,000
ARP Data (1995-1996)	0.1	0.0000028	180,000	6,400,000
Ground Water				
NAWWS	0.2	0.0000057	88,000	2,500,000
NAWWS (99.5% population)	0.015	0.0000004	1,200,000	35,000,000

1 MOE for nasal tumors (0.5 mg/kg/day)
2 MOE for stomach tumors (14 mg/kg/day)

Table 27: Drinking Water Carcinogenic MOEs - (Adult Female)

STUDY	Concentration (ppb)	Exposure (mg/kg/day)	MOE[1]	MOE[2]
MCL	2	0.0000666	7,500	210,000
Surface Water				
USGS - Alachlor	0.22	0.0000073	68,000	1,900,000
ARP Data	0.1	0.0000033	150,000	5,400,000
Ground Water				
NAWWS	0.2	0.0000066	76,000	21,000,000
NAWWS (99.5% population)	0.015	0.0000005	1,000,000	28,000,000

1 MOE for nasal tumors
2 MOE for stomach tumors

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At this time the Agency is not making any recommendations on the level of MOEs to be considered acceptable for dietary (drinking water) risk. However, given the magnitude of the calculated MOEs, dietary (drinking water) cancer risk is not expected to be of concern.

c. Aggregate (Food and Water)

Aggregate Chronic Dietary (Food Source and Drinking Water) Risk

This assessment combines the food residue exposure estimates with drinking water exposure estimates to calculate an aggregate chronic exposure. Percent RfDs for aggregate chronic dietary risk were calculated for adult males, adult females, and children (1 - 6 years). All RfDs were rounded to one significant figure.

Adult Male - Alachlor

Using the refined adult male food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 23:

Exposure = 0.000007 mg/kg/day +0.0000057 mg/kg/day = 0.0000127 mg/kg/day

% RfD = 0.0000127 / 0.01 (100)= 0.1 %

Using the refined adult male food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 23:

Exposure = 0.000007 mg/kg/day + 0.0000062 mg/kg/day = 0.0000132 mg/kg/day

%RfD =0.0000132 / 0.01 (100) = 0.1 %

Using the refined adult male food source exposure from Table 21 and ARP (12 state area surface water) from Table 23:

Exposure = 0.000007 mg/kg/day +0.0000028 mg/kg/day = 0.0000098 mg/kg/day

% RfD = 0.0000098 / 0.01 (100) = 0.1 %

Adult Male - Alachlor and Alachlor ESA

Using the refined adult male food source exposure from Table 21 and USGS reservoir (Midwest surface water) exposure from Table 23:

Exposure = 0.000007 mg/kg/day + 0.0000062 mg/kg/day + 0.0000857 mg/kg/day = 0.0000989 mg/kg/day

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% RfD = 0.0000989 / 0.01 (100) = 1 %

Adult Female Alachlor

Using the refined adult female food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000066 mg/kg/day = 0.0000166 mg/kg/day

% RfD = 0.0000166 / 0.01 (100) = 0.2 %

Using the refined adult female food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000073 mg/kg/day = 0.0000173 mg/kg/day

% RfD = 0.0000173 / 0.01 (100) = 0.1%

Using the refined adult female food source exposure from Table 21 and ARP (12 state area surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000033 mg/kg/day = 0.0000133 mg/kg/day

% RfD = 0.0000133 / 0.01 = 0.1%

Adult Female - Alachlor and Alachlor ESA

Using the refined adult female food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000073 mg/kg/day +0.0001 mg/kg/day = 0.0001173 mg/kg/day

% RfD = 0.0001173 / 0.01 (100) = 1 %

Child (1-6 years) - Alachlor

Using the refined child (1-6 years) food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 24:

Exposure = 0.000029 mg/kg/day + 0.00002 mg/kg/day = 0.000049 mg/kg/day

% RfD = 0.000049 / 0.01 (100) = 0.5%

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Using the refined child (1-6 years) food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 25:

Exposure = 0.000029 mg/kg/day + 0.000022 mg/kg/day = 0.000051 mg/kg/day

% RfD = 0.000051 / 0.01 (100) = 0.5 %

Using the refined child (1-6 years) food source exposure from Table 21 and ARP (12 state area surface water) from Table 25:

Exposure = 0.000029 mg/kg/day + 0.00001 mg/kg/day = 0.000039 mg/kg/day

% RfD = 0.000039 / 0.01 (100) = 0.4 %

Child (1 - 6 years) - Alachlor and Alachlor ESA

Using the refined child (1-6 years) food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 25:

Exposure = 0.000029 mg/kg/day + 0.000022 mg/kg/day + 0.0003 mg/kg/day = 0.000351 mg/kg/day

% RfD = 0.000351 / 0.01 (100) = 4 %

All % RfDs for aggregate chronic dietary risk are well below 100%. Chronic dietary risk from alachlor from food containing residues of alachlor and from consumption of water containing residues of alachlor per se and/or residues of alachlor ESA is not of concern.

Aggregate Carcinogenic Dietary (Food and Water) Risk (MOE Approach)

MOEs for aggregate carcinogenic dietary risk were calculated for adult males and females. All MOEs were rounded to two significant figures. Per the recommendations of the Metabolism Committee, alachlor ESA is not included in the carcinogenic assessment.

Adult Male

Using the refined adult male food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 23:

Exposure = 0.000007 mg/kg/day +0.0000057 mg/kg/day = 0.0000127 mg/kg/day

MOE (nasal) = 0.5 / 0.0000127 = 39,000

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MOE (stomach) = 14 / 0.0000127 = 1,100,000

Using the refined adult male food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 23:

Exposure = 0.000007 mg/kg/day + 0.0000062 mg/kg/day = 0.0000132 mg/kg/day

MOE (nasal) = 0.5 / 0.0000132 = 38,000

MOE (stomach) = 14 / 0.0000132 = 1,100,000

Using the refined adult male food source exposure from Table 21 and ARP (12 state area surface water) from Table 23:

Exposure = 0.000007 mg/kg/day +0.0000028 mg/kg/day = 0.0000098 mg/kg/day

MOE (nasal) = 0.5 / 0.0000098 = 51,000

MOE (stomach) = 14 / 0.0000098 = 1,400,000

Adult Female

Using the refined adult female food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000066 mg/kg/day = 0.0000166 mg/kg/day

MOE (nasal) = 0.5 / 0.0000166 = 30,000

MOE (stomach) = 14 / 0.0000166 = 840,000

Using the refined adult female food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000073 mg/kg/day = 0.0000173 mg/kg/day

MOE (nasal) = 0.5 / 0.0000173 = 29,000

MOE (stomach) = 14 / 0.0000173 = 810,000

Using the refined adult female food source exposure from Table 21 and ARP (12 state area surface water) from Table 24:

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Exposure = 0.000010 mg/kg/day + 0.0000033 mg/kg/day = 0.0000133 mg/kg/day

MOE (nasal) = 0.5 / 0.0000133 = 38,000

MOE (stomach) = 14 / 0.0000133 = 1,100,000

At this time the Agency is not making any recommendations on the level of MOEs to be considered acceptable for aggregate (food and water) dietary risk. However, given the magnitude of the calculated MOEs (ranging from 29,000 to 1,400,000), aggregate carcinogenic dietary risk from all food uses for which tolerance reassessments have been performed is not expected to be of concern.

Aggregate Carcinogenic Dietary (Food and Water) Risk (Q_1^* Approach)

Aggregate carcinogenic dietary risk using the Q_1^* approach were calculated for adult males and females. All risks were rounded to two significant figures. Per the recommendations of the Metabolism Committee, alachlor ESA is not included in the carcinogenic assessment.

Risk = (Q_1^*)(exposure)

Adult Male

Using the refined adult male food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 23:

Exposure = 0.000007 mg/kg/day + 0.0000057 mg/kg/day = 0.0000127 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000127 mg/kg/day] = 1.0×10^{-6}

Using the refined adult male food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 23:

Exposure = 0.000007 mg/kg/day + 0.0000062 mg/kg/day = 0.0000132 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000132 mg/kg/day] = 1.1×10^{-6}

Using the refined adult male food source exposure from Table 21 and ARP (12 state area surface water) from Table 23:

Exposure = 0.000007 mg/kg/day +0.0000028 mg/kg/day = 0.0000098 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000098 mg/kg/day] = 7.8×10^{-7}

Adult Female

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Using the refined adult female food source exposure from Table 21 and NAWWS (Midwest ground water) exposure from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000066 mg/kg/day = 0.0000166 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000166 mg/kg/day] = 1.3 x 10^{-6}

Using the refined adult female food source exposure from Table 21 and USGS reservoir (Midwest surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000073 mg/kg/day = 0.0000173 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000173 mg/kg/day] = 1.4 x 10^{-6}

Using the refined adult female food source exposure from Table 21 and ARP (12 state area surface water) from Table 24:

Exposure = 0.000010 mg/kg/day + 0.0000033 mg/kg/day = 0.0000133 mg/kg/day

Risk = [0.08 $(mg/kg/day)^{-1}$][0.0000133 mg/kg/day] = 1.1 x 10^{-6}

All carcinogenic risks estimated using the Q_1^* are within the risk range considered by the Agency to represent negligible risk.

d. Occupational

Short Term Risk

For the short-term risk assessment, a NOEL of 150 mg/kg/day was used to calculate the MOE. The Agency used a 60 kg body weight, the Agency's default female body weight since the selected endpoint is from a developmental study. Since the NOEL is from an oral study, the dermal absorption factor of 24% was used to estimate oral-equivalents for the dermal exposure.

Intermediate Term Risk

For the intermediate-term risk assessment, a NOEL of 50 mg/kg/day was used to calculate the MOE. The Agency used a 70 kg body weight, the Agency's default adult body weight. Since the NOEL is from a dermal study, use of the dermal absorption factor is not appropriate.

Estimates of short-term and intermediate-term occupational risk to alachlor are summarized in Tables 28 and 29. All MOEs have been rounded to 1 or 2 significant figures.

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Table 28: Short-Term Risk from Alachlor

Exposure Scenario (Scenario #)	Crop/ Rate[a]	Baseline Absorbed Total Dose (mg/kg/day)[b,e]	Baseline MOE[c]	PPE Absorbed Dose[b,f] (mg/kg/day)	PPE MOE[c]	Eng. C Absorbed Dose[b,g] (mg/kg/day)	Eng. C MOE[c]	Biomonitoring Internal Dose (mg/kg/day)[d]	Biomonitoring MOE[c]
Mixer/Loader Exposure									
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	Corn 4.0	16.3	9	0.27	560	N/A	N/A	0.01764	8500
	Soybean 3.0	12.2	12	0.20	750	N/A	N/A	N/A	N/A
Mixing/Loading Liquids for Groundboom Application (1b)	Corn 4.0	3.7	41	0.061	2,500	N/A	N/A	0.004032	37,000
	Soybean 3.0	2.8	54	0.046	3,300	N/A	N/A	N/A	N/A
Mixing/Loading Granulars for Drop Type Tractor Drawn Spreader Application (2)	Corn 4.0	0.019	7,900	N/A	N/A	N/A	N/A	0.00002070	720,000
	Soybean 3.0	0.014	11,000	N/A	N/A	N/A	N/A	N/A	N/A
Mixing/Loading Dry Flowables for Aerial Application (3a)	Corn 4.0	0.41	370	N/A	N/A	N/A	N/A	0.0004424	34,000
	Soybean 3.0	0.31	480	N/A	N/A	N/A	N/A	N/A	N/A
Mixing/Loading Dry Flowables for Groundboom Application (3b)	Corn 4.0	0.094	1,600	N/A	N/A	N/A	N/A	0.0001024	150,000
	Soybean 3.0	0.07	2,100	N/A	N/A	N/A	N/A	N/A	
Applicator Exposure									
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	Corn 4.0	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.030	5000	N/A	N/A
	Soybean 3.0	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.022	6800	N/A	N/A
Aerial Application of Liquids - Helicopter - Enclosed Cockpit (5)	Corn 4.0	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.012	13000	N/A	N/A
	Soybean 3.0	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.009	17000	N/A	N/A
Groundboom Application of Liquids (6)	Corn 4.0	0.023	6,500	N/A	N/A	N/A	N/A	0.004032	35,000
	Soybean 3.0	0.017	8,800	N/A	N/A	N/A	N/A	N/A	N/A
Granular Drop Type Tractor Drawn Spreader Application (7)	Corn 4.0	0.014	11,000	N/A	N/A	N/A	N/A	0.002454	61,000
	Soybean 3.0	0.01	15,000	N/A	N/A	N/A	N/A	N/A	N/A

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Table 28: Short-Term Risk from Alachlor

Exposure Scenario (Scenario #)	Crop/ Rate[a]	Baseline Absorbed Total Dose (mg/kg/day)[b,e]	Baseline MOE[c]	PPE Absorbed Dose[b,f] (mg/kg/day)	PPE MOE[c]	Eng. C Absorbed Dose[b,g] (mg/kg/day)	Eng. C MOE[c]	Biomonitoring Internal Dose (mg/kg/day)[d]	Biomonitoring MOE[c]
Mixer/Loader/Applicator									
Mixing/Loading and Application for Dry Bulk Fertilizer (8)	See text								
Flaggers									
Flaggers for Aerial Applications (9)	Corn 4.0	0.063	2,400	N/A	N/A	N/A	N/A	N/A	N/A
	Soybean 3.0	0.047	3200						

PPE personal protective equipment
Eng. C engineering controls
a Rates are from Alachlor labels EPA Reg Nos. 524-344, 524-403, 524-418, 524-422 and 524-314.
b Absorbed Total Dose ((daily dermal exposure * dermal absorption rate 0.24) + (daily inhalation exposure)) / 60 kg.
c MOE = NOEL (150 mg/kg/day) / absorbed total dose.
d Biomonitoring (See Table 16) Estimated only for 4 lb ai.
e See Table 13 footnotes for explanation of calculations
f See Table 14 footnotes for explanation of calculations and description of PPE
g See Table 15 footnotes for explanation of calculations and description of engineering controls

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Table 29: Intermediate-Term Risk from Alachlor

Exposure Scenario (Scenario #)	Crop/ Rate[a]	Baseline Total Dose[b,e] (mg/kg/day)	Baseline Total Dermal MOE[c]	PPE Daily Total Dose[b,f] (mg/kg/day)	PPE Total MOE[c]	Eng. C Daily Total Dose[b,g] (mg/kg/day)	Eng. C Total MOE[c]	Biomonitoring Internal Dose (mg/kg/day) [d]	Biomonitoring MOE[c]
Mixer/Loader Exposure									
Mixing/Loading Liquids for Aerial Application and Chemigation (1a)	Corn 4.0	58.0	0.9	0.54	93	0.18	280	0.01764	2800
	Soybean 3.0	43.5	1	0.39	130	N/A	N/A	N/A	N/A
Mixing/Loading Liquids for Groundboom Application (1b)	Corn 4.0	13.3	4	0.2	250	N/A	N/A	0.004032	12,000
	Soybean 3.0	9.9	5	0.17	300	N/A	N/A	N/A	N/A
Mixing/Loading Granulars for Drop Type Tractor Drawn Application (2)	Corn 4.0	0.04	1,300	N/A	N/A	N/A	N/A	0.0000207	2,400,000
	Soybean 3.0	0.03	1,700					N/A	N/A
Mixing/Loading Dry Flowables for Aerial Application (3a)	Corn 4.0	1.42	35	0.82	61	No data	No data	0.0004424	110,000
	Soybean 3.0	1.05	47	0.61	82			N/A	N/A
Mixing/Loading Dry Flowables for Groundboom Application (3b)	Corn 4.0	0.32	160	N/A	N/A	N/A	N/A	0.0001024	490,000
	Soybean 3.0	0.24	210					N/A	N/A
Applicator Exposure									
Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (4)	Corn 4.0	See Engineering Controls		See Engineering Controls	See Engineering Controls	0.10	500	N/A	N/A
	Soybean 3.0					0.08	630	N/A	N/A
Aerial Application of Liquids - Helicopter - Enclosed Cockpit (5)	Corn 4.0	See Engineering Controls		See Engineering Controls	See Engineering Controls	0.042	1,200	N/A	N/A
	Soybean 3.0					0.031	1,600	N/A	N/A
Groundboom Application of Liquids (6)	Corn 4.0	0.072	690	N/A	N/A	N/A	N/A	0.004032	12,000
	Soybean 3.0	0.054	930	N/A	N/A	N/A	N/A	N/A	N/A
Granular Drop Type Tractor Drawn Spreader Application (7)	Corn 4.0	0.047	1,100	N/A	N/A	N/A	N/A	0.002454	20,000
	Soybean 3.0	0.036	1,400					N/A	N/A

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Table 29: Intermediate-Term Risk from Alachlor

Exposure Scenario (Scenario #)	Crop/ Rate[a]	Baseline Total Dose[b,e] (mg/kg/day)	Baseline Total Dermal MOE[c]	PPE Daily Total Dose[b,f] (mg/kg/day)	PPE Total MOE[c]	Eng. C Daily Total Dose[b,g] (mg/kg/day)	Eng. C Total MOE[c]	Biomonitoring Internal Dose (mg/kg/day) [d]	Biomonitoring MOE[c]
Mixer/Loader/Applicator									
Mixing/Loading and Application for Dry Bulk Fertilizer (8)	See text								
Flaggers									
Flaggers for Aerial Applications (9)	Corn 4.0	0.206	240	N/A	N/A	N/A	N/A	N/A	N/A
	Soybean 3.0	0.154	330						

N/A - not applicable

a From Alachlor labels EPA Reg Nos. 524-344, 524-403, 524-418, 524-422 and 524-314.
b Total dose = (daily dermal exposure) + (daily inhalation exposure) / 70 kg.
c MOE = NOEL (50 mg/kg/day) / total dose (mg/kg/day).
d Biomonitoring (See Table 16) Estimated only for 4 lb ai.
e See Table 13 footnotes for explanation of calculations
f See Table 14 footnotes for explanation of calculations and description of PPE
g See Table 15 footnotes for explanation of calculations and description of engineering controls

Occupational Risk Characterization

Short-Term Exposure

Using the registrant-submitted biomonitoring data, all short-term MOEs are much greater than 100.

Using PHED data for estimating short-term risk the MOEs are more than 100 at **baseline** for scenarios:
(2) mixing/loading granulars for drop type tractor drawn spreader application,
(3a) mixing/loading dry flowables for aerial application,
(3b) mixing/loading dry flowables for groundboom application,
(6) liquid groundboom application,
(7) granular drop type tractor drawn spreader application, and
(9) flaggers

Using PHED data **with additional PPE** and the corresponding decreases in exposure, the MOEs are more than 100 for short-term risk for scenarios:
(1a) mixing/loading liquids for aerial application and chemigation, and
(1b) mixing/loading liquids for groundboom application.

Using PHED data **with engineering controls** (no other data were available) the calculated MOEs are more than 100 for short-term risk for scenarios:
(4) liquid aerial application (fixed-wing), and
(5) liquid aerial application (helicopter).

Thus, it was possible to achieve MOEs greater than 100 for all scenarios for which data existed in PHED.

Intermediate-Term Exposure

Using the registrant-submitted biomonitoring data, all intermediate MOEs are much greater than 100.

Using PHED for intermediate term risk the MOEs are more than 100 at **baseline** for risk for scenarios:
(2) mixing/loading granulars groundboom application,
(3b) mixing/loading dry flowables for groundboom application,
(6) liquid groundboom application, and
(9) flaggers.

Using PHED **with additional PPE** and the corresponding decreases in exposure the MOEs are more than 100 for intermediate-term risk for scenarios:

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(1a) mixing/loading liquids for aerial application (for rate of 3.0 lb ai/acre for soybeans), and
(1b) mixing/loading liquids for groundboom application.

Using PHED **with engineering controls** and the corresponding decreases in exposure the MOEs are more than 100 for intermediate-term risk for scenarios:
(1a) mixing/loading liquids for aerial application (for the rates of 4.0 lb ai/acre for corn),
(4) aerial application of liquids (fixed-wing aircraft), and
(5) aerial application of liquids (helicopter).

However, despite available PPE mitigation measures, it was not possible to achieve an MOE of greater than 100 for scenario (3a) mixing/loading dry flowables for aerial application. There are no engineering controls currently available for dry flowable formulations. Therefore, estimation of exposure and resultant risk was not performed.

Dry Bulk Fertilizer Scenario

Using information provided by Monsanto, the Agency estimated MOEs for mixer/loaders using a liquid alachlor product to impregnate dry bulk fertilizer, and for applicators applying the treated fertilizer. This assessment was based on information provided by Monsanto in which the processes involved in treating fertilizer with alachlor and applying the treated fertilizer were described. (MRID No. 44492302)

Dry bulk fertilizer impregnated with alachlor is typically prepared by local agricultural dealers, and is then transported to the fields and applied. According to the information provided by Monsanto there is a division of labor, in that most dealers, even small dealer operations, usually have different individuals running the mixing equipment and applying the mix to fields. This is because of the different skill requirements and to achieve better productivity. Thus, the Agency performed separate assessments for mixer/loaders, and applicators. If an individual were to mix/load/apply, then the risk would increase correspondingly.

There is also a Granu-Blend system, which is a system for applying granular alachlor at the same time as application of the fertilizer, and is thus similar to the mixer/loader and applicator scenarios for granular materials discussed in other sections of this alachlor RED chapter.

Mixer/Loaders

The Agency's preliminary review of exposure to workers impregnating dry bulk fertilizer with liquid formulations of alachlor expressed concern over an absence of data and the potential for significant exposure.

According to the labels the blending must be performed by commercial fertilizer or chemical dealerships properly equipped for the procedure. The amount of fertilizer and alachlor handled depends on the number of acres to be treated. According to alachlor labels, from 200 to 450 lbs. of

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impregnated fertilizer may be applied per acre, preplant to corn, grain sorghum, and soybeans. The maximum single application rate for alachlor is 4 lbs ai/acre per new labels approved by the Agency on June 30, 1998.

According to the University of Illinois Extension Service: The herbicide is metered from a mini-bulk tank (several hundred gallons) to a mixing drum via a closed system. The herbicide is sprayed onto the fertilizer, which is stirred by an auger that lifts it to the top of the drum. After impregnation, the treated fertilizer is gravity-fed through a hopper onto a conveyor belt leading to an auger truck, which carries it to the field. At the field, the auger truck feeds the treated fertilizer onto the applicator vehicle, which dispenses it from either a rotary spinner or a boom with numerous outlets. The transfer of the treated fertilizer in each instance is nearly dust-free, as it has been moistened by the herbicide. Because all processes are mechanized, there is minimal contact of either the mixer at the treatment site or the loader at the transfer sites. Applicator exposure is minimized by the use of a closed cab.

The information supplied by Monsanto indicates that impregnation of fertilizer in a mixing tower is typically a closed system operation. Monsanto provided a diagram of a mixing/loading tower which specifies that up to 120 tons of fertilizer can be processed per hour. If the tower were assumed to process for 8 hours per day, then this would be 960 tons of fertilizer processed per 8 hour day. At 3 to 4 lbs active ingredient per 200 lbs fertilizer, each ton of fertilizer would require 30 to 40 lbs of alachlor active ingredient. Thus, the total amount of active ingredient for 960 tons at the 4 lb ai rate is (960)(40) = 38400 lbs, and at the 3 lb ai rate is (960)(30) = 28800 lbs. The new information submitted by Monsanto, and confirmed by the Agency, specified that the typical or average fertilizer use rate is approximately 400 lbs/acre. At 4 lbs active ingredient per 400 lbs fertilizer, each ton of fertilizer would require 20 lbs of alachlor active ingredient. Thus, the total amount (based on 400 lbs fertilizer per acre) for 4 lbs ai handled is (960)(20) = 19,200 lbs.

Using the above information, the Agency has estimated risk for mixers/loaders impregnating the dry bulk fertilizer assuming use of engineering controls (metered delivery from a mini-bulk tank). Only the dermal values will be used in this assessment, since technical alachlor is classified as toxicity category III, and for liquids, the unit inhalation exposure value is insignificant (differing by several orders of magnitude) when compared to the unit dermal exposure value.

Daily exposure (mg/day) is estimated using the following equation:

unit exposure (mg/lb ai) x lbs ai handled per day

Daily dose (mg/kg/day) is calculated by dividing the daily exposure (mg/day) by the body weight (bw) of the worker. For the short-term scenario, the Agency used a 60 kg body weight, the Agency's default adult female body weight since the selected endpoint is from a developmental study. Since the selected endpoint is from an oral study, the exposure must be adjusted to account for dermal exposure. The dermal absorption factor is 24 percent (0.24).

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Thus, for the short-term scenario, absorbed daily dose = daily exposure (mg/day) / 60 kg x 0.24.

For the intermediate-term scenario, the Agency used a 70 kg body weight, the Agency's default adult body weight. Since the NOEL is from a dermal toxicity study, the dermal exposure will not need to be adjusted by the dermal absorption factor.

Thus, for the intermediate-term scenario, daily dose = daily exposure (mg/day) / 70 kg.
Risk, in terms of margins of exposure (MOE), is calculated by using the following equation:

NOEL (mg/kg/day) / daily dose (mg/kg/day) = MOE.

All MOEs are rounded to one or two significant digits. For the short-term scenario, the NOEL is 150 mg/kg/day. For the intermediate-term scenario, the NOEL is 50 mg/kg/day. Generally, the Agency has no concerns for an MOE greater than or equal to 100 for non-cancer effects when the NOEL used in estimating the MOE is from an animal study.

The PHED V1.1 unit dermal exposure for a closed mixing/loading mechanical transfer system (single layer clothing - with gloves) is 0.009 mg/lbs ai - high confidence.

Table 30: Short-Term with Engineering Controls (Closed Transfer System)

Unit Exposure (mg/lbs ai)	Application Rate (lbs ai/day)	Daily Exposure (mg/day)	Daily Dose (mg/kg/day)	MOE
0.009	38400	346	1.38	110
0.009	28800	259	1.04	140
0.009	19200	173	0.69	220

Table 31: Intermediate-Term with Engineering Controls (Closed Transfer System)

Unit Exposure (mg/lbs ai)	Application Rate (lbs ai/day)	Daily Exposure (mg/day)	Daily Dose (mg/kg/day)	MOE
0.009	38400	346	4.9	10
0.009	28800	259	3.7	14
0.009	19200	173	2.5	20

The Agency made assumptions in performing this assessment and acknowledges that many of the assumptions were deliberately intended toward performing an upper-end assessment. One of the most conservative of these assumptions was that the mixing tower would run at full capacity for

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8 hours a day, thus generating 960 tons of alachlor impregnated fertilizer. It could require 32 to 96 truckloads per day (assuming 10 to 30 tons of fertilizer per truck) to spread the towers output. The impregnated fertilizer market is likely to be a custom operation, in that (1) the blending occurs on an as needed/as ordered basis, and (2) only the amount ordered is prepared.

All intermediate-term MOEs are less than 100; however, the Agency acknowledges that the estimation of these MOEs did contain the conservative estimate of the mixing tower working 8 hours per day. The short-term MOEs are greater than 100 considering mitigation with a closed transfer system. Only the dermal component of the exposure - no inhalation exposure component - was considered.

The Agency also has concerns that the data in PHED may not adequately represent this scenario. This is not a typical usage under agricultural field conditions. The amount of alachlor necessary to impregnate the tons of fertilizer that can be processed in a day is far too large to be handled by opening individual bottles or containers (as data collected for PHED), and probably involves transfer from large containers such as tanker trucks or railroad tank cars.

Extrapolating a unit exposure in the range of 19200 to 38400 lb ai/day from the available data in PHED is likely to result in an over-estimate. The Agency does not have any bulk transfer/loading data. This type of exposure data may be necessary for refining this assessment, and a possible option for Monsanto would be to supply data per GLN 875.2400 (dermal exposure) and GLN 875.2500 (inhalation exposure) for mixer/loaders.

Applicators - Baseline - Open Cab

The Agency has no data for spreader trucks applying treated fertilizer, and therefore selected from PHED “solid broadcast spreader application - open cab" as a suitable surrogate. The dermal unit exposure value (baseline - single layer clothing, no gloves, open cab) for a granular drop-type spreader applicator is 0.01 mg/lb ai, and the inhalation unit exposure value (baseline - open cab) is 0.0012 mg/lbs ai (PHED V1.1, **low confidence dermal and inhalation**). Inhalation and dermal unit exposures will be combined for the applicator scenario since the values are within two orders of magnitude.

MOEs for both the short-term and intermediate-term scenarios have been estimated. However, the Agency believes that the intermediate-term scenario is the most appropriate scenario for estimating risk, since available information indicates that for pre-plant herbicide and fertilizer applications that a “window” of approximately 28 days is available once the weather and field conditions are right and the equipment can enter the fields.

For the short-term scenario, the total daily absorbed exposure (mg/day) is estimated using the following equation:

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[dermal unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated x dermal absorption factor] + [inhalation unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated]

Given:

dermal unit exposure = 0.01 mg/lbs ai,
inhalation unit exposure = 0.0012 mg/lbs ai,
maximum application rate = 4 lbs ai per acre,
max number of acres treated = 800
typical number of acres treated = 500
dermal absorption factor = 0.24

Therefore:

Max total daily absorbed exposure = (0.01)(4)(800)(0.24) + (0.0012)(4)(800)
= 11.52 mg/day.
Typical total daily absorbed exposure = (0.01)(4)(500)(.24) + (0.0012)(4)(500)
= 7.2 mg/day

Total daily absorbed dose (mg/kg/day) is calculated by dividing the total daily absorbed exposure (mg/day) by 60 kg, the Agency's default adult female body weight since the NOEL used in estimating short-term risk is from a developmental study.

Max total daily dose = 11.52 mg/day / 60 kg = 0.192 mg/kg/day

Typical total daily dose = 7.2 mg/day / 60 kg = 0.12 mg/kg/day

Risk is estimated by using the following equation:

MOE = NOEL (mg/kg/day) / max total daily dose (mg/kg/day) = 150 / 0.192 = 780

MOE = NOEL (mg/kg/day) / typical total daily dose (mg/kg/day) = 150 / 0.12 = 1300

For the short-term scenario, the MOE for applicators applying fertilizer impregnated with alachlor at the maximum application rate of 4 lbs ai to 800 acres per day is 780, and to 500 acres per day is 1300. If lower application rates such as 3 lb ai/acre were to be used in the calculation, the MOEs would be even higher.

For the intermediate-term scenario, the total daily exposure (mg/day) is calculated using the following equation:

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[dermal unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated] + [inhalation unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated]

Given:

dermal unit exposure = 0.01 mg/lbs ai,
inhalation unit exposure = 0.0012 mg/lbs ai,
maximum application rate = 4 lbs ai per acre,
max number of acres treated = 800
typical number of acres treated = 500

Therefore:

Max total daily exposure = (0.01)(4)(800) + (0.0012)(4)(800) = 35.84 mg/day.

Typical total daily exposure = (0.01)(4)(500) + (0.0012)(4)(500) = 22.4 mg/day

Total daily dose (mg/kg/day) is calculated by dividing the daily exposure (mg/day) by 70 kg, the Agency's default male body weight.

Max total daily dose = 35.84 (mg/day) / 70 kg = 0.512 mg/kg/day

Typical total daily dose = 22.4 (mg/day) / 70 kg = 0.32 mg/kg/day

Risk is estimated by using the following equation:

MOE = NOEL (mg/kg/day) / max total daily dose (mg/kg/day) = 50 / 0.512 = 98

MOE = NOEL (mg/kg/day) / typical total daily dose (mg/kg/day) = 50 / 0.32 = 160

For the intermediate-term scenario, the MOE for applicators applying fertilizer impregnated with alachlor equals 98 at the 4 lbs ai rate for 800 acres and 160 at the 4 lbs ai rate for 500 acres.

The Agency made assumptions in performing this risk assessment and acknowledges that many of the assumptions were deliberately used with the intent of performing an upper-end risk assessment. Additionally, the Agency had only low confidence data due to the number of replicates (5) in PHED.

Applicators - Use of Engineering Controls

The Agency has no data for spreader trucks applying treated fertilizer, and therefore selected from PHED "solid broadcast spreader application - closed cab" as a suitable surrogate. The dermal unit exposure (closed cab) is 0.002 mg/lb ai, and the inhalation unit exposure (closed cab) is 0.00022

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mg/lbs ai (PHED V1.1, **low confidence dermal; high confidence hands and inhalation; no PFs were used**). Inhalation and dermal unit exposures will be combined for the applicator scenario since the exposures are within two orders of magnitude.

MOEs for both the short-term and intermediate-term scenarios have been estimated. For the short-term scenario, the total daily absorbed exposure (mg/day) is estimated using the following equation:

[dermal unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated x dermal absorption factor] + [inhalation unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated]

Given:

dermal unit exposure = 0.002 mg/lbs ai,
inhalation unit exposure = 0.00022 mg/lbs ai,
maximum application rate = 4 lbs ai per acre,
max number of acres treated = 800
typical number of acres treated = 500
dermal absorption factor = 0.24

Therefore:

Max total daily absorbed exposure = (0.002)(4)(800)(.24) + (0.00022)(4)(800)
= 2.24 mg/day.
Typical total daily absorbed exposure = (0.002)(4)(500)(.24) + (0.00022)(4)(500)
= 1.4 mg/day

Total daily absorbed dose (mg/kg/day) is calculated by dividing the total daily absorbed exposure (mg/day) by 60 kg, the Agency's default adult female body weight since the NOEL is from a developmental study.

Max total daily dose = 2.24 (mg/day) / 60 kg = 0.037 mg/kg/day

Typical total daily dose = 1.4 (mg/day) / 60 kg = 0.0233 mg/kg/day

Risk is estimated by using the following equation:

MOE = NOEL (mg/kg/day) / max total daily dose (mg/kg/day) = 150 / 0.037 = 4000

MOE = NOEL (mg/kg/day) / typical total daily dose (mg/kg/day)
= 150 / 0.0233 = 6400

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For the short-term scenario, the MOE for applicators applying fertilizer impregnated with alachlor at the maximum application rate of 4 lbs ai to 800 acres per day is 4000, and to 500 acres is 6400. If lower application rates such as 3 lbs ai were to be used in the calculation, the MOEs would be even higher.

For the intermediate-term scenario, the total daily exposure (mg/day) is calculated using the following equation:

[dermal unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated] + [inhalation unit exposure (mg/lb ai) x application rate (lbs ai/acre) x number of acres treated]

Given:

dermal unit exposure = 0.002 mg/lbs ai,
inhalation unit exposure = 0.00022 mg/lbs ai,
maximum application rate = 4 lbs ai per acre,
max number of acres treated = 800
typical number of acres treated = 500

Therefore:

Max total daily exposure = (0.002)(4)(800) + (0.00022)(4)(800) = 7.1 mg/day.

Typical total daily exposure = (0.002)(4)(500) + (0.00022)(4)(500) = 4.44 mg/day

Total daily dose (mg/kg/day) is calculated by dividing the daily exposure (mg/day) by 70 kg, the Agency's default male body weight.

Max total daily dose = 7.1 (mg/day) / 70 kg = 0.101 mg/kg/day

Typical total daily dose = 4.44 (mg/day) / 70 kg = 0.063 mg/kg/day

Risk is estimated by using the following equation:

MOE = NOEL (mg/kg/day) / max total daily dose (mg/kg/day) = 50 / 0.101 = 490

MOE = NOEL (mg/kg/day) / typical total daily dose (mg/kg/day) = 50 / 0.063 = 790

For the intermediate-term scenario, the MOE for applicators applying fertilizer impregnated with alachlor using a closed cab, at the 4 lbs ai rate to 800 acres is 490, and to 500 acres is 790.

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With one exception (a MOE of 98), all MOEs, both short-term and intermediate-term, are greater than 100. Generally, the Agency has no concerns for an MOE greater than or equal to 100, for non-cancer effects when the NOEL used in estimating the MOE is from an animal study.

Additional Occupational Exposure Studies

Handler Studies

Optimally, worker exposure assessments are based on adequate data of acceptable quality. Handler exposure studies are sometimes required for reregistration in situations in which no data or no acceptable data exist. In this case exposure data are necessary to assess exposure to alachlor resulting from the process of impregnating dry bulk fertilizer. While the Agency has used PHED data in its assessment, the PHED data used are not directly related to this type of process. It appears that this is a closed system; however, exposure may be significant based on the large volumes of alachlor involved. PHED does not contain any data for transferring from mini-bulk containers. Therefore, additional confirmatory data are required. The confirmatory data should address the dry bulk fertilizer impregnation process, with alachlor in mini-bulk containers. This data should address both dermal and inhalation exposure at both outdoor and indoor (at least partially enclosed) sites.

Post-Application Studies

The Agency believes that, based on the current uses of alachlor, post-application exposure will be low and therefore is not requiring post-application exposure studies at this time.

e. FQPA Considerations

Aggregate Risk

In examining aggregate risk, FQPA directs EPA to take into account the available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure can include pesticides residues in drinking water, pesticide uses in and around the home, and pesticide uses in non-residential settings, such as schools or parks.

Alachlor is used on food crops. Alachlor as well as its metabolites have been detected in both ground and surface water. Therefore, specific consideration of potential risks to infants and children, as well as aggregate exposures, is warranted.

Alachlor is a restricted use chemical. The Agency has not identified any alachlor products that are intended for home use, or uses in/around schools, parks, or other public areas. Therefore, a residential exposure and risk assessment was not required. For alachlor there is no residential component to be added to the dietary (food and water) assessment.

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Acute Aggregate Risk

Based on the available toxicity database, an acute dietary risk assessment was not required.

Chronic Aggregate Risk

Since alachlor has no residential uses to aggregate with the dietary assessment, the chronic aggregate risk assessment is the same as the dietary (food and water)assessment. As previously discussed in this document, the percent RfDs were calculated for adult males, adult females, and children (1 - 6 years) using the food exposure estimated by DRES, and one source of drinking water. All percent RfDs were rounded to one significant figure.

Table 32: Summary of Alachlor Aggregate Risk	
Source of Drinking Water	% RfD
Adult Male	
NAWWS (Midwest groundwater)	0.1
USGS reservoir (Midwest surface water)	0.1
ARP 12 state area surface water	0.08
Adult Female	
NAWWS (Midwest groundwater)	0.1
USGS reservoir (Midwest surface water)	0.1
ARP 12 state area surface water	0.1
Child (1 - 6 years)	
NAWWS (Midwest groundwater)	0.5
USGS reservoir (Midwest surface water)	0.5
ARP 12 state area surface water	0.4

There are some data (USGS reservoir Midwest surface water) available on detections of the alachlor ESA degradate. Using these data, aggregate risk can be estimated for consumption of water containing both parent alachlor and alachlor ESA.

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Table 33: Summary of Alachlor and Alachlor ESA Aggregate Risk	
Population Group	% RfD
Adult Male	1%
Adult Female	1%
Child (1 - 6 years)	4%

All % RfD values are well below 100%. Aggregate chronic dietary risk from all food uses for which tolerance reassessments have been performed is not expected to be of concern.

Carcinogenic (MOE Approach) Aggregate Risk

Since alachlor has no residential uses to aggregate with the dietary assessment, the carcinogenic aggregate risk assessment is the same as the carcinogenic (food and water) dietary assessment. As previously discussed in this document, the carcinogenic MOEs were calculated for adult males and adult females, using the food exposure estimated by DRES, and one source of drinking water. All cancer MOEs were rounded to two significant figures.

Table 34: Summary of Alachlor Aggregate Carcinogenic (MOE Approach) Risk		
Source of Drinking Water	MOE Nasal Tumors	MOE Stomach Tumors
Adult Male		
NAWWS (Midwest groundwater)	39,000	1,100,000
USGS reservoir (Midwest surface water)	38,000	1,100,000
ARP 12 state area surface water	51,000	1,400,000
Adult Female		
NAWWS (Midwest groundwater)	30,000	840,000
USGS reservoir (Midwest surface water)	29,000	810,000
ARP 12 state area surface water	38,000	1,100,000

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At this time the Agency is not making any recommendations on the level of MOEs to be considered acceptable for the carcinogenic MOE approach aggregate risk. However, given the magnitude of the calculated MOEs, aggregate carcinogenic risk from all food uses for which tolerance reassessments have been performed is not expected to be of concern.

Carcinogenic (Q_1^* Approach) Aggregate Risk

Since alachlor has no residential uses to aggregate with the dietary assessment, the carcinogenic aggregate risk assessment is the same as the carcinogenic (food and water) dietary assessment. As previously discussed in this document, the carcinogenic risks were calculated for adult males and adult females, using the food exposure estimated by DRES, and one source of drinking water. All risk estimates were rounded to two significant figures.

Table 35: Summary of Alachlor Aggregate Carcinogenic (Q_1^* Approach) Risk

Source of Drinking Water	Risk
Adult Male	
NAWWS (Midwest groundwater)	1.0×10^{-6}
USGS reservoir (Midwest surface water)	1.1×10^{-6}
ARP 12 state area surface water	7.8×10^{-7}
Adult Female	
NAWWS (Midwest groundwater)	1.3×10^{-6}
USGS reservoir (Midwest surface water)	1.4×10^{-6}
ARP 12 state area surface water	1.1×10^{-6}

All carcinogenic risks estimated using the Q_1^* are within the risk range considered by the Agency to represent negligible risk.

Cumulative Effects

The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by setting a new safety standard for the establishment of tolerances. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides,

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although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

At present there is no methodology for applying the information in the Agency's files concerning common mechanism issues for most risk assessments. But, there are pesticides for which the common mechanism issues can be resolved. For example, pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Due to the structural similarities with acetochlor, metolachlor, butachlor, and propachlor, alachlor may fall into the second category. However, at this time the Agency has not yet made a final decision concerning a possible common mechanism of toxicity for these five chemicals to scientifically apply that information to the tolerance decision. The process has begun, but is not yet completed. Therefore, for the purposes of this decision document, the tolerance decision will be reached based upon the best available and useful information for alachlor only. The risk assessment has been performed for alachlor only assuming that no common mechanism of toxicity exists. However, these decisions will be reexamined after methodologies and procedures for integrating information concerning common mechanism of toxicity into risk assessments are developed by the Agency.

Monsanto must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether alachlor shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for alachlor need to be modified or revoked.

c. Environmental Assessment

1. Use Characterization

Alachlor is a herbicide registered for use on the following crops: succulent and dry beans; field, pop, and sweet corn; peanuts; grain sorghum; and soybeans.

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Use in Corn and Soybean Areas

Corn is grown in almost every state in the continental U.S. Major corn-growing areas include the Midwest and Great Plains states (from Ohio west to Nebraska and from southern Minnesota/Wisconsin south to Illinois/Missouri), the Mississippi River Valley, and the East Coast (from southeastern Pennsylvania to North Carolina) (USDA National Agricultural Statistics Service, 1996 Harvested Acres by County). These regions include such wildlife-rich areas as the Prairie Pothole region, Sandhills Lake region of Nebraska, and coastal/estuarine regions of the Delmarva peninsula and North Carolina. Many of these areas are used by waterfowl and shorebirds as breeding, feeding, and migratory resting grounds. In addition, corn may be grown in the vicinity of freshwater and estuarine/marine aquatic habitats. This can lead to exposure of aquatic resources from the off-site movement of chemicals applied to cornfields near such habitats.

The corn-growing region includes localized areas which have a high potential vulnerability for contamination of shallow ground water with pesticides (Kellog et al., 1992). Such vulnerable areas include the eastern coastal plain from southern Georgia to New Jersey, eastern Nebraska, and southern portions of the Great Lakes region. While the majority of corn-growing areas are dominated by soils which have a moderate runoff potential and moderate infiltration and permeability (also referred to as Hydrologic Group B soils), localized regions are more susceptible to runoff (Kellog et al., 1992). Areas with significant percentages of soils with moderately high to high runoff potential (Group C and D soils) include the Gulf Coast region of Texas, the lower Mississippi River Valley, the Missouri River Valley in South Dakota, the extreme eastern coastal plain of Georgia, South Carolina, and North Carolina, and portions of the Ohio River Valley. These soils are more prone to runoff because of slow permeability (low saturated hydraulic conductivities) and/or a relatively shallow water table.

Use in Sorghum Areas

Major sorghum-growing areas in the U.S. are the central and southern Great Plains (from Nebraska south to Texas and from eastern Colorado to Missouri) and the Mississippi River Valley from southern Illinois to Louisiana (USDA National Agricultural Statistics Service, 1996 Harvested Acres by County). The number of acres planted to sorghum appears to be increasing in the coastal plains of the Carolinas and Georgia. While the geographic extent of the sorghum area is less than that of corn, it does include significant areas of wildlife habitat. It may also be found in the vicinity of estuarine/marine habitats, especially along the Gulf Coast region of Texas. Potential exposure of aquatic resources may occur from the off-site movement of chemicals applied to sorghum fields near such habitats.

Sorghum is more tolerant of dry conditions than corn and is typically grown in warmer climates which have a lower rainfall than the corn region. Overall, the major sorghum areas also have a lower potential vulnerability for contamination of shallow ground water, except in the southeastern U.S., where the acreage of sorghum is increasing (Kellog et al. 1992). Large areas of Texas and the Mississippi River Valley are dominated by the high runoff potential Hydrologic Group C and D soils.

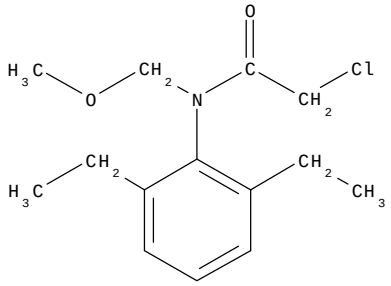
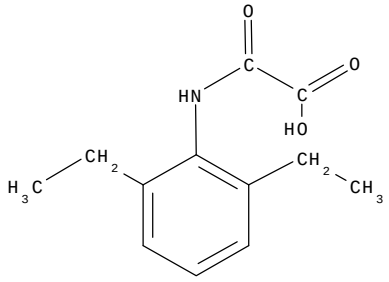
In such areas, the adjacent aquatic habitats may be vulnerable to off-site movement of chemicals from runoff.

Use on peanuts areas

Peanuts are grown primarily in the southern Coastal Plain, from Virginia to Alabama and in the plains of central Texas and Oklahoma (USDA National Agricultural Statistics Service, 1996 Harvested Acres by County). The Coastal Plain region includes significant areas used by waterfowl and shorebirds as breeding, feeding, and migratory resting grounds. Peanut-growing areas may occur in the vicinity of freshwater and estuarine/marine aquatic habitats. The Coastal Plain includes a large percentage of areas with a high potential vulnerability for contamination of shallow ground water with pesticides (Kellog et al., 1992).

Figure B: Alachlor and Its Degradates

The structures of alachlor and four of its degradates are illustrated in Figure B:

Nomenclature	Chemical Structure
Alachlor 2-Chloro-2',6'-diethyl-N-methoxymethylacetanilide	
Alachlor - DM-Oxanilic Acid 2',6'-Diethyloxanilic acid (Compound III)	

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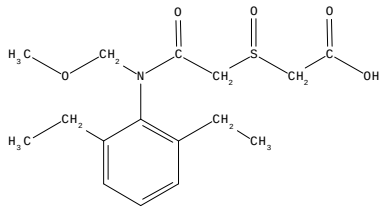
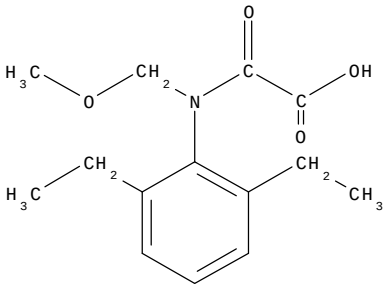
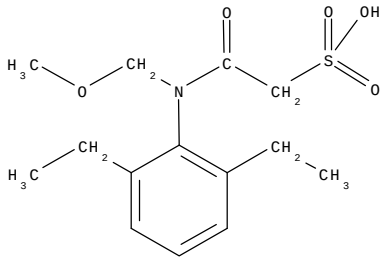
Alachlor Sulfinylacetic Acid (N-Methoxymethyl-N-(2,6-diethylphenyl)-2-amino-2-oxoethyl)-sulfinylacetic acid (Compound VIII)	
Alachlor Oxanilic Acid 2',6'-Diethyl-N-methoxymethyloxanilic acid (Compound X)	
Alachlor Sulfonic Acid 2',6'-Diethyl-N-methoxymethyl-2-sulfoacetanilide (Compound XI)	

2. Ecological Toxicity Data

Ecological effects data are used by the Agency to determine the toxicological hazards of pesticides to various terrestrial and aquatic nontarget organisms. These tests can include acute and chronic scenarios. These data are then integrated with the environmental fate and exposure data when the Agency performs a risk characterization.

The following studies provide the basis for the Ecological Effects Hazard Assessment.

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a. Terrestrial Animals

To evaluate the toxicity of a pesticide to birds, the following tests are required using technical grade material:

- An avian single-dose oral (LD_{50}) study on one species, preferably mallard or bobwhite quail;
- A subacute dietary (LC_{50}) study using one waterfowl species, preferably the mallard duck;
- A subacute dietary (LC_{50}) study using one upland game species, preferably bobwhite quail or ring-necked pheasant.

Tests on wild mammals may be required, depending on intended use pattern, environmental fate characteristics, and results of lower tier studies such as acute and subacute toxicity tests.

An acute contact LD_{50} for honey bees is required if the proposed use will result in exposure of honey bees.

Birds, Acute

The requirement for a measurement of acute oral toxicity to birds is fulfilled based on one acceptable study, which indicates slight toxicity. Results follow in Table 36. (MRID No. 00079523)

Table 36: Avian Acute Oral Toxicity

Species	% Test Material (TGAI)	LD_{50} (mg/kg)	Fulfills Guidelines
Bobwhite quail	92.3	1499	Yes

Birds, Subacute

The requirement for a measurement of subacute dietary toxicity is fulfilled based on two acceptable studies, which indicate that the chemical is practically nontoxic to birds. Results follow in Table 37. (MRID Nos. 43087101, 43087001)

Table 37: Avian Subacute Dietary Toxicity

Species	% Test Material (TGAI)	LC_{50} (mg/L)	Fulfills Guidelines
Bobwhite Quail	95.4	>5620	Yes
Mallard Duck	92.3	>5620	Yes

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Birds, Chronic

When birds are expected to be exposed to pesticides for long periods of time or exposed during the breeding and nesting season avian reproduction studies are sometimes required. Avian reproduction studies for alachlor are required based on the following criteria:

- Birds are expected to be subjected to repeated or continued exposure to alachlor and or its degradates preceding or during breeding season. Alachlor is generally applied in the early spring months when birds are most actively breeding.
- Alachlor and its metabolites or degradates are stable in the environment to the extent that potentially chronically toxic amounts may be present in avian feed.
- In a rat teratological study both maternal and developmental effects were observed at 400 mg/kg/day (MRID No. 00043645)
- Reproduction studies with acetochlor, a pesticide whose chemical structure is very similar to alachlor, have shown reproductive effects to mallard duck at 150 ppm and bobwhite quail at 750 ppm (MRID Nos. 43383101, 43383102). In a partially acceptable reproduction study conducted with metolachlor on mallard duck, eggs in 10, 100, and 1000 ppm test concentrations showed eggshell thinning (MRID No. 0162292).

Mammals

Ecological effects data on toxicity data to mammals will not be required for alachlor at this time. Available toxicity data on rats (health effects data requirement) indicate an acute LD_{50} of 930 mg/L. Mammalian LD_{50}s are not used directly to determine whether LOCs are exceeded, but do provide some indication of level of toxicity. The available data indicates that alachlor is slightly toxic to small mammals.

Insects

Honey bee acute contact studies conducted with technical ingredient and 42% formulation products have been reviewed. These studies indicated low toxicity toward honey bees, with LD_{50} levels greater than 36.2 µg ai/bee for the technical and greater than 100 µg ai/bee for the formulated product. (MRID Nos. 00074486 and 00028772)

Table 38: Toxicity to Honey Bees

%Test Material (TGAI)	LD_{50} (µg ai/bee)	Fulfills Guidelines
Technical	>36.2	Yes
42.2% Formulation	>100	Yes

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b. Aquatic Animals

Freshwater Fish

To evaluate toxicity of a pesticide to freshwater fish, LC_{50} measurements are required for two species, using technical grade active ingredient. One study should use a cold water species, preferably rainbow trout. The other should use a warm water species, preferably bluegill sunfish. Chronic toxicity testing is required for evaluation of possible effects to growth or reproduction of fish exposed to persistent pesticides. This requirement is fulfilled by Early Life-stage Testing of one species of freshwater fish.

The data requirement is fulfilled for alachlor based on studies submitted. Studies submitted indicate moderate toxicity to warm- and cold- water fish. LC_{50} values are displayed in Table 39. Precautionary toxicity statements are required on labels based on MRID No. 43862601 which shows alachlor to be *highly toxic on a chronic basis to freshwater fish* growth, reproduction and development. Acute toxicity of alachlor and tested formulations is moderate. (MRID Nos. 00023615, 00023616, 00028549, 00028550, 00028551, 00028553, 00028554, 00028555, 00031524, 00031525, 40098001)

Table 39: Acute Toxicity to Freshwater Fish

Species	% Test Material (TGAI)	LC_{50} (mg/L)	Fulfills Guidelines
Toxicity Based on Exposure to Technical Active Ingredient			
Bluegill Sunfish	90	2.8	Yes
	100	4.3	Yes
Rainbow Trout	90	1.8	Partially
	100	2.4	Yes
Toxicity Levels Based on Exposure to End-Use Product			
Bluegill Sunfish	43EC	3.2	Partially
	45	6.2	Partially
	42.4	7.9	Partially
Rainbow Trout	42.5	3.6	Partially
	45	3.7	Partially
	44	4.2	Partially
	43	1.4	Yes

Table 39: Acute Toxicity to Freshwater Fish			
Species	% Test Material (TGAI)	LC_{50} (mg/L)	Fulfills Guidelines
	43	3.2	Yes

Table 40: Chronic Toxicity To Freshwater Fish in mg ai/L				
Species	% Test Material	NOEL	LOEC	Fulfills Requirement
Rainbow trout	Technical	0.187	0.388	Yes

Toxicity to Freshwater Invertebrates

To evaluate acute toxicity to freshwater aquatic invertebrates, an EC_{50} measurement is required based on technical grade active ingredient, preferably using first instar Daphnia magna, or early-instar amphipods, stoneflies, mayflies, or midges. The requirement is fulfilled based on studies submitted. Results are displayed in Table 41. The studies submitted indicate moderate to slight acute toxicity for this category, based on studies reviewed to date. (MRID Nos. 00028549, 00028555, 00031526, 40098001).

Table 41: Toxicity to Freshwater Invertebrates			
Species	% Test Material (TGAI)	EC_{50} (mg/L)	Fulfills Guidelines
Toxicity Based on Exposure to Technical Active Ingredient			
Water Flea Daphnia magna	90	10	Yes
	93	21	Yes
Midge	93	3.2	Yes
Toxicity Levels Based on Exposure to End-Use Product			
Water Flea Daphnia magna	49	33	Partially
	45	22	Partially
	42.4	27	Partially
	43	7.7	Yes
Midge	45	2.5	Yes

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Chronic toxicity to freshwater invertebrates is determined by exposing one species of freshwater invertebrate, preferably Daphnia magna, to the pesticide for a full generation and observing effects on growth and reproduction. In 21-day full lifecycle testing alachlor was shown to be *highly chronically toxic* to growth and reproduction of freshwater invertebrates. Chronic LOEC and NOEC values are displayed in Table 42. Based on the high chronic toxicity of this pesticide appropriate environmental warning labels are required. (MRID No. 43774707)

Table 42: Chronic Toxicity Based on Exposure to Technical Active Ingredient

Species	% Test Material (TGAI)	LOEC mg ai/L	NOEC mg ai/L	Fulfills Requirement
Water Flea, Daphnia magna	94.6	0.23	0.11	Yes

Acute Toxicity of Pesticide Metabolites to Freshwater Animals

Aquatic testing with metabolites of pesticide compounds is requested when metabolites are likely to be persistent in the aquatic habitats in amounts greater than or equal to the parent compound. Four studies have been submitted to aid in characterization of the acute toxicity of alachlor sulfonic and oxanilic acids to freshwater invertebrate and fish species. The studies indicate that these degradate compounds display low acute toxicity to the tested species. The submitted studies are summarized in Table 43. (MRID Nos. 43774703, 43774704, 43774705, and 43774706)

Table 43: Acute Testing with Alachlor Metabolites

Species Tested	Degradate and % ai	LC_{50}/EC_{50} (mg ai/L)	Fulfills Guidelines
Daphnia magna	Sulfonic acid, 91.5%	EC_{50}>104 mg/L	Yes
	Oxanilic acid, 92.4%	EC_{50}>95 mg/L	Yes
Rainbow trout	Sulfonic acid, 91.5%	LC_{50}>104 mg/L	Yes
	Oxanilic acid, 92.4%	LC_{50}>95 mg/L	Yes

Estuarine and Marine Animals

The use pattern of alachlor includes applications to major crops that are sometimes grown in close proximity to estuarine and marine environments.

The toxicity measurements required are a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp or mysid, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study

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with an estuarine mollusk species. The data requirement is fulfilled for alachlor based on the studies submitted (MRID Nos. 44524301, 44524302, 44524303). LC50/EC50 values are shown in Table 44.

Table 44: Acute Toxicity to Estuarine/Marine Species

Species	% Test Material (TGAI)	LC_{50}/EC_{50} (mg/L)	Fulfills Guideline
Sheepshead minnow	93.8	LC_{50}=3.9	Yes
Mysid	93.8	LC_{50}=2.4	Yes
Eastern Oyster	93.8	EC_{50}=1.6	Yes

A study submitted to the Agency (Kirby-Smith, et. al., 1993), indicates that, in general, there were no significant differences in diversity, numbers and/or biomass between those creeks and estuaries that received pesticidal run-off (farm creeks) and those that didn't (forested creeks). The data derived from this study is confounding because results did not compare with laboratory toxicity data and EEC estimates. During the course of this study there did not appear to be any significant chronic adverse effects in terms of species diversity, biomass, energy transfer or nutrient cycling, occurring in the system.

c. Plants

Data from studies submitted to the Agency, though incomplete, indicate *high toxicity to aquatic and terrestrial plants.*

Terrestrial Plants

Studies were required to establish toxicity to nontarget terrestrial plants. Two studies were received. Of the ten species of terrestrial plants tested, seven had EC_{25} levels for vegetative vigor less than maximum permitted rates on present labels. Seedling emergence was also effected in most of the species tested. Based on the data provided, *alachlor is highly toxic to nontarget terrestrial plants.* (MRID Nos. 42468601, 42468701)

Table 45: Toxicity to Terrestrial Plants

Measurement Endpoint	Most Sensitive Species Tested	NOEL (lbs a.i./A)	EC_{25}(lbs a.i./A)
Vegetative Vigor[a]			
Phytotoxicity	Ryegrass	0.019	undetermined

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Table 45: Toxicity to Terrestrial Plants			
Measurement Endpoint	Most Sensitive Species Tested	NOEL (lbs a.i./A)	EC_{25}(lbs a.i./A)
21-Day Survival	Onion	0.22	0.31
21-Day Height	Ryegrass	0.037	0.12
21-Day Weight	Ryegrass	0.037	0.044
Germination and Growth			
6-Day Seed Germination	Cabbage	0.67	undetermined
6-Day Seedling Emergence	Ryegrass	0.019	0.04
21-Day Survival	Onion	0.037	0.011
Phytotoxicity	Lettuce	0.0093	undetermined
Height	Ryegrass	0.0023	0.011
Weight	Ryegrass	0.0023	0.0067

[a.] Based on a supplemental study with 94.6% active ingredient that fulfills guideline requirements.
[b.] Based on a supplemental study with 94.2% active ingredient that fulfills guideline requirements.

Aquatic Plants

Studies were required to establish toxicity to nontarget aquatic plants. The requirement is partially fulfilled by the single study submitted. However, to completely fulfill data requirements for aquatic plant testing additional studies must be submitted for acute toxicity to an aquatic macrophyte, a marine diatom, a blue-green algae and a freshwater diatom. Based upon the one study available, *alachlor is highly toxic to aquatic plants.* (MRID No. 42763801) Also, effects on aquatic plants are expected to result in indirect effects on aquatic animals, e.g., by habitat modification or restricted food supply.

Table 46: Toxicity to Aquatic Plants			
Species Tested	%Test Material	Toxicity (µg/L)	Fulfills Guidelines
Freshwater Green alga *Selenastrum capricornutum*	98.6	NOEL=0.35 LOEL=0.69 EC_{50}=1.64 (growth effects)	Yes, partially

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d. Conclusions

The available toxicity data for alachlor, indicate that it is:

- Slightly to practically non-toxic to birds on an acute oral basis (LD_{50} of 1500 mg/kg), but chronic data are not available.
- Slightly toxic to mammals, based on a rat study (LD_{50} of 930 mg/kg).
- Slightly toxic to honey bees (LD_{50} >36 µg/bee).
- Slightly to moderately toxic on an acute basis to freshwater aquatic animals (LC_{50} /EC_{50} 1-33 ppm).
- Highly to moderately toxic to freshwater aquatic animals on a chronic basis (NOEC$\geq$0.1 ppm, LOEC$\geq$0.2 ppm).
- Moderately toxic to saltwater fish (LC_{50} 3.9 ppm), moderately toxic to saltwater mysid (LC_{50} 2.4 ppm) and moderately toxic to shellfish (EC_{50} 1.6 ppm).
- Highly toxic to aquatic plants (based on a single species tested: NOEL=0.35 ppb, LOEL=0.69 ppb, EC_{50}=1.64 ppb).

Therefore, a potential risk to nontarget terrestrial and aquatic plants, and endangered plant species exists. Additionally, the available information on the major alachlor degradates indicate that the degradates appear to be less toxic to aquatic organisms than the parent.

3. Environmental Fate Data

The following studies provide the basis for the Environmental Fate Assessment.

a. Degradation

<u>GLN 161-1 Hydrolysis:</u>

In an acceptable study, [^{14}C] Alachlor (carbonyl labeled) applied at 50 ppm was relatively stable in sterile commercial pH 3, 6, and 9 buffer solutions, natural lake water, and deionized water that were incubated in the dark at 25°C for 30 days. [^{14}C] Alachlor comprised 97.5-98.7% of the applied radioactivity in all test solutions, with no discernible pattern of decline. The degradate 2',6'-Diethyl-N-methoxymethyl acetanilide was $\leq$1.57% of the applied.

As part of the same study, [^{14}C] alachlor, at 2 ppm, degraded very slowly in nonsterile lake water, when incubated at an unspecified temperature for 30 days. After 30 days of treatment, alachlor was 88.8% of the applied concentration in the test solution. Five nonvolatile compounds were identified, at $\leq$2.7% of the applied. (MRID No. 00134327)

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GLN 161-2 Photolysis in Water:

This data requirement will be waived based on the UV absorption spectrum of alachlor in water. The current policy is to concur with waivers for this requirement when the electronic spectrum of the chemical does not show significant absorption between 290 and 800 nm, because photodegradation can only take place when there is an overlap between absorption regions of the spectrum of the chemical and the irradiation spectrum of the light source. A submitted study indicated that the UV absorption spectrum of alachlor in water shows no absorption at wavelengths above 290 nm. (MRID No. 00023012)

GLN 161-3 Photodegradation on Soil:

The Agency will require no additional data to support the Photodegradation on Soil data requirement at this time. Although the Agency does not have any information about the photolytic behavior of any of the major degradates of alachlor at this time, an acceptable study will not be required because the absorption spectrum of the chemical in water does not show significant absorption at wavelengths above 290 nm.

b. Metabolism

GLN 162-1 Aerobic Soil Metabolism:

Three different studies conducted on various soil types have shown similar half-lives, ranging from 6 to 21 days. The degradation products were identified only in two of the studies, one of which is acceptable and the other is supplemental. Three of the four major degradates were observed in both studies. The compound (N-methoxymethyl-N-(2,6-diethylphenyl)-2-amino-2-oxoethyl) sulfinylacetic acid, which was up to 15.9% of the applied in one supplemental study (MRID No.# 00101531), was not observed in the acceptable study (MRID No. 00134327). All major metabolites were monitored in the available Terrestrial Field Dissipation study.

In an acceptable study [^{14}C] alachlor applied at 2 ppm degraded with estimated half-lives of 2-3 weeks in silt, loamy sand, and silt loam soils incubated in the dark at 25°C and 75% of field moisture capacity for 175 days. In the silt loam soil, alachlor was 87.7% or the applied at the initiation of the study, 47.4% at 21 days, and 1.6% at 175 days. In the loamy sand, alachlor was 98.5% of the applied at 0 days, 52.4% at 14 days, and 2.5% at 175 days. In the silt soil, alachlor was 99.0% of the applied at day 0, 40.4% at day 14, and 0.7% at 175 days.

Four degradates were detected, with significant concentrations (≥ 10% of the applied):

- Alachlor DM-oxanilic acid was a "water soluble" metabolite that increased gradually to a maximum of 5.3% of the applied at 50 days post-treatment in the silt loam, it decreased to 3.9% at 175 days. It increased to a maximum of 15.8-17.0% of the applied at 175 days post-treatment (last test interval) in the loamy sand and silt soils;

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- Alachlor oxanilic acid was a "water soluble" metabolite, and was a maximum of 12.7-22.4% of the applied at 28-50 days post-treatment in all soil types and decreased to 2.9-13.4% of the applied at 175 days post-treatment;

- Alachlor ESA was a "water soluble" metabolite, which increased to a maximum of 24.9% of the applied at 50 days post-treatment in the silt loam, 16.9% of the applied at 175 days post-treatment in the loamy sand, and 16.0% of the applied at 21 days post-treatment in the silt soil. It decreased to 11.2-18.6% of the applied at 175 days post-treatment in the silt loam and silt soils.

- 2',6'-diethyl-2-hydroxy-N-methoxymethylacetanilide was the only major "methylene chloride soluble" degradate and increased to a maximum of 6.7-10.2% of the applied at 7-21 days post-treatment and decreased thereafter to ≤1.1% of the applied at 175 days in all soil types.

Nine other degradates were also identified, at ≤10% of the applied. After 175 days incubation, $^{14}CO_2$ was 16.17-30.00% of the applied. [^{14}C] volatiles were ≤1.15% of the applied, and unextracted [^{14}C] residues totaled 19.25-20.76% of the applied. (MRID No. 00134327)

In a second study (found to be supplemental), [^{14}C] alachlor (phenyl ring-labeled) applied at 2 ppm degraded with half-lives of 6-12 days in silt, loamy sand, and silt loam soils incubated in the dark at 25°C for 62 days. The soils were also treated with [^{14}C] alachlor encapsulated in a polyurea polymer. The rate of degradation is similar for the encapsulated [^{14}C] alachlor, with half-lives of 8-11 days.

Four major degradates were identified in the soil. These degradates were observed in all three soil types at 62 days; however, testing at various test intervals (monitoring through time) was performed only for the silt soil:

- Alachlor DM-oxanilic acid comprised a maximum of 14.4% of the applied radioactivity in the silt soil at 62 days post-treatment. It comprised 2.9-7.3% of the applied at 62 days in the loamy sand and the silt loam;

- Alachlor oxanilic acid comprised a maximum of 9.7-10.0% of the applied radioactivity in the silt soil at 20 days post-treatment. It decreased to ≤3.7% of the applied at 62 days in the loamy sand and the silt loam;

- Alachlor sufinylacetic acid comprised 15.9-16.2% of the applied radioactivity in the silt loam soil at 62 days post-treatment. It was a maximum of 12.6-13.3% of the applied in the silt soil at 20 days post-treatment, decreasing to ≤9.7% at 62 days; and

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- Alachlor ESA comprised a maximum of 6.5% of the applied radioactivity in the silt soil at 30 days post-treatment and ≤5.1% at 62 days. It was 2.7-4.1% of the applied in the loamy sand and silt loam at 62 days.

This study provides supplemental information about the rate of degradation of alachlor and the identity of alachlor degradates under aerobic conditions. This study is deficient because up to 22.3% of the applied radioactivity was not characterized. (MRID No. 00101531)

In a third study (also supplemental) [^{14}C] alachlor applied at 4 ppm degraded appreciably, with a half-life of <18 days in sandy loam, silt loam, and silty clay loam nonsterile soils incubated at ≤32°C in a greenhouse. [^{14}C] Alachlor was ≤0.5 ppm in all three soil types 72 days after treatment. The degradate 2-chloro-2',6'-diethylacetanilide was detected at all sampling intervals at ≤0.8 ppm, with no definite pattern of formation or decline.

This study was conducted in a greenhouse. It provides supplemental information about the aerobic soil metabolism of alachlor by identifying one alachlor degradate. The study is deficient when evaluated according to current guidelines because it was conducted in the greenhouse, and material balances could not be confirmed. (MRID No. 00023014)

c. Mobility/Leachability of Alachlor

GLN 163-1 Mobility, Leaching and Adsorption/Desorption:

Based upon the studies available and the structural features of the chemicals, it appears that alachlor degradates, as well as parent alachlor, *have a high potential to leach.*

An acceptable study partially satisfies the requirement by providing information about the mobility of *unaged* alachlor. To satisfy the data requirement a supplemental Batch Equilibrium study was submitted for alachlor ESA, which is the major degradate observed in the aerobic soil metabolism studies.

[^{14}C] Alachlor (carbonyl labeled), at 3.5 lb a.i./A, was very mobile in 30 cm columns of silt, sand, and loamy sand soils that were leached with 20 inches of water. The leachate from the silt, sand, and loamy sand soil columns contained 40.9-96.9% of the applied radioactivity. This radioactivity was "mainly" alachlor. The following degradate was identified in these leachates, but not quantified: 2',6'-diethyl-N-methoxymethylacetanilide.

[^{14}C] Alachlor was mobile in columns of silt loam soil treated under similar conditions. The leachate from the silt loam soil contained 0.5-0.6% of the applied radioactivity. The radioactivity remaining throughout the soil columns increased from 1.9-5.4% of the applied in the 0- to 2-cm segment, to 10.9-12.9% in the 10- to 14-cm segments, and declined to 0.1% in the 28- to 30-cm segment. The following compounds were detected in the leachates at 5-23% of the recovered

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radioactivity: 2',6'-diethyl-N-methoxymethylacetanilide, 2-chloro-2',6'-diethylacetanilide, and 2',6'-diethyl-N-methoxymethyl-2-methylthioacetanilide.

The analysis of selected soil extracts of all four soils indicated that the radioactivity was "mainly" alachlor. There was no clear correlation between the mobility of alachlor and the soil composition; however, it appears that higher organic matter contents favor adsorption of the chemical to the soil.

Although this study had been found acceptable and provides information about the mobility of parent alachlor, the following details are noted because they could have had an effect on the observed results: The columns were packed using a wooden dowel; it is not reported if the columns were saturated prior to leaching. In addition, it is reported that the water "was added at a rate slower than the infiltration capacity of the soil." These conditions could have affected the observed leaching behavior. The parent alachlor could have leached even more under saturated flow conditions which would be the maximum flow rates. (MRID No. 00134327)

In a leaching study, [^{14}C] alachlor residues leached through the columns, with ≈96%, ≈51%, and 0% of the recovered having leached through a gravelly sand, sandy loam, and a silty clay loam soil columns, respectively. The soil columns measured 20 cm (8 inches, recommended 30 cm), and were leached with 10 inches of water (recommended 20 inches). This study was considered scientifically valid in the original reviews. However, the Agency now believes that these studies only provide supplemental information, since leaching and soil retention were reported based on ^{14}C rather than concentrations of alachlor and its degradates. The study indicates a high level of leaching in sand, sandy loam, and silty clay loam. (MRID Nos. 00027139, and 00027140)

Based on a supplemental Adsorption/Desorption experiment [^{14}C] alachlor, at 1-10 ppm, appears to have a high mobility in three soil types. The K_d values, calculated based on [^{14}C] instead of actual alachlor concentrations, decreased with a decrease in soil organic matter. The mean K_d values were 3.74 for a silty clay loam, 2.88 for sandy loam, and 0.80 for a gravelly sand.

In a supplemental column leaching study alachlor applied at 5 kg ai/A appeared to be very mobile in a Lakeland sand, with 59% of the applied alachlor recovered from the leachates of a 30 cm soil column, eluted with 8 inches (20 cm) of water. Alachlor was less mobile in other soils tested, with maximum leaching depths of 18 cm, 10 cm, and 4 cm in Collenbey sand, silt loam, and sandy clay loam columns, respectively. The level of leaching appeared to be related to the percent organic matter, with lower leaching of the soils having higher organic matter.

However, the study does not meet the Subdivision N Guidelines because the columns were eluted with only 8 inches of water. (Subdivision N Guidelines recommends elution with 20 inches of water.) In addition, no attempts were made to measure possible degradates or total residues. Therefore, the Agency is concerned about the validity of the study since insufficient elution water was applied to demonstrate the mobility of alachlor in the soils. This study is now deemed supplemental

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and gives an indication of the level of leaching in sandy clay loam, silt loam, and sand. (MRID No. 00078301)

Based on supplemental column leaching studies, aged (30 days) *uncharacterized* [^{14}C] residues of alachlor were mobile in 30 cm columns with sandy loam soil, treated at 3.5 lb a.i./A, and leached with 20 inches of water. The radioactivity recovered in the leachate totaled 29.1-31.5% of the applied. Approximately 10 compounds were isolated from the leachates each at $\leq$0.7% of the applied radioactivity. The major component found in the soil samples was [^{14}C] alachlor.

This portion of the study (aged) is not acceptable, because the soil was aged for 30 days, which may be a period of time considerably longer than one half-life. The aerobic soil metabolism studies show estimated half-lives between 2 and 3 weeks. After the aging period, and prior to leaching, the soil was not characterized; therefore, it is not possible to determine if either sufficient parent compound remained at the time of leaching, or what was the ratio of the degradates formed. (MRID No. 00134327)

d. Mobility of Alachlor Degradates

Mobility and Adsorption/Desorption of Alachlor ESA:

Based on batch equilibrium studies, uniformly phenyl ring-labeled [^{14}C]-alachlor ESA (sodium salt), at approximately 6.0, 1.0, 0.2, and 0.04 μg/mL, was determined to be *very mobile* in Sable silty clay loam:calcium chloride solution slurries (1:5) that were equilibrated in the dark for 24 hours at approximately 25°C. Freundlich K_{ads} value was 0.45 and K_{OC} value was 15. Following one desorption step, Freundlich K_{des} value was 1.43. Material balance ranged from 95.8 to 110.9% of the applied for the definitive study.

Based on batch equilibrium studies, uniformly phenyl ring-labeled [^{14}C]-alachlor ESA, at approximately 6.0, 1.0, 0.2, and 0.04 μg/mL, was determined to be very mobile in Sarpy sandy loam, Spinks sandy loam, and Katy loam:calcium chloride solution slurries (1:5) that were equilibrated in the dark for 24 hours, at approximately 25°C. Accurate Freundlich K_{ads} values could not be calculated because levels of adsorbed [^{14}C]-alachlor ESA metabolite were very low. Adsorption values in these three soils were approximately 0% (MRID No. 44405301).

The study on alachlor ESA does not fully fulfill the data requirement, because Freundlich adsorption values could not be calculated in three of the soils. However, the study provides supplemental information about the mobility of alachlor ESA, which has been detected in greater concentrations than parent alachlor. The Agency believes that a new study would not provide new information about the mobility of alachlor ESA other than confirming that this degradate is very mobile; therefore, no additional data on the mobility of alachlor ESA are required at this time.

The registrant has submitted Adsorption/Desorption studies for two propachlor soil metabolites. Propachlor is structurally similar to alachlor. The mobility characteristics of alachlor

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and propachlor, as well as other physico-chemical characteristics are similar as well. The registrant proposed to use the mobility data on propachlor degradates as surrogate data for alachlor degradates. This was accepted by the Agency since (1) the propachlor degradates are structurally similar to alachlor degradates, and (2) the propachlor degradates are very mobile, which is comparable to the available information on the mobility of alachlor ESA. Results obtained for the propachlor degradates are as follows:

Based on batch equilibrium studies, propachlor oxanilic acid was determined to be very mobile in loamy sand, sandy loam, loam, and silty clay loam soil: solution slurries. Freundlich K_{ads} values ranged from 0.03 to 0.08. Table 47 summarizes the results obtained in the study. (MRID No. 42485703)

Table 47: Mobility and Adsorption/Desorption for Propachlor Oxanilic Acid

	K_{ads}	K_{OC}	K_{Des}	K_{OC}
loamy sand	0.03	8	4.48	1120
sandy loam	0.04	2	15.86	886
loam	0.08	7	4.34	391
silty clay loam	0.06	10	20.91	3428

An acceptable propachlor sulfonic acid study is available, which can be used to partially satisfy the data requirement for alachlor. Based on batch equilibrium studies, propachlor sulfonic acid was determined to be very mobile in sand, sandy loam, loam, and silty clay loam soil:solution slurries. Freundlich K_{ads} values ranged from 0.03 to 0.07. Table 48 summarizes the results obtained in the study. (MRID No. 42485704)

Table 48: Mobility and Adsorption/Desorption for Propachlor Sulfonic Acid

	K_{ads}	K_{OC}	K_{Des}	K_{OC}
sand	0.03	7	1.33	317
sandy loam	0.06	6	6.24	624
loam	0.05	5	1.73	156
silty clay loam	0.07	3	1.23	47

Mobility characteristics compared for alachlor and propachlor**:**

An examination of the mobility characteristics of alachlor and propachlor show that both are very mobile. Generally, propachlor is more mobile than alachlor (except in the Ray silt). It is

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observed that %CEC (% cation exchange capacity) and %OM (% organic matter) are good predictors of alachlor mobility (higher mobility when %CEC is lower, and higher mobility when %OM is lower). This trend is only general for propachlor. The Agency believes that for both alachlor and propachlor degradates, that the negative charges play an important role in predicting the mobility.

Table 49: Mobility Characteristics for Alachlor

Soil type	% sand	% silt	% clay	% OM	% CEC	% radioactivity found in leachates
sand	86.0	11.0	1.8	0.7	5.1	86.7-96.9
silt	4.6	84.2	10.0	1.2	10.4	78.2-82.2
loamy sand	75.1	17.8	4.8	2.4	11.3	40.9-43.4
silt loam	2.4	68.0	25.3	3.4	24.6	0.5-0.6

Table 50: Mobility Characteristics for Propachlor

Soil type	% sand	% silt	% clay	% OM	% CEC	Ave. % radioactivity found in leachates
Lintonia sand	86.0	11.0	1.8	0.7	5.1	83.1-95.9
Ray silt	4.6	84.2	10.0	1.2	10.4	40.6-71.4
Spinks loamy sand	75.1	17.8	4.8	2.4	11.3	71.0-84.0
Drummer silt loam	2.4	68.8	25.3	3.4	24.6	2.9-7.9

The Agency believes that the mobility requirements for alachlor metabolites have been partially satisfied with the submission of mobility data of the propachlor degradates: propachlor oxanilic acid and propachlor sulfonic acid. The Agency believes that these degradates show substantial structural similarity to alachlor degradates, therefore they can be used for a preliminary assessment of the mobility of alachlor degradates. The Agency believes that the available data

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confirms that all the four major degradates of alachlor are very mobile under normal environmental conditions.

e. Volatility

GLN 163-2 and 163-3 Laboratory and Field Volatility:

This data requirement was waived, based on the relatively low vapor pressure and levels of volatiles in the aerobic soil metabolism study.

Alachlor has a vapor pressure of 2.2×10^{-5} mm Hg at 24°C (MRID No. 00152209). Since this value is relatively low, volatility may not be an important route of dissipation for alachlor. In addition, the acceptable Aerobic Soil Metabolism study (MRID No. 00134327) showed the presence of small amounts of [^{14}C] volatiles ($\leq$1.15% of the applied after 175 days of incubation). In a supplemental aerobic soil metabolism study (MRID No. 00101531) [^{14}C] volatiles were $\leq$4.84% of the applied after 40-62 days. This suggests that volatilization is not a significant route of dissipation for alachlor.

f. Field Dissipation

GLN 164-1 Terrestrial Field Dissipation:

Field dissipation has been evaluated at sites in Chico and Hickman, California. (MRID Nos. 42528001, 42528002, 42528003, 42528004, 43774701) Both terrestrial field dissipation studies were conducted in California, despite the fact that alachlor is widely used throughout the United States. These two studies are not adequate to fully characterize the range of field conditions to which alachlor may be exposed. Despite this fact, a new additional terrestrial field dissipation study will not be required. The Agency believes that a new study would not provide substantial new information.

The study conducted in Chico, California is acceptable and can be used to partially satisfy the Terrestrial Field Dissipation (164-1) data requirement. Alachlor (Lasso ®4-EC), applied once at 4 lb a.i./A, dissipated with an observed half-life of approximately 11 days from a plot of loam/sandy clay loam soil in Chico, California, that was planted to corn immediately after treatment. Alachlor was detected at a depth of 18- to 24-inches (at test intervals 7 and 14 days). In the 0- to 6-inch soil depth, alachlor averaged 0.781-0.798 ppm at 0-1 days post-treatment, 0.641 ppm at 7 days, and 0.350 ppm at 11 days. Two samples showed $\geq$0.124 ppm at 14 days, both in the 12- to 18- and 18- to 24-inch soil depths. In addition, five minor detections occurred at 36- to 48-inch soil depth at $\leq$0.016 ppm at 11-18 days. The rainfall plus irrigation totaled 6 inches through 18 days post-treatment.

The following degradates were detected in the soil:

- Alachlor oxanilic acid was detected through 44 days post-treatment in the 0- to 6- and 6- to 12-inch soil depths, at averages $\leq$0.047 ppm. There were 15 individual

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detections through 44 days in the 0- to 6-inch soil depth and 10 individual detections through 21 days in the 6- to 12-inch soil depth. There were also sporadic detections in the soil depths up to 36- to 48-inch at ≤0.023 ppm. These included 5 detections in the 12- to 18-inch soil depth (14-120 days), 2 detections in the 18- to 24-inch soil depth (18 and 180 days), and 2 detections in the 36- to 48-inch soil depth (44 days);

- Alachlor sulfinylacetic acid was detected from 7 through 44 days post-treatment in the 0- to 6- and 6- to 12-inch soil depths, at averages ≤0.039 ppm. There were 13 individual detections through 44 days in the 0- to 6-inch soil depth and 11 individual detections through 44 days in the 6- to 12-inch soil depth. There were 5 sporadic detections in the soil depths up to 18- to 24-inch at ≤0.020 ppm at 14 and 18 days;

- Alachlor ESA was detected from 1 through 44 days post-treatment in the 0- to 6- and 6- to 12-inch soil depths, at averages ≤0.027 ppm. There were 14 individual detections through 44 days in the 0- to 6-inch soil depth, 10 individual detections through 90 days in the 6- to 12-inch soil depth; and 4 detections each in the 12- to 18- and the 18- to 24- soil depths (at ≤0.022 ppm) at 14-78 days. Two sporadic detections at ≤0.011 ppm were observed in the 24- to 36-inch soil depth, at 18, and 44 days.

- Alachlor DM-oxanilic acid was detected sporadically at ≤0.061 ppm through 90 days after treatment, in the 0- to 6- and 6- to 12-inches depths. In addition, there was 1 detection each in the 12- to 18- and the 18- to 24-inch soil depths (90 and 44 days), and 2 detections in the 24- to 36-inch soil depth (14 and 78 days).

Three samples were tested per test intervals. The lowest limit at which the method was validated for each metabolite is 0.01 ppm. Detections below this level were reported as <0.01 ppm.

Examination of the soil composition data of the Chico plot shows an increasing percent of clay with soil depth (to a maximum of 65% clay in the 24- to 36-inch soil depth). This "clay pan" reduces the flow of water into deeper soil layers, decreasing the possibility of leaching of both parent alachlor and its degradates. It is possible that under conditions that would favor the flow of water into deeper soil layers, further leaching would have been detected.

The study conducted in Hickman, California is acceptable and can be used to partially satisfy the Terrestrial Field Dissipation data requirement.

Alachlor (Lasso® E.C.), applied once at 4 lb a.i./A, dissipated with a registrant-calculated half-life of 6.2 days from the 0-6 inch soil depth of a bareground plot of sandy loam soil in Hickman, California. The field was bareground to simulate preemergent application to a crop. In the 0-6 inch soil depth, alachlor averaged 1.363-1.458 ppm at 0-1 days post-treatment, 0.932 ppm on day 7 after application, and 0.220 ppm on day 21 after application. Alachlor remained mostly in the 0-6 inch soil

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depth. Detections averaging 0.018-0.046 ppm were reported in the 6-12 inch soil depth on days 0 and 1 after application.

The following degradates were detected in the soil:

- Alachlor DM-oxanilic acid was detected in the 0-6 inch soil depth from day 1 through day 366 after treatment at average levels from 0.006-0.048 ppm (no clear pattern of formation or decline). The chemical was detected in the 6-12 inch soil depth only on day 182 after application, with an average value of 0.004 ppm.

- Alachlor oxanilic acid was detected in the 0-6 inch soil depth from day 0 through day 366 after application at average levels from 0.005 to 0.058 ppm, with no clear pattern of formation and decline. At three test intervals, detections were reported in the 6-12 inch soil layer. On days 0, 125, and 182, the oxanilate levels were 0.004, 0.004, and 0.013 ppm, respectively. The chemical was also detected in the 12-18 and 18-24 inch soil layers on day 182 after application, with average values of 0.007, and 0.008, respectively.

- Alachlor sulfinylacetic acid was observed at low levels in the 0-6 inch soil layer from day 1 to 182 after application, at average levels ranging from 0.002 to 0.017 ppm. In addition, the chemical was detected in the 6-12 and 18-24 inch soil layers on day 182 after application, with average values of 0.004 ppm in both cases,

- Alachlor ESA was observed at low levels from day 0 through day 366 after application at average levels ranging from 0.003-0.010 ppm. Detections were also reported in the 6-12 inch soil depth on days 182 and 366 after application, with average values of 0.004 and 0.008 ppm, respectively. Furthermore, the chemical was detected in the 12-18 inch soil depth on day 182 after application, with an average value of 0.003 ppm

Another study conducted at Madera, California was considered invalid since the alachlor concentrations found at all levels in the soils was $\leq$0.1 ppm. The application rate was 4 lb a.i./A. When conducting a Terrestrial Field Dissipation study, the soils are sampled immediately after treatment. Generally, it is expected that the highest concentration of active ingredient would be observed at that test interval. Thereafter, a pattern of decline should be observed and a half-life is calculated. Since the alachlor concentrations found at all levels in the soils was $\leq$0.1 ppm, there was no pattern of decline. Thus, this study is not representative of typical behavior for the test conditions.

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g. Bioaccumulation

GLN 165-4 Bioaccumulation in Fish:

This data requirement was waived. Alachlor has a relatively high water solubility (240 ppm), and a low octanol/water partition coefficient of 434 (one study reports as low as 35). Chemicals with these physico/chemical properties are not expected to bioaccumulate substantially in fish. Therefore, the Agency will require no additional information on the Bioaccumulation in Fish (165-4) data requirement for alachlor at this time.

h. Spray Drift

GLN 201-1 and 201-2 Spray Drift/Droplet Spectrum and Field Evaluation:

Alachlor is highly toxic to nontarget plants. Since alachlor can be applied aerially, data to satisfy 201-1 and 201-2 was required in a 1991 DCI. The Spray Drift Task Force (SDTF), a consortium of pesticide registrants, has submitted to EPA a series of studies intended to characterize spray drift potential due to various factors, including application methods, equipment, meteorological conditions, crop geometry, and droplet characteristics. EPA is currently evaluating these studies, which include ground spray as well as aerial application methods. After its review of the studies, the Agency will determine whether a reassessment of the potential risks from the application of alachlor to nontarget organisms is warranted. The results would be used to assess the extent of exposure to nontarget plants. This data requirement is *not satisfied*, and is being held in Reserve, pending the evaluation of the work of the industry's SDTF. The registrant is a member of the SDTF.

4. Environmental Fate Assessment

Based on acceptable and supplemental studies, the following conclusions can be drawn:

Alachlor is stable to abiotic processes (hydrolysis, photolysis in aqueous media, or photodegradation on soil). The major dissipation routes for the chemical appear to be microbially mediated degradation and leaching. Alachlor is degraded at moderate rates ($t_{½} \approx$ 2-3 weeks) in aerobic soils, with several degradates observed, including alachlor DM-oxanilic acid, alachlor ethane sulfonic acid (alachlor ESA), alachlor oxanilic acid, and alachlor sulfinylacetic acid. Currently the Agency does not have valid K_d's for alachlor. The registrant indicated that a K_{OC} of 124 has been reported by USDA/ARS in their Internet Web site. However, the Agency has not reviewed the study used to determine the K_{OC}. The column leaching study for the parent alachlor indicates that it is very mobile and is not appreciably adsorbed to soils with low organic matter. A batch equilibrium study on alachlor ESA shows that this degradate is very mobile. The findings in the field confirm the predicted fate from laboratory studies.

Alachlor dissipated at moderate rates in the field; the observed half-lives of 6 and 11 days are of the same order of magnitude of the half-lives observed in various aerobic soil metabolism studies

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(2-3 weeks). It appears that the persistence and mobility of the chemical may increase as it reaches deeper soil horizons which have lower organic matter content and decreased biological activity, thus increasing its potential to leach into groundwater.

a. Degradation and Metabolism

Alachlor is a soluble molecule (240 ppm in water at 20°C), with an octanol/water partition coefficient of 434, and a vapor pressure of 2.2×10^{-5} mm Hg at 24°C.

Alachlor was stable to hydrolysis in buffered solutions at pH's 3, 6, and 9. It was also relatively stable in natural lake water. Alachlor does not show any absorption bands above 240 nm in the absorption spectrum; therefore, it is not expected to undergo photolysis in water or on soil.

In soils, under aerobic soil metabolism conditions, alachlor appears to degrade at a moderate rate. Results of three different studies (one acceptable and two supplemental) show that alachlor degrades with half-lives in the range of 6-21 days. The studies include use of different sites, different formulations, and different soil types. Several degradates were observed in the studies. The major degradates in the aerobic soil metabolism studies were alachlor DM-oxanilic acid (with a maximum of 17.0% of the applied), alachlor ESA (24.9% of the applied), alachlor oxanilic acid (22.4% of the applied), and alachlor sulfinylacetic acid (16.2% of the applied). Of these major "water-soluble" degradates, alachlor sulfinylacetic acid was not observed in the valid aerobic soil metabolism study. However, it was observed in a supplemental study. All four degradates appear to be more persistent than alachlor, since significant concentrations remained in the soils at the end of the aerobic soil metabolism studies.

CO_2 is the ultimate degradate; it comprised 16.17-30.00% of the applied after 175 days in a valid study. Unextracted residues comprised $\leq$20.76% of the applied at the same test interval.

b. Mobility

Based upon both supplemental and acceptable studies, parent alachlor appears to be highly mobile in soils. In a column leaching study, in three of the soils with lower organic matter, alachlor was very mobile: silt, sand, and loamy sand soil (0.7-2.4% OM) columns, the leachates contained 40.9-96.9% of the applied radioactivity. In another soil with a higher organic matter content, the mobility was lower: silt loam soil (3.4% OM), the leachates had only $\leq$0.6% of the applied radioactivity; however, even though the water was added at a rate slower than the infiltration capacity, substantial downward movement was observed through the column, with a total of 53.5-57.7% of the applied radioactivity found in the soil segments from 9- to 18-cm.

Since all the major water soluble degradates of alachlor have carboxylic or sulfonic acid functional groups, which render a negative (anionic) character to the molecule under normal environmental conditions, it is expected that the degradates will be highly mobile in soils. This is supported by the available mobility data for the degradates of propachlor (propachlor sulfonic acid

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and propachlor oxanilic acid), which are structurally similar to the degradates of alachlor; the data for these degradates of propachlor has been used as surrogate data in lieu of the original alachlor metabolites. In addition, a batch equilibrium study on alachlor ESA shows that this degradate is very weakly absorbed. Quantitative results could be obtained in only one of the soils (very mobile in Sable silty clay loam, Freundlich K_{ads} value was 0.45 and K_{OC} value was 15).

c. Bioaccumulation

Alachlor is not expected to bioaccumulate significantly in fish, based on high solubility (240 ppm), and relatively low octanol/water partition coefficient (434).

d. Field Dissipation

In a Terrestrial Field Dissipation study conducted in Chico, California, alachlor, at 4 lb. a.i./A, dissipated with a half-life of 11 days from loam/sandy clay loam soil planted to corn. This half-life is consistent with those reported in various aerobic soil metabolism studies. Most of the alachlor was found in the 0- to 18-inch soil layers, with occasional detections in the 18- to 24-, 24- to 36-, and 36- to 48-inch layers (the deepest layer sampled), indicating a large potential for leaching. The four major water-soluble metabolites of alachlor were also monitored in this study. The soil composition data in this study shows increasing percent of clay with soil depth (to a maximum of 65% clay in the 24- to 36-inch soil depth). This "clay pan" reduces the flow of water into deeper soils layers, decreasing the possibility of leaching of both parent alachlor and degradates.

Degradates of alachlor in the Chico Terrestrial Field Dissipation study (alachlor oxanilic acid, alachlor sulfinylacetic acid, and alachlor ESA derivatives) were detected in the 0- to 6- and 6- to 12-inch soil depths at average concentrations of 0.010-0.045 ppm. Detections were observed through 36- to 48- soil depth for the oxanilic acid, 18- to 24-inch soil depth for alachlor sulfinylacetic acid and alachlor ESA, and 6- to 12-inch soil depth for the alachlor DM-oxanilic acid. Generally, detections of these alachlor degradates occurred through 44-90 days post-treatment in the subsoils. Once moved to the subsoils, these degradates appear to persist.

Alachlor, applied once at 4 lb a.i./A, dissipated with a registrant-calculated half-life of 6 days from the 0-6 inch soil depth of a bareground plot of sandy loam soil in Hickman, California. The field was bareground to simulate preemergent application to a crop. Alachlor remained mostly in the 0-6 inch soil depth. Detections averaging 0.018-0.046 ppm were reported in the 6-12 inch soil depth on days 0 and 1 after application.

In the Hickman, California Terrestrial Field Dissipation study the following degradates were detected: alachlor DM-oxanilic acid, which was detected in the 0-6 inch soil depth from day 1 through day 366 after treatment, and in the 6-12 inch soil depth only on day 182 after application (with an average value of 0.004 ppm). Alachlor oxanilic acid was detected in the 0-6 inch soil depth from day 0 through day 366 after application, in addition, at three test intervals, detections were reported in the 6-12 inch soil layer. Alachlor oxanilic acid was also detected in the 12-18 and 18-24

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inch soil layers on day 182 after application. Alachlor sulfinylacetic acid was observed at low levels in the 0-6 inch soil layer from day 1 to 182 after application, and in the 6-12 and 18-24 inch soil layers on day 182 after application. Alachlor ESA was observed at low levels from day 0 through day 366 after application at average levels ranging from 0.003-0.010 ppm. Detections were also reported in the 6-12 inch soil depth on two test intervals. Furthermore, alachlor ESA was detected in the 12-18 inch soil depth on day 182 after application, with an average value of 0.003 ppm.

e. Volatility

Volatilization is not expected to be an important route of dissipation for alachlor. The chemical has relatively low vapor pressure (2.2×10^{-5} mm Hg). Furthermore, the amount of volatiles in the aerobic soil metabolism studies were negligible.

f. Spray Drift

The labels indicate that alachlor may be applied aerially. No alachlor-specific spray drift studies were reviewed. The Spray Drift Task Force (SDTF), a consortium of pesticide registrants, has submitted to EPA a series of studies intended to characterize spray drift potential due to various factors, including application methods, equipment, meteorological conditions, crop geometry, and droplet characteristics. EPA is currently evaluating these studies, which include ground spray as well as aerial application methods. After its review of the studies, the Agency will determine whether a reassessment of the potential risks from the application of alachlor to nontarget organisms is warranted.

5. Terrestrial Exposure Assessment

Nongranular applications:

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). Terrestrial estimated environmental concentrations (EECs) for nongranular formulations were derived from maximum application rates up to 4.0 lb ai/acre.

Table 51: Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm)

Food Items	EEC (ppm) Max. Residue		EEC (ppm) Mean Residue	
	1 lb ai/acre	4 lb ai/acre	1 lb ai/acre	4 lb ai/acre
Short grass	240	960	85	340
Tall grass	110	440	36	144

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Table 51: Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm)				
Food Items	EEC (ppm) Max. Residue		EEC (ppm) Mean Residue	
	1 lb ai/acre	4 lb ai/acre	1 lb ai/acre	4 lb ai/acre
Broadleaf plants and small insects	135	540	45	180
Fruits, pods, seeds, and large insects	15	60	7	28

Granular applications:

EECs for broadcast granular applications are calculated on the basis of mass (in mg) per area (square foot), corrected for the fraction of the pesticide left on the surface. For unincorporated broadcast applications, the entire fraction of the pesticide is assumed to remain on the surface. The label for granular formulation prescribes adjusting the desired application rate by the fraction: band width (inches) / row spacing (inches).

6. Ground Water Monitoring Data

The following studies provided ground water monitoring data that were used to develop the water resource and aquatic exposure assessments for alachlor.

a. Introduction

Ground-water monitoring data collected, since 1991, by the USGS and the Acetochlor Registration Partnership (ARP) have found alachlor parent in two to eight percent of ground-water wells sampled. Up to 1.5 percent of these wells were found to have alachlor residues above the MCL of 2.0 µg/L. These recent monitoring data are in agreement with earlier studies, such as those reported in Pesticides in Ground Water Data. The maximum and minimum alachlor concentrations were 15.89 µg/L and 0.05 µg/L, respectively.

Monitoring data collected by the USGS (Kolpin and Goolsby, 1995; Kolpin et al., 1995; Kolpin et al., 1996) also indicates that in addition to alachlor, more than 40 percent of the wells sampled in Midcontinental US were contaminated with alachlor ESA degradate and/or 16 percent were contaminated with the alachlor 2,6-diethylaniline degradate. There are no ground water monitoring data on the other two major degradates (alachlor oxanilic acid and sulfinylacetic acid). These results correspond with the fate data, which indicate that these alachlor degradates are more mobile and persistent than the parent compound.

These recent studies reflect that current alachlor use may still result in ground water concentrations which exceed the LOCs for alachlor parent as detections have occurred which exceed

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the current MCL of 2.0 µg/L. Since a much greater proportion of ground water wells are impacted by alachlor degradates, if an MCL or cancer risk level is established for alachlor ESA at the same level as alachlor parent, concern would be much greater than for the parent compound only.

Similar chemicals, acetochlor, metolachlor, and propachlor, have also been found in ground water. Approximately, the same percentage of wells have been found to be contaminated by propachlor (1.2%) as alachlor (1.8%), although many fewer wells have been analyzed for propachlor. Although the number of wells sampled for metolachlor and alachlor are similar, there are approximately twice as many wells with detections of alachlor (1.8%) residues then metolachlor (0.96%). Acetochlor, with a maximum of 2.17 µg/L, was detected in eight wells (4.6%) of 173 in the registrant's ground-water monitoring study.

Detections of alachlor degradates in ground water are important because ground water may represent an important means of exposure. Four major degradates have been identified for alachlor: alachlor DM oxanilic acid, alachlor sulfinylacetic, alachlor sulfonic acid (ESA), and alachlor oxanilic acid. As noted above, the four degradates are more persistent than the parent compound. Batch equilibrium studies were previously requested on the degradates to assess their mobility. The registrant has proposed using adsorption data from two propachlor degradates as surrogate data for the alachlor degradates. This is acceptable for two degradates, but will still require the determination of the mobility for the alachlor ESA degradate.

b. Recent Groundwater Monitoring Data

USGS Midcontinent Ground Water Monitoring Studies:

In 1991, the USGS sampled 303 wells from a reconnaissance well monitoring network in near-surface aquifers distributed across 12 Midwestern states. (Kolpin et. al., 1995) These wells were distributed geographically and hydrogeologically by state, aquifer class (unconsolidated vs bedrock), and relative depth. At least 25% of the land within a 3.2 km radius of the well was in corn or soybean production during the 1990 growing season. One hundred wells were resampled during 1992 by selecting wells using a stratified random design based upon State and aquifer class.

The USGS found that five of the six most frequently detected pesticide compounds detected in ground water of 12 Midwestern states were pesticide metabolites. Kolpin et. al. (1996) also demonstrated that as the analytical reporting limits are decreased, there is an increase in the differences in frequencies of detections. Alachlor ESA is reported almost 10 times more frequently than parent alachlor at the 0.05 µg/L level.

Alachlor was detected in 6 wells (2%) out of 303 wells in 1991 and 5 wells (5%) out of 100 wells in 1992 in near-surface aquifers in 12 Midwestern states (Kolpin et. al., 1995). The alachlor reporting limits were 0.05 and 0.002 µg/L for 1991 and 1992, respectively. Alachlor ESA was the most frequently detected compound in 1992. It was found in 33 wells (45%) of 73 wells for which the degradates were analyzed, with a reporting limit of 0.10 µg/L. In the same study, metolachlor

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was detected in 12 wells (4%) out of 303 in 1991; and, 11 wells (11%) out of 100 in 1992, with the same reporting limits as stated for alachlor.

Additional samples were collected in 1993 (110 wells) and 1994 (38 wells) from unconsolidated aquifers (Kolpin et al., 1996). Alachlor was detected in 10 wells (3.3%) out of 303 wells. Alachlor parent was found in 5.9% of the 153 wells for which metabolites were analyzed. The maximum alachlor concentration detected was 4.27 µg/L, with a reporting limit of 0.05 µg/L. Alachlor ESA was found in 70 wells (45.3%) of 153 wells analyzed for degradates. The maximum concentration of alachlor ESA was 8.63 µg/L, with a 0.10 µg/L reporting limit. A second alachlor degradate, 2,6-diethylaniline, was also detected in 15 wells (16%) of 94 wells analyzed. The maximum concentration was 0.02 µg/L with a reporting limit of 0.003 µg/L.

Atrazine degradates deisopropylatrazine (10% of 303 well; maximum concentration of 1.17 µg/L) and deethylatrazine (22.8% of 303 wells; maximum concentration 2.20 µg/L) were also detected. Metolachlor was also detected at levels above 0.05 µg/L in 8 wells (2.7%) out of 300 (Goolsby et. al., 1995).

Table 52: Summary of Wells with Detections of Alachlor ESA

Study	Number of Wells			Concentrations (µg/L)	
	Sampled	Detected	Percent Detected	Maximum Concentration	Reporting Limit
USGS 1992	73	33	45%	-	0.1
USGS 1993	153	70	45.3%	8.63	0.1
USGS 1994	38	25	65.8%	8.6	0.1
USGS-IOWA 1995	106	69	65.1%	14.78	0.1
Wisconsin 1993 vulnerable wells	293	206	70%	26.7 (ave. = 4.89)	1.0[1]

[1] Analyzed by immunoassay

Acetochlor Registration Partnership Ground Water Monitoring Program (ARP-GWMP):

As a requirement for the registration of acetochlor, the two acetochlor registrants are conducting a ground-water monitoring program in seven major use states. Analytes are parent (no degradates) alachlor, acetochlor, atrazine, dimethenamid, and metolachlor (only the first three were reported). Ground-water samples are collected monthly from 175 wells located in corn producing areas. The annual report from the first year of monitoring (only for acetochlor, alachlor, and atrazine)

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covers the 13-month period, from December 1994 to December 1995. The limits of detection and quantification for all analytes are 0.03 µg/L and 0.05 µg/L, respectively.

The text of the annual report indicates that alachlor was detected in 45 samples (2.6%) out of 1720 (27 of which were greater than 0.1 µg/L). Acetochlor residues were detected in 25 of 1720 samples (15 of which were greater than 0.1 µg/L) and atrazine was detected in 651 samples (427 were greater than 0.1 µg/L) out of 1720.

Results for the three pesticides are summarized in Table 53 below. Fourteen of the wells had alachlor detects greater than limit of quantification (LOQ - 0.05 µg/L), six wells had detections of acetochlor above the LOQ, and 75 wells had atrazine detections above the LOQ. Twenty-seven wells had alachlor detections above the limit of detection (LOD) of 0.03 µg/L, 93 wells had detections of atrazine above the LOD, and eight wells had acetochlor levels above the LOD.

Two of the fourteen wells with alachlor detections had detections on more than one sampling date. One of these wells was located in Illinois. The first detection of alachlor for this well (May 1995) was also the greatest (13.05 µg/L) concentration. Alachlor concentrations in this well declined with time, reaching 0.42 µg/L by December 1995. The second well with multiple detections was located in Kansas. The first detection (0.3 µg/L) was reported in March 1995. The highest detections for this well occurred in May 1995 (14.17 µg/L) and June (15.89 µg/L) and then generally declined, reaching 3.64 µg/L by December 1995. Seven other wells also had alachlor detections in March 1995. According to the registrant, these detections in Kansas and Illinois are linked to surface runoff and ponding near the wellhead rather than leaching. New wells were installed, and follow up sampling indicates that the underlying aquifers are not contaminated with alachlor.

Table 53: Detections and Concentrations (in µg/L) of Acetochlor, Alachlor, and Atrazine in Study Conducted by the Registrants of Acetochlor.

Statistic	Acetochlor	Alachlor	Atrazine
Number of Samples with Detects ≥0.05 µg/L (% of samples)	18 (1.0)	30 (1.7)	539 (31.3)
Number of Wells (% of 173)	8 (4.6%)	14 (8.1%)	75 (43.4%)
Number of Samples[1]	1720	1720	1720
Mean	0.39	3.38	0.75
Standard Deviation	0.52	4.89	5.88
Minimum	0.06	0.05	0.05
1st Quartile	0.11	0.12	0.11

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Table 53: Detections and Concentrations (in µg/L) of Acetochlor, Alachlor, and Atrazine in Study Conducted by the Registrants of Acetochlor.			
Statistic	Acetochlor	Alachlor	Atrazine
Median	0.25	0.73	0.24
3rd Quartile	0.38	5.06	0.56
Maximum	2.17	15.89	131.53[2]

[1] It was not possible to determine whether data identified as missing were no data or below detection limit.

[2] The next highest value for atrazine was 30.03 µg/L.

Alachlor, Metolachlor and Propachlor in the Pesticides in Ground Water Data Base**:**

The Pesticides in Ground Water Data Base (PGWDB) (USEPA, 1992) reports that alachlor was detected in 25 states, in 467 wells of 25933 sampled (1.8%). Of the wells with detections 99 wells (0.4%) had concentrations above the MCL. The PGWDB reported propachlor detections in 33 (1.2%) wells [in five states] out of 2718 wells sampled in eleven states. The concentrations ranged from 0.02 to 3.5 µg/L, thus the maximum concentration exceeded the MCL of alachlor (2 µg/L), but not the Lifetime Health Advisory (HAL) for propachlor (90 µg/L).

The PGWDB also summarizes a number of studies which included metolachlor. Metolachlor has been analyzed for in 29 states and detected in 20 states. Detections occurred in 213 (1%) wells out of 22,255 wells sampled, with concentrations ranging from 0.02 to 157 µg/L. Three exceeded the lifetime Health Advisory (LHA) of 70 µg/L for metolachlor, but typically appear to less than 10 µg/L.

Table 54: Summary of Alachlor, Metolachlor, and Propachlor Ground Water Monitoring Data from the Pesticides in Ground Water Data Base			
Detection Information	Alachlor	Metolachlor	Propachlor
	Number of Wells (Percent of Wells)		
MCL or HAL (µg/L)	2	70	90
≥ MCL	99 (0.38)	3 (0.01)	0 (0.00)
< MCL	368(1.42)	210(0.94)	33(1.21)
Total Detections	467(1.80)	213(0.96)	33(1.21)
Total Sampled	25993	22255	2718

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Table 54: Summary of Alachlor, Metolachlor, and Propachlor Ground Water Monitoring Data from the Pesticides in Ground Water Data Base			
Detection Information	Alachlor	Metolachlor	Propachlor
	Number of Wells (Percent of Wells)		
Number States with detections	25	20	5
Number of States with monitoring	35	29	11
Range of concentrations (µg/L)	trace to 3000	0.001 to 157	0.02 to 3.5

National Pesticide Survey (NPS)**:**

The EPA National Pesticide Survey (USEPA, 1990) was conducted to provide a statistical estimate of the frequency and concentration of pesticide contamination of drinking water wells in the United States. From April 1988 to February 1990, EPA collected water samples and well information from over 1300 community water systems and rural domestic drinking water wells. Based on these data, EPA estimated that alachlor contamination occurred at or above the detection limit in about 3,140 (0.03 percent) of rural domestic wells nationwide. The detection limit for alachlor was 0.5 µg/L which likely resulted in the lower frequency of detection reported for alachlor compared with other studies. Alachlor was not found in samples collected from community water supply wells. Also, degradates of alachlor were not analyzed in the NPS.

National Alachlor Well Water Survey (NAWWS**):**

From 1987 - 1990, at the request of the EPA, Monsanto conducted the National Alachlor Well Water Survey (NAWWS), a large-scale retrospective monitoring study patterned after EPA's National Pesticide Survey of drinking water wells. (MRID Nos. 41400001, 41400002, 41400003, 41400004) This study was statistically designed to estimate the proportion of rural domestic wells in alachlor use areas with detectable concentrations of alachlor (Holden et al., 1990, 1992). Monsanto also chose to include atrazine, cyanazine, metolachlor, and simazine as analytes in the NAWWS. The limit of detection for most chemicals (including alachlor) was approximately 0.03 µg/L. No degradates were analyzed in this study.

Wells selected for the NAWWS study were located in the rural portion of 89 counties, in 26 states where alachlor was used in 1986. Wells were selected based on county-level sales information and vulnerability estimates in counties where corn, soybeans or peanuts were grown. A total of 1430 private rural wells were sampled. Alachlor was estimated to have been used within a half-mile of 58.8 percent of the wells during the last five years. Hydrogeologic characteristics of the aquifers sampled

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were not directly measured; however, the probability that a well was installed in a confined (less vulnerable) or unconfined (more vulnerable) aquifer was estimated by Monsanto. Nearly one-third of the wells sampled were estimated to tap surficial, "vulnerable" aquifers. Over one-half of the wells were located within 300 feet of surface-water sources (e.g. streams or ponds).

Alachlor detections were reported in nearly one percent of the wells sampled in the NAWWS (Holden and Graham, 1992). Based on the monitoring results (summarized in Table 55), alachlor was estimated to occur in 0.78 percent (46,800 wells) of the six million private, rural domestic wells in the alachlor use area. Wells in the study area are estimated to supply drinking water to approximately 20 million people. Alachlor was estimated to occur at levels exceeding the MCL of 2 µg/L in about 0.02 percent of private rural drinking water wells in the alachlor use area, or about 1,200 wells.

Table 55: Estimated Percentage of Wells with Detections of Alachlor from the National Alachlor Well Water Survey (NAWWS).

Concentration (µg/L)	Percentage of wells with alachlor	estimated number of wells[1]	standard error (percent of wells)
>0.03	0.78	46,800	0.29
0.1	0.36	22,000	0.22
0.2	0.32	19,000	0.20
0.5	0.06	3,600	0.03
1.0	0.03	1,800	0.02
> 2.0	0.02	1,200	-

[1] estimated by EPA, based on total rural domestic water wells in the alachlor use area (6,000,000 wells).

USGS Ground Water Study in IOWA (1995)**:**

The USGS, University of Iowa Hygienic Laboratory, and the Iowa Department of Natural Resources have been involved in a joint program to monitor municipal wells in Iowa since 1982, known as the Iowa Ground Water Monitoring Program (IGWM). In the summer of 1995, the USGS sampled 106 municipal wells, representing the major aquifer systems in the state in order to determine the occurrence of selected herbicide compounds (Kolpin and Kalkhoff, 1996). All samples were analyzed for alachlor and alachlor ESA, with a reporting limit of 0.05 µg/L for all analytes.

Alachlor was detected in 7.5 percent of wells in the network, with a maximum of 0.63 µg/L. Alachlor ESA was the most frequently detected compound, found in 65.1 percent of wells, at a maximum concentration of 14.78 µg/L. Consistent with other studies, alachlor ESA was detected

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almost 9-times as frequently as parent alachlor. Factors found to influence the frequency of detection of both parent and degradates were: well depth, water age, dissolved oxygen content, and aquifer type. Both parent and degradates are found much more frequently in shallow wells (defined as ≤50 meters deep), in post-1953 age water, and under reducing conditions. Alluvial and bedrock/karst aquifers had the most frequent incidence of pesticide detections in this study.

Wisconsin DATCP Alachlor Study**:**

Following the reports of alachlor ESA in ground water in Ohio in 1993, Wisconsin's Department of Agriculture Trade and Consumer Protection (DATCP), with the assistance of Monsanto, began testing monitoring wells and private water supply wells for alachlor ESA in the summer of 1993. Results indicated that alachlor ESA was present in a large number of samples, and it was decided to include alachlor ESA in a Wisconsin survey of private wells most at risk. Wells were selected in an area of high alachlor use from wells that had previous detections of triazine herbicides or high concentrations of nitrate. The program was designed to indicate whether or not a problem existed with alachlor or alachlor ESA in wells most at risk. Alachlor was detected in 12 of the 293 samples (4 percent) at concentrations ranging from 0.21 - 6.91 µg/L. Alachlor ESA was detected in 206 of 293 samples (70 percent) at concentrations ranging from 1.09 - 26.7 µg/L. In part because of these results, the State of Wisconsin established an interim health advisory (20 ppb) and is considering proceeding to establish an enforcement standard for alachlor ESA.

State of Florida Monitoring Program**:**

Prior to the ban on the use of alachlor in the State of Florida, Monsanto conducted a ground-water monitoring study for alachlor in conjunction with the Florida Department of Agriculture and Consumer Services (FDACS). The main focus of this study was the monitoring of alachlor in open hole bedrock wells in Jackson County, in northern Florida. After confirmed detections of alachlor were reported in 13 of 100 wells, the sampling was expanded to include 310 wells in 10 counties.

Alachlor was detected in 189 samples, from 46 (15 percent) of 310 wells during sampling from July 1989 to May 1990. Reported concentrations ranged from trace levels to 135 µg/L in a well in Levy county. This high concentration is above the child one-day health advisory for the chemical, which is 100 ppb. Concentrations in that particular well above the 100 ppb level were still detected after 18 months. This pattern (persistent high concentrations of alachlor) was observed in many wells with lesser concentrations although still above the MCL. FDACS stated that although Jackson County is underlain by karst limestone, these conditions were not found throughout the 10 county area where alachlor was detected. The State of Florida does not consider the detections in this study to be the result of point-source contamination.

State of New York- Suffolk County**:**

From 1990 to 1992, the Suffolk County Department of Health Services (SCDHS) analyzed private wells near a plant nursery for alachlor residues. Alachlor was detected in 14 of the 63 wells,

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11 of which had at least one detection equal to or greater than the 2.0 ppb MCL. The highest concentration detected was 49 µg/L. Subsequent sampling of 92 wells near plant nurseries resulted in a single detection of alachlor at 0.6 µg/L.

The SCDHS did not find any evidence to suspect point source contamination. In their response to the 1996 draft, the registrant indicated that they suspect that point source contamination may have occurred. It is indicated that subsequent monitoring has shown that levels in most wells are dropping below the MCL.

State of North Carolina:

The University of North Carolina-Asheville Environmental Quality Institute (EQI) conducted a study from 1989 to 1992 to gather information on the spatial distribution of pesticides in rural water supply wells in eastern North Carolina (Maas et. al., 1995). Alachlor was one of eight chemicals investigated, with a method detection limit of 0.13 µg/L. Samples were collected from 171 sites, which corresponded to individual wells. Alachlor was detected at 8.8 percent of the 171 sites, with concentration that ranged from 0.23 to 68 µg/L. Five of the detections were above the 2.0 ppb MCL. Multiple samples were collected over approximately a year and a half. Results indicated that alachlor contamination was not a seasonal phenomenon, but persists over longer periods of time in eastern North Carolina. Two of three wells that were re-sampled maintained levels of alachlor above the MCL for over a year. The third had an initial detection at 0.3 µg/L, declined to below the detection limit a half year later, increasing again to above the MCL one year after the original sampling.

The EQI study concluded that the majority of detections of alachlor encountered in the study appeared to be the result of normal agricultural use. Only one of the wells was located near a pesticide mixing area (within 100 feet).

The study authors reported that alachlor detection was not significantly related to distance from pesticide mixing, storage and loading areas suggesting that the observed groundwater contamination was not a result of point sources. The authors also found that alachlor was detected in wells more frequently further from cropped fields, and that the compound was detected in areas that had received no application for at least several years. These data were interpreted as showing that the detected alachlor came from a great distance from the well or from applications in the distant past. The authors concluded that well water contamination was not a seasonal phenomenon but persists over time.

The Interagency Study of the Impact of Pesticide Use on Groundwater in North Carolina was conducted in 1991-1996 (Wade et. al., 1997). In phase I of this study 55 wells representing the state's major drinking water aquifers were sampled at least twice and analyzed for pesticides. No attempt was made to select these wells where pesticides were known to have been used. In phase II, 97 shallow monitoring wells were installed and sampled at least twice. Phase II wells were located in areas believed to represent the highest risk, and were adjacent to or down gradient from areas of

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pesticide application. When pesticides were detected in phase II wells additional sampling was done from nearby domestic supply wells. Forty-six domestic supply wells were sampled in this phase.

Alachlor was not detected in phase I or phase II wells. Alachlor was detected in two domestic supply wells near phase II wells that had other pesticides detected. One of the wells with alachlor was a "shallow bored well" located within an agricultural field and had been used to fill spray equipment. Two other domestic wells within 0.5 miles did not have detectable pesticides. The other well with alachlor detected was a "bored well of unknown depth" located 100 feet from corn field on an adjacent farm. Alachlor was detected in this well at two separate sampling events at 9.2 ppb and 5 ppb. Three other monitoring and domestic wells near this well did not have detectable alachlor.

Continued sampling following completion of the study by the North Carolina Department of Agriculture has not detected additional alachlor groundwater contamination. However, the alachlor degradation products, including alachlor ESA, have been detected in groundwater at concentrations ranging up to 22 ppb. (H. Wade, Personal communication, 1998)

c. Possible Concerns

Since the degradation of alachlor appears to be much slower in aquifers than in the soil root zone and since alachlor ESA is reported more frequently than alachlor in ground water, (Kolpin et al., 1996) concluded that the degradation of alachlor occurs prior to being transported to the aquifer. They theorize that if alachlor degradation occurred after reaching the aquifer, the frequency of detections of alachlor and alachlor ESA would be more similar. They also report that alachlor ESA appears to be persistent in shallow aquifers, because 90 percent of the wells having alachlor ESA concentrations exceeding 0.10 µg/L remained at that level during all subsequent samples (1-year time interval). If an MCL or cancer risk level is established for alachlor ESA at the same level as alachlor parent and because of the much higher percentages of wells having degradate detections, the concern for the population being exposed to levels of alachlor exceeding levels of concern is much greater than for the parent compound only.

Irrigation appears to increase the probability of contaminating ground water. The frequency of herbicide detection (35%) with irrigation within a radius of 3.2 km was greater than the frequency of herbicide detections (19%) without irrigation (Kolpin and Goolsby, 1995).

7. Surface Water Monitoring Data

The following studies provided surface water monitoring data that were used to develop the water resources and aquatic exposure assessments for alachlor.

a. Introduction

Alachlor can contaminate surface water at application via spray drift. Substantial fractions of applied alachlor could also be available for runoff for several weeks post-application. The relatively

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low soil/water partitioning of alachlor indicates that most of alachlor runoff will occur via dissolution in runoff water (as opposed to adsorption to eroding soil).

b. Surface Water Data

Acetochlor Registration Partnership Data for 1995-1996:

This study is the most extensive data on alachlor concentrations in finished surface drinking water available to the Agency. (MRID No. 44592401) Samples were collected at 179 different sites (drinking water utilities) in the following 12 states: Delaware, Illinois, Indiana, Iowa, Kansas, Maryland, Minnesota, Missouri, Nebraska, Ohio, Pennsylvania, and Wisconsin. Samples were collected approximately once every two weeks from April through early September. Two to three additional samples were collected at most sites, one to two in the Fall and one in the Winter. Unfiltered samples were analyzed for total alachlor.

A TWMC was estimated by the Agency for each monitoring site in the ARP. These sites were then ranked from highest to lowest. Based on the reanalysis of data covering 1995 and 1996, Table 56 provides maximum and 90th percentile (upper 10th percentile) concentrations (peak and annual TWMC).

Table 56: Summary of 1995 and 1996 Alachlor Monitoring by the ARP

Statistic	Calculation for a given site	Summary Across Sites	
		Maximum Value for any Site (µg/L)	Value Equaled/Exceeded on 10% of Sites (µg/L)
Peak Concentrations	Highest Value Observed 1995-1996, for any Site	4	0.63
Annual Time Weighted Mean	Weighted Mean for 1995-1996, for any Site (weight by time)	0.36	0.1

USGS 1989, 1994, and 1995 Midwestern Stream Reconnaissance Studies :

Since the data submitted by the Acetochlor Registration Partnership was for samples collected at set intervals once every two weeks, it is probable that the data are generally substantially lower than peak alachlor concentrations associated with post-application runoff events. Such peak alachlor concentrations are probably more closely represented by post-application data collected by the USGS in reconnaissance studies conducted on numerous Midwestern streams. The USGS (Goolsby and Thurman, 1991; Goolsby, 1995; Goolsby, 1996) conducted reconnaissance surveys of numerous Midwestern streams in 1989, 1994, and 1995 to determine post-application, and in some cases pre-application and Fall concentrations of various herbicides including alachlor. Pre-application samples

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collected in 1989 and 1994 and Fall samples collected in 1989 had alachlor concentrations much less than 1 µg/L, and generally below the detection limit of 0.05 µg/L.

Since post-application samples were generally collected during the first major runoff event after application, the concentrations in those samples should more closely represent peak alachlor concentrations. The maximum post-application alachlor concentrations for 1989, 1994, and 1995 were 51.3, 10.1, and 19.9 µg/L, respectively. The 90th percentile (upper 10th percentile) post-application alachlor concentrations for 1989, 1994, and 1995 were 12, 6.5, and 2.0 µg/L, respectively. The substantially lower concentrations in 1994/1995 than in 1989 may reflect reported decreases in alachlor use.

In 1989, a pre-application sample, a post-application sample, and a Fall sample were collected from 48 of the sites. The maximum and 90th percentile (upper 10th percentile) annual TWMCs were 11.6 and 3.4 µg/L, respectively. Annual TWMCs based on 4 quarterly samples (as specified to determine compliance with the Safe Drinking Water Act) probably would have been somewhat lower (but not more than 25% lower).

In 1994 and 1995, samples were analyzed for alachlor ESA as well as alachlor. Alachlor ESA concentrations are much higher than alachlor. This also appears to be true in early spring even before alachlor application.

USGS 1991-1992 Study of 8 River Locations Mississippi River Basin:

The USGS (Coupe et. al., 1995) sampled 8 locations on rivers within the Mississippi Basin from April 1991 through March-September 1992 (depending on location) and analyzed the samples for numerous insecticides and herbicides including alachlor. Samples were collected twice per week from May 6 to July 15 1991, once per every two weeks from November 1991 to February 1992, and once per week at other times. The samples were filtered (0.7 µ) and analyzed for dissolved alachlor. The maximum peak and 1991 annual time weighted mean concentrations over the 8 sites were 3.6 µg/L and 0.43 µg/L, respectively (both in the Platte River at Louisville, NE).

For three sites (with the highest 1991 alachlor concentrations) pre-application concentrations of less than 0.1 ppb in early spring rapidly increased to several ppb during post-application runoff events in May and June, then rapidly declined to background levels by mid-late summer. The White River at the Hazelton, IN site was the only one of those three sites at which sampling was performed far enough into 1992 to give a second set of alachlor peaks (1992) in addition to the 1991 set. Alachlor concentrations in 1992 were lower than in 1991 at that site.

USGS 1992 Midwestern Reservoir Reconnaissance Study:

The USGS (Goolsby et. al., 1993) sampled each of 76 Midwestern reservoirs four times during 1992 and analyzed them for various herbicide degradates and herbicides including alachlor and alachlor ESA. Alachlor was detected above a detection limit of 0.05 µg/L in 36%, 48%, 26% and

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16% of the samples collected in late April to mid-May, late June to early July, late August to early September and late October to early November, respectively. Alachlor ESA was detected more frequently (72, 79, 77, and 64%) and at higher concentrations than alachlor. The highest alachlor and alachlor ESA concentrations were for samples collected in June or July of 1992. The maximum and 95th percentile alachlor concentrations for June-July over the 76 reservoirs appear to be between 5 and 10 µg/L. The maximum and 95th percentile alachlor ESA concentrations for June-July appear to be between 10 and 20 µg/L. After June-July, alachlor concentrations appear to decrease more substantially than alachlor ESA concentrations.

Missouri River Public Water Supplies Association 1990 Study:

The Missouri River Public Water Supplies Association (MRPWSA) sampled the raw water of 8 surface water supplies within the Missouri River Basin. (Keck 1991) Samples were collected daily May-July 1990. The maximum peak and May-July mean concentrations were 14.9 and 0.47 ug/L, respectively (both at Kansas City, MO). However, the second highest peak and May-July mean concentrations were 2.9 and 0.29 µg/L, respectively.

State of Illinois 1986-1988 Study:

The State of Illinois (Moyer and Cross, 1990) collected 4-7 samples per year from each of 30 flowing surface water sites during 1986-1988 and analyzed the unfiltered samples for numerous pesticides including alachlor. The maximum alachlor peaks over the 30 sites were 5.6, 8.5, and 18 ug/L for 1986, 1987, and 1988, respectively. The maximum alachlor annual TWMCs over the 30 sites were 0.65, 0.76, and 2.0 µg/L for 1986, 1987, and 1988, respectively. The maximum three year TWMC over the 30 sites was 0.81 µg/L.

The State of Illinois (Taylor, 1994) recently summarized pesticide data for surface water samples collected from 34 stations from October 1, 1985, through February 15, 1994. Thirty of the stations were the same ones discussed in the Moyer and Cross 1990 document, but the Taylor summary represents a update to February 1992. A total of 1278 samples were analyzed for alachlor at a detection limit of 0.05 µg/L. Apparently assuming non-detects were equal to the detection limit, Illinois reported maximum, 95th percentile, 90th percentile, and mean total (unfiltered sample) alachlor concentrations over the 34 sites and 9 years of 18 µg/L, 0.90 µg/L, 0.32 µg/L, and 0.065 µg/L respectively.

Monsanto 1986 Finished Surface Water Supply Study**:**

In 1986, Monsanto sampled 30 finished surface water supply systems approximately weekly from April through August or September and analyzed the samples for 5 herbicides including principally alachlor. (MRID No. 40265901) The community water systems sampled represented 4 combinations of Lasso ®(alachlor) use and average soil susceptibility to runoff (high use/high runoff, low use/high runoff, high use/low runoff, low use/low runoff). The susceptibility to runoff was estimated from the weighted average of hydrological classifications (A, B, C, D) of soils within the

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drainage area. Of the 30 community water systems sampled, 13, 2, and 15 were classified as using sources which drain areas with high, intermediate, and low susceptibility to runoff, respectively. The maximum and 90th percentile (upper 10th percentile) peak alachlor concentrations over the 30 systems were 9.5 and approximately 6.0 µg/L, respectively. The maximum and 90th percentile (upper 10th percentile) alachlor annual TWMCs over the 30 systems were 1.1 and approximately 0.73 µg/L respectively.

Monsanto 1985 Finished Surface Water Supply Study:

In 1985, Monsanto had sampled 24 finished surface water supply systems different from the ones sampled in 1986. (MRID No. 00158911) They also sampled raw water. Samples were collected approximately weekly from April 1995 through August or September 1995 and analyzed alachlor parent only. The community water systems sampled represented areas of high, medium and low alachlor use.

The maximum and 90th percentile (upper 10th percentile) peak alachlor concentrations in finished water over the 30 systems were 12 and approximately 4.2 ug/L, respectively. The maximum and 90th percentile (upper 10th percentile) alachlor annual TWMCs over the 30 systems were 1.5 and approximately 0.62 µg/L, respectively.

Alachlor has a low soil/water partitioning coefficient. Therefore, the primary treatment processes employed by most surface water drinking water supply systems are not expected to be effective in removing it.

USGS 1984-1985 Study on the Cedar River Basin, IA:

The USGS (Squillace and Engberg, 1988) collected samples at 6 locations within the Cedar River Basin (5 along the Cedar River, and one along the Shell Rock River). Samples were collected approximately monthly from May 1984 through September 1985 at the Floyd and Cedar Falls sampling locations, and from May 1984 through November 1985 at the other 4 locations.

Two sets of samples were collected. One set was centrifuged for the determination of the dissolved concentrations of herbicides. "Total recoverable" herbicide concentrations consisting of both extractable adsorbed and dissolved herbicides were determined in the sample set not centrifuged.

The maximum peak and annual TWMC concentrations over the 12 site-years were 23 and 3.3 µg/L respectively. The next highest peak and annual TWMCs were 21 and 1.9 µg/L, respectively. The maximum two year TWMC over the 6 sites was 1.7 µg/L.

Baker 1982-1985 Study on Ohio Tributaries to Lake Erie:

Baker collected samples at various times including several times per week from mid-April to mid-August from 8 Ohio tributaries to Lake Erie during 1982-1985 and analyzed them for many

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pesticides including alachlor. (MRID No. 41065205) Alachlor Peak and 4/15-8/15 TWMCs concentrations were reported.

The maximum and 90th percentile (upper 10th percentile) peak alachlor concentrations over the 30 site-years are 76 and 32 µg/L, respectively. The maximum and 90th percentile (upper 10th percentile) 4/15-8/15 TWMCs over the 24 site-years are 3.3 and 2.7 µg/L, respectively.

Baker 1983-1987 Lake Erie Basin Case Study

The Water Quality Laboratory at Heidelberg College, Ohio (Baker et. al., 1991) sampled seven Ohio streams and rivers of the Lake Erie Basin for a number commonly used herbicides and insecticides, including alachlor. Samples were collected and analyzed at frequent intervals (daily) during the pesticide use period mid-April to mid-August, especially during runoff producing storm events, and twice per month during the remainder of each year's cycle. Samples were collected at existing USGS Gaging Stations. Alachlor was detected above the level of detection (0.1 ug) at all sampling stations in all years during the study. Alachlor peak and time weighed mean concentrations (TWMC) were reported.

The maximum peak concentration over the five-year study of 91.47 ug/L (n=410) occurred in the smallest basin, Lost Creek. The maximum TWMC over the study period of 1.74 ug/L (n=534) occurred in Honey Creek basin, the third smallest basin, but the second highest in agriculture intensity.

Kirby-Smith 1987-1991 Study on the South River Estuary North Carolina:

In a study of effects of pesticides on marine and estuarine aquatic biota from farmland runoff, alachlor was monitored in several headwater streams of the South River in the Pamlico Sound, North Carolina. (MRID No. 441095503) Data collected during the conduct of this study provided valuable information on the concentrations of alachlor in estuarine waters from known pesticide applications.

Dissolved alachlor concentrations increased from background (residual) levels of approximately 0.019 µg/L to a maximum of 48 µg/L following pesticide applications and significant rainfall. Alachlor concentrations rapidly decreased to less than 1 µg/L following the termination of pesticide applications and after several runoff producing rain events had occurred. Eventually, concentrations returned to background level, although specific timing could not be determined from the submitted study.

c. Possible Concerns over Alachlor and Alachlor ESA in Surface Water

According to available data, the potential risks to fish and aquatic invertebrates posed by alachlor in surface water are low. Potential risks to aquatic plants posed by alachlor are currently

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being assessed by the Agency. The potential risks of alachlor ESA to fish, aquatic invertebrates and aquatic plants has not been well characterized.

In analyzing surface water concentration data, the Agency considers the frequency that annual averages exceed the drinking water MCL (for alachlor, 2 µg/L), and the frequency that peak concentrations exceed the MCL by a factor of 4 or more: Compliance with the Safe Drinking Water Act is based on comparison of the MCL to an arithmetic average of four quarterly measurements. Consideration of 4 times the MCL (4MCL) is of interest because if one or more of four measurements exceeds 4MCL, then the average of the measurements exceeds the MCL.

Originally, most of the Agency's concern over alachlor in drinking water was due to individual alachlor measurements frequently exceeding 4 times the MCL. The frequency of exceedances of 4MCL was greatest in the 1989 USGS reconnaissance study in which samples were collected during major runoff events following application, and in the study by Baker (1988), in which samples were apparently collected at least 3 times a week and not time composited. They were less frequent in the 1994 and 1995 USGS reconnaissance studies (which were also designed to capture peak concentrations) possibly due to decreases in alachlor use.

With the exception of 2 site-years in the 1984-1985 USGS study of the Cedar River Basin and one site-year in the 1986-1988 Illinois EPA study, none of the annual TWMCs for alachlor exceeded the MCL of 2 µg/L. This includes the 1985-1986 Monsanto studies of drinking water supplies and the recent 1995 Acetochlor Registration Partnership study of 175 sites over 12 states. In that study, the maximum annual TWMC was 0.4 µg/L. Although the study used set sampling intervals that may often miss peak concentrations associated with runoff events, the once every two weeks sampling from April through September and the Fall and Winter samples (a total of 14/site) is much more than the 4 quarterly samples required under the SDWA. Again, the relatively low alachlor concentrations compared to some earlier studies may reflect substantial decreases in alachlor use.

8. Water Resource Assessment

a. Ground Water Assessment

Alachlor exhibits the properties associated with chemicals that are found in ground water. The chemical has a high solubility and mobility in soils. Once the chemical reaches deeper soil layers with lower organic matter content and lower microbial populations, it will persist. An independent study conducted for EPA indicates that alachlor half-lives at different depths in a sandy loam and a silt loam soil increased to about 250 to 600 days at a depth of 5 feet (Lavy et al., 1993). Alachlor has been found to leach in the field at soil depths of up to 36- to 48-inches (the deepest layer sampled). Considering the nature of the chemical (i.e., moderately persistent and very mobile in many soils), there is a strong possibility of movement to ground water, especially in vulnerable areas. This has been confirmed by a substantial number of detections reported in the "Pesticides in Ground Water Database," and in the National Alachlor Well Water Survey conducted by the registrant, from which

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EPA determined that alachlor residues have had a significant impact on ground-water quality throughout the use area.

Several sources of information on monitoring/detections of alachlor and alachlor metabolites in ground water are reviewed in this document. That information confirms that alachlor and alachlor degradates will move into ground water. These monitoring data are summarized in Table 57.

Table 57: Summary of Wells with Detections of Alachlor (Parent).

Study	Well type	Number of Wells (%)			
		Sampled	Alachlor Detected	Concentration <MCL	Concentration ≥MCL
USGS (1991-1994)	drinking	303	10 (3.3%)	9 (3.0%)	1 (0.3%)
ARP-GWMP	monitoring	173	27 (15.6%)	25 (14.5%)	2 (1.2%)
PGWDB	mixed, most drinking	25933	467 (1.8%)	368 (1.4%)	99 (0.4%)
NPS	drinking	1300	1 (<0.1%)	0 (0%)	1 (<0.1%)
NAWWS	drinking	1430	28 (2.0%)	26 (1.8%)	2 (0.1%)
Florida	drinking	310	46 (15%)		
North Carolina	drinking	171	15 (8.8%)	10 (5.9%)	5 (2.9%)

PGWDB = Pesticides in Ground Water Database,
NPS = National Pesticide Survey;
NAWWS = National Alachlor Water Well Survey,
USGS = U.S. Geological Survey Midcontinent Study,
ARP-GWMP = Acetochlor Registration Partnership Ground-Water Monitoring Program.

Persistence of Alachlor in Ground Water:

Ground-water monitoring studies have shown that alachlor contamination is common in use areas. Recent data suggests that alachlor can persist in the subsurface for years and that ground water contamination can be expected long after use has stopped. Maas et. al. (1995) found evidence that low concentrations of alachlor in drinking water wells persisted over long periods, and contamination can move off-site via transport in ground water. In Florida, significant alachlor contamination still occurs years after all alachlor use was canceled in February 1991. Sixteen wells found to have alachlor at concentrations greater than 2.0 ppb prior to the ban have been sampled yearly since 1991. The mean alachlor concentrations in these wells have not changed over time (Simons and Fisher, 1997; R.E. Fisher, personal communication, 1998).

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Alachlor Exposure from Drinking Ground Water:

Results of several studies designed to assess the occurrence of alachlor in drinking water wells makes it possible to roughly estimate the number of people exposed to the compound by drinking contaminated ground water. Based on U.S. Census data the National Ground Water Association (NGWA) estimates that 53% of the American public relies on ground water for their drinking water. This includes about 282,000 public supply wells and approximately 15.1 million households using private wells. While there is little evidence of contamination in public supply wells a significant number of private house hold wells will be contaminated. It is possible that a large number of people in the U.S. can expect to be exposed to alachlor in their drinking water. Hundreds of thousands of people living in households supplied by private wells will have alachlor and/or alachlor degradates in their drinking water as a result of labeled use of the compound. Large numbers of Americans can expect to have alachlor concentrations above the current Maximum Contamination Level (MCL) of 2.0 ppb in their drinking water as a result of labeled use of the compound. MCLs are established for public drinking water supplies and are not enforceable for private water supplies. A one-time detection above the MCL does not necessarily constitute a violation in public water systems or trigger requirements for mitigation. Such actions are based on average annual concentrations, which is a time-weighted average of all detections, including the exceedance value, for the entire year. Since drinking water violations reported by EPA's Office of Water are for public water supplies and are based on average annual concentrations, the frequency of such exceedances is likely to be less than the frequency of individual detections above the MCL reported here.

The National Alachlor Well Water Survey (MRID No. 41400001) was designed primarily to assess the occurrence of alachlor in rural wells in high alachlor use areas. The study estimated 6 million wells, serving 20 million households, occurred in the alachlor use areas, based on Monsanto's 1986 alachlor sales data. The majority of the wells were near agricultural areas, and 40% were within 300 feet of fields where alachlor target crops were grown. Alachlor was detected in 2.0 % (standard error of 0.25) of sampled wells at measurable concentrations. The survey found 0.18 % (standard error of 0.12) of the sampled wells had alachlor concentrations above 2.0 ppb. No significant differences were seen in wells on farm and non-farm properties. Exposure estimates by Monsanto (assuming a nonlinear distribution for detections, which is reasonable for pollutant data with asymmetric distributions and a relatively low occurrence of events) suggest that more than 100,000 people in the study area had detectable levels of alachlor in their water supply, 35,000 would be exposed to concentrations of $\geq$ 0.2 ppb, and more then 3,000 people would have alachlor concentrations above 2.0 ppb. Weaknesses in the survey include: (a) the NAWWS use area underestimated the alachlor use area defined by Resources For the Future, (b) the study was conducted in a relatively dry year (1988) which would have minimized the potential for leaching, and (c) the estimates do not include small community wells that serve more than 15 households or more than 25 people, which may underestimate the total number of people exposed to alachlor in drinking water (Rappaport, ICF, 1991).

Two studies in North Carolina examined levels of alachlor in drinking water wells (Maas et. al., 1995; Wade et. al., 1997). NGWA estimates that North Carolina has 912,000 household wells

and 20,000 public and community supply wells. In eastern North Carolina, 8.8% of drinking water wells sampled between 1989 and 1992 contained measurable alachlor concentrations and 2.9 % were above the current MCL of 2.0 ppb (Maas et. al. 1995). This study also found that contamination is not always confined to wells in or close to fields to which alachlor was applied. Results of the eastern North Carolina study show a higher percentage of wells with alachlor contamination than that found in the NAWWS study. This study, conducted primarily within the coastal plain, may reflect potential exposure in an area in which the ground water is highly vulnerable to contamination from pesticides (as delineated by Kellog et. al., 1992).

Sampling in Florida found that 9.4 % of drinking water wells were contaminated with alachlor and 5.5 % had alachlor concentrations above 2.0 ppb (Simons and Fisher, 1997). Most of the well contamination at high levels may be a result of mixing and transfer operations or other point sources (R.E. Fisher, personal communication, 1998), and the owners have been provided with water treatment systems or an alternate supply. In Florida, about 794,500 households are served by private wells; 16,000 are on public and community supply wells. Concerns about such exposure resulted in a ban of the use of alachlor in Florida. Since the 1991 ban, average alachlor concentrations in wells initially found to have levels above 2.0 ppb have not changed, and individual treatment systems are still required to provide safe drinking water to these households. More than five years after alachlor use was banned, these wells still show contamination.

Despite the large amount of uncertainty associated with exposure estimates, they provide an indication of the magnitude of people who can expect to have alachlor in their drinking water. Tens of millions of Americans rely on domestic wells for their drinking water and the majority of these are in rural areas. Even if a few wells in any study show significant levels of alachlor contamination, or only a few percent of wells are contaminated, this is suggestive of a large number of people being exposed.

There are additional concerns related to contamination of ground water used for drinking water supply. Alachlor appears to be persistent under aquifer biological and geochemical conditions. This means that alachlor can appear in ground water years after use and can migrate with ground water away from use areas. Alachlor contamination has resulted in loss of untreated ground water as a source of drinking water in Florida and other states. Years after alachlor was banned, the resource is still degraded.

b. Surface Water Assessment

Alachlor can contaminate surface water at application via spray drift. Substantial fractions of applied alachlor could be available for runoff for several weeks post-application. The relatively low soil/water partitioning of alachlor indicates that most runoff will occur via dissolution in runoff water (as opposed to adsorption to eroding soil). The persistence of alachlor in surface waters with high microbiological activities should be somewhat limited by its susceptibility to biodegradation. Persistence will also be limited in waters with short hydrological residence times by flow out of the system. However, its resistance to abiotic hydrolysis and direct aqueous photolysis, coupled with its

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low volatilization potential should make alachlor more persistent in waters with low microbiological activities and long hydrological residence times.

Alachlor may also enter freshwater, estuaries, and coastal marine water in areas of interaction with ground water. Presence in fresh surface water of alachlor ESA before application suggests that there has been input to rivers and streams from ground water.

There is an extensive body of information on levels of alachlor and alachlor degradates in surface water. Table 58 summarizes the major surface water studies:

Table 58: Summary of Major Surface Water Sources with Alachlor Detections by Study.

Study	Number of Sites	Maximum Peak (ug/L)	Maximum TWMC[1] (ug/L)
ARP - 1995-1996	175-179	4.0	0.36
USGS - Midwestern Stream Recon. 1989	48	51.3	11.6
USGS Mississippi River Basin Study 1991-1992	8	3.6	0.43
State of Illinois 1986-1988	30	18	0.81
Monsanto Finished Surface Water Study 1986	30	9.5	1.1
Monsanto Finished Surface Water Study 1985	30	12	1.5
USGS Cedar River Basin Study 1984	6	23	1.7
Ohio Tributaries to Lake Erie 1982-1985	8	76	3.3[2]
Lake Erie Basin Case Study 1983-1987	7	91.47	1.74

[1]TWMC: Time weighted mean concentrations, annual unless otherwise noted.
[2] Time weighted mean concentration calculated over a 4 month period of the study; April 15 to August 15

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The monitoring results primarily reflect residue detections in lotic waters, such as rivers and streams, or large lentic bodies of water, such as man-made reservoirs and lakes. Therefore the levels observed may have been affected by dilution, degradation, or adsorption to soil or sediment, relative to edge-of-field levels (values occurring close to sites of application immediately following runoff events). Edge-of-field levels may be better represented by modeling. (However, at this time only screening level modeling has been undertaken.) Also, the model scenarios represent small, static bodies of water. Reported peak concentrations are affected systematically by the intensity of sampling: with less frequent sampling there is higher probability of levels in the environment that substantially exceed the highest values detected.

Of the surface water monitoring data available, the USGS Midwestern Stream Reconnaissance Studies (1989, 1994, 1995) give what are probably the values closest to the most extreme edge-of-field levels. In that study peak exposures were 51.3 µg/L for 1989, 10.1 µg/L for 1994, and 19.9 µg/L for 1995. The 90th percentile values (upper 10th percentile values) were 12, 6.5, and 2.0 µg/L for the same years.

c. Alachlor Degradates in Water

The major degradates of alachlor are alachlor DM-oxanilic acid, alachlor oxanilic acid, alachlor sulfinylacetic acid, and alachlor ethane sulfonic acid (alachlor ESA). While uncertainty exists concerning the environmental or health effects of these breakdown products, available data suggest that the degradates are more persistent and mobile than parent alachlor. Limited monitoring data suggest that alachlor ESA is often found in ground water wells 5-10 times more frequently then the parent compound. Alachlor ESA has been detected frequently in Midwestern reservoirs and streams at concentrations much greater than alachlor. High concentrations of alachlor ESA in flowing water even in early spring, before alachlor application, may reflect discharges from ground water. The major degradates may be available for runoff longer than alachlor, and will probably be transported primarily by dissolution in runoff water. The degradates will probably readily partition into the water column and in addition to alachlor ESA, other degradates may also be more persistent in surface water than alachlor.

9. Aquatic Exposure Assessment

Preliminary aquatic EECs are estimated using GENEEC (GENeric Expected Environmental Concentration), a screening model that provides an upper-bound estimate of EECs on a high exposure site. The GENEEC program uses basic environmental fate values (adsorption to soil, degradation in soil before runoff and in water) and pesticide label information (rates, intervals, incorporation, method of application) to estimate the EECs in a one-hectare, two-meter deep pond following the treatment of a 10 hectare field. The runoff event occurs two days after the last application. The model accounts for direct deposition of spray drift onto the water body (assuming 5% of the application rate for aerial spray applications and 1% for ground spray applications). Some of the input parameters used for the alachlor GENEEC runs are listed in Table 59.

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Table 59: Environmental Fate Parameters used to Predict Alachlor EECs	
Parameter	Value
water solubility (ppm)	242 ppm
Koc	190
aerobic soil metabolism, t1/2	21 days[1]
hydrolysis t1/2, pH 7	Stable
aerobic aquatic metabolism, t1/2	175 days
aqueous photolysis t1/2	80 days

[1]The aerobic soil metabolism half-lives in three studies was 6-21 days.

GENEEC modeling was performed for a range of use scenarios based on combinations of application rate (1-6 lb ai/acre) that were on the label at the time the modeling was performed. Ground spray and granular applications were evaluated along with the effects of incorporation. In addition to scenarios involving a single application, a scenario was evaluated with two 2 applications of 2 lb ai/acre by ground spray without incorporation, separated by 30 days. On June 30, 1998, new labels were accepted by the Agency in which the maximum single application rate is 4 lb ai/acre. Thus, the 6 lb ai/acre rates were eliminated from this discussion.

Peak EECs (representing concentration immediately following runoff) ranged from 33 ppb for 1 lb ai/A to 133 ppb for 4 lb ai/A. The 56-day average EECs ranged from ranged from 27.4 ppb to 110 ppb for the same range of application rates.

Table 60: Alachlor Screening Level Aquatic EECs Generated by GENEEC				
Application Rate/Method/Incorporation	EEC Estimates Over Time (ppb)			
	Peak	4 Days	21 Days	56 Days
1.0lb Granular/Ground/none	33	32.7	30.7	27.4
2.0lb Granular/Ground/none	66.3	65.5	61.5	58.9
4.0lb Granular/Ground/none	133	131	123	110
1.25lb ai/groundspray/none	39	38	36	32
2.5lb ai/groundspray/none	78	77	72	65
3.0 lb ai/groundspray/none	94	93	87	78

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Table 60: Alachlor Screening Level Aquatic EECs Generated by GENEEC				
Application Rate/Method/Incorporation	EEC Estimates Over Time (ppb)			
	Peak	4 Days	21 Days	56 Days
4.0lb ai/groundspray/none	125	124	116	104
4.0 lb ai/groundspray/2.0 inch incorporation	64	63	59	53
2.0 lb ai/A twice groundspray/no incorp./30 day interval	92	91	85	76

For comparison, of the surface water monitoring data available, the USGS Midwestern Stream Reconnaissance Studies (1989, 1994, 1995) give what are probably the closest values to peak exposures occurring close to application sites soon after application. Peak exposures were 51.3 µg/L for 1989, 10.1 µg/L for 1994, and 19.9 µg/L for 1995. The 90th percentiles (upper 10th percentiles) were 12, 6.5, and 2.0 µg/L for the same years.

The Agency has reviewed an extensive body of information on levels of alachlor and alachlor degradates in surface water. This database for alachlor is substantially greater than that available for most pesticides. These monitoring results primarily reflect residue detections in lotic waters such as rivers and streams or large lentic bodies of water such as man-made reservoirs and lakes. As such the data are good indications of what residue levels might be expected after residues have traveled farther down the watershed. These residue detections are influenced by a number of factors including dilution by the respective waterbody, time of monitoring, position of monitoring stations, and the number of measurement samples recorded over time (when averaging sample detection levels). Thus, this information should be used as an indication of levels which might be expected after dilution, organic degradation, and soil or sediment adsorption factors have acted on the chemical for the period of time between application and actual sampling at respective monitoring stations. In many cases, peak concentrations of alachlor occur during early to late spring months when rainfall events lead to higher than average runoff. Simple averages of measured concentrations are biased towards representing those time periods with more samples, a bias that can be eliminated by using TWMCs.

An additional limitation of the monitoring information is the likelihood that some actual environmental concentrations will exceed the highest levels detected. The chance that a peak concentration will not be detected is expected to differ among monitoring studies, depending on the frequency of sampling and on the variability of environmental concentrations.

Tables 61 and 62 summarize two studies, one conducted by the US Geological Survey in 1991 and one conducted by the State of Illinois in 1990.

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Table 61: USGS Mississippi River Basin Survey, 1991-1992[1]			
Location Sampled (24 Samples per location)	Alachlor Concentration (µg/L)		
	Peak	Arithmetic average	Annual TWMC
White River, Hazelton, In.	3.2	0.3	0.22
Ohio River, Grain Chain, Il.	0.40	0.08	0.07
Miss. River, near Clinton, IA.	0.85	0.16	0.10
Illinois River, Valley City, Il	3.00	0.40	0.22
Platte River, Louisville, NE	3.60	0.43	0.22
Missouri River, Hermann, Mo.	0.92	0.19	0.12
Miss. River, near Thebes, Il.	0.86	0.27	0.23
Miss. River, Baton Rouge, LA.	0.46	0.12	0.09

[1]Based on bi-weekly samples May to August and weekly samples Sept. to Dec. 1 (Coupe et. al., 1995).

Table 62: Illinois Surface Water Survey, 1986-1988[1]		
Site Type	Alachlor Concentration as a Range (over sites and years) (ug/L)	
	Range of Peak values	Range of annual TWMC
Illinois Rivers (21 Sites-18 Rivers)	0.02- 8.5	0.02-0.65
Illinois Creeks (9 Creeks)	0.02-18.0	0.02-2.0

[1] Based on samples from 30 sites representing different streams and rivers, 4-7 samples per yr at each site (Moyer and Cross, 1990).

In addition to surface water data reviewed by the Agency, the following data (see Table 63) is reported by the Chesapeake Bay Fall Line Toxics Monitoring Program, representing the period from March 1992 to February 1993. Monitoring data is based on one station per river. This data has not been reviewed by the Agency. At this time it is viewed as supplementary information that tends to confirm concerns for adverse effects on aquatic organisms. Also, the study represents an East Coast tributary and thus provides a wider geographical scope for the monitoring data.

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Table 63: Summary of Chesapeake Bay Fall Line Toxics Monitoring Program for Alachlor Detections in Major Streams.		
Location	Range detected µg/L	Mean µg/L
Susquehanna River	<2.05-23.1	4.4
Potomac River	2.5-20.9	4.1
James River	7.5-20.2	2.9

10. Comparative Assessment with Other Acetanilides

a. Environmental Fate Characteristics

Alachlor, acetochlor and metolachlor are moderately persistent while propachlor appears to be the least persistent of all the acetanilides. However, the available aerobic soil metabolism values ($t_{½}$ and DT_{50}) for the four chemicals are within the same order of magnitude. All of the compounds are highly mobile.

An inspection of the physico-chemical characteristics of these chemicals reveals that alachlor has the second lowest molecular weight. Alachlor has a high solubility in water, although it is lower than the solubility of acetochlor and metolachlor. All the compounds have relatively low octanol/water partition coefficients, low vapor pressures, low calculated Henry's Law constants, and relatively low bioaccumulation factors.

Further investigation of the environmental fate characteristics reveals that all four chemicals are relatively stable to hydrolysis and photolysis in water. Three of the compounds are stable to photolysis on soil while metolachlor has a half-life of 8 days. In general, it appears that the important routes of dissipation for these compounds are aerobic soil metabolism and leaching. The aerobic soil metabolism 50% dissipation rates range from 2.7 days for propachlor, to 2-3 weeks for alachlor, and 67 days for metolachlor. The available studies indicate that anaerobic soil metabolism is not an important route of degradation for the acetanilides.

The half-lives observed in the field are of the same order of magnitude of the half-lives of aerobic soil metabolism studies in all cases. Results of the field studies confirm aerobic soil metabolism as an important route of dissipation for the four compounds.

b. Ecotoxicity

The comparative analysis of the ecotoxicity data for propachlor, alachlor, acetochlor, and metolachlor is based on data taken from the OPP/EFED Pesticide Ecotoxicity Data Base-1997. Only

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those studies classified as Core data were used in the analysis. Category terminology was taken directly from Brooks, et al. (1973).

Table 64 summarizes the environmental fate characteristics of the four acetanilides. Tables 65 through 71 show the ecological toxicity data available for birds, mammals, freshwater fish, estuarine fish, freshwater aquatic invertebrates, and estuarine invertebrates. The analysis suggests that this group of acetanilides are similar in toxicity. Propachlor appears to be more toxic to fish and aquatic invertebrates while acetochlor is more toxic to birds. However, no clear differences are evident.

Avian Species

On an acute oral basis, the toxicity data suggest that acetochlor is the most toxic of the four herbicides (49 mg/kg), followed in order by propachlor, alachlor and metolachlor. The avian subacute dietary data suggest that acetochlor is slightly more toxic (4171 ppm) than the other three herbicides. In general, both the acute and subacute avian toxicity data indicate that all four herbicides are practically non-toxic to slightly toxic to avian species on both an acute and subacute basis. These data suggest a low risk to most avian species from either acute or subacute exposure from the use of these four herbicides.

Mammalian Species

No mammalian toxicity data are available for alachlor. Available toxicity data suggest that propachlor is practically nontoxic while acetochlor and metolachlor are moderately toxic to mammalian species.

Fish Species

The 96-hour LC_{50} values generally indicate that propachlor is highly toxic while alachlor, acetochlor and metolachlor are moderately toxic to freshwater fish species. Available toxicity data for alachlor, acetochlor and metolachlor suggest that these herbicides are only moderately toxic to estuarine fish species.

Aquatic Invertebrates

The freshwater aquatic invertebrate 48-hour LC_{50}/EC_{50} data suggest that propachlor is the most toxic (0.79 ppm) of the four herbicides, ranging from moderately to highly toxic to freshwater invertebrates. The 48-hour LC_{50} values generally indicate that alachlor, acetochlor and metolachlor are moderately to slightly toxic to freshwater invertebrate species. Available toxicity data for alachlor, acetochlor and metolachlor indicate that these herbicides are only moderately toxic to estuarine invertebrate species.

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c. Comparative Assessment Tables for the Acetanilides Alachlor, Acetochlor, Metolachlor, and Propachlor

The following Tables provide a comparison of environmental fate and ecological toxicity data for the acetanilides alachlor, acetochlor, metolachlor, and propachlor.

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Table 64: Comparison of the Environmental Fate Characteristics of Alachlor, Acetochlor, Metolachlor, and Propachlor:

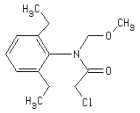
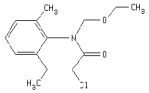
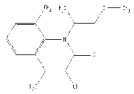
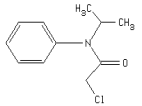
Characteristic	Alachlor	Acetochlor	Metolachlor	Propachlor
Chemical Structure				
Empirical Formula	$C_{14}H_{20}NO_2Cl$	$C_{14}H_{20}NO_2Cl$	$C_{15}H_{22}NO_2Cl$	$C_{11}H_{14}NOCl$
Molecular Weight	269.80	269.80	283.80	211.69
Vapor Pressure (mm Hg)	$2.2x10^{-5}$	$4.40x10^{-5}$	$1.30x10^{-5}$	$7.90x10^{-5}$
Log K_{OW}	2.64	3.0		2.30
Henry's Constant (atm m^3/mol)	$3.2x10^{-8}$	$7.0x10^{-8}$	$9.16x10^{-9}$	$3.59x10^{-8}$
Solubility in water (ppm)	240	223	530	613
Hydrolysis	Stable at pH 3.0, 6.0, and 9.0	Stable at pH 5.0, 7.0, 9.0	Stable at pH 5.0, 7.0, 9.0	Stable at pH 5.0, 7.0, 9.0
Photolysis in Water	Not expected to be an important route of degradation, based on UV absorption spectrum	Stable	70 days	Stable
Photolysis on soil	Not expected to be an important route of degradation, based on UV absorption spectrum	Stable	8 days	Not an important route of degradation
Aerobic Soil Metabolism	2-3 weeks in three soil types	8-14 days one study reports 110 days	67 days	2.7 days

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Table 64: Comparison of the Environmental Fate Characteristics of Alachlor, Acetochlor, Metolachlor, and Propachlor:

Characteristic	Alachlor	Acetochlor	Metolachlor	Propachlor
Anaerobic Soil Metabolism	Not available	230 days in sandy loam soil	81 days	146 days in a clay-loam sediment/lake water system
Mobility	Very mobile in loamy sand, silt and sand, mobile in silt loam in column leaching studies Estimated K_{OC}=190	K_d variable between 0.81-7.5	K_d between 0.08 and 4.81	Propachlor K_{ads}=0.45-1.39; K_{OC}=73-138, in loamy sand, sandy loam, loam, silty clay loam. Propachlor oxanilic acid K_{ads}=0.03-0.08, K_{OC}=391-3428. Propachlor sulfonic acid K_{ads}=0.03-0.07, K_{OC}=47-624
Terrestrial Field Dissipation	11 days in Chico, California	8-36 days at 5 sites in the United States	Supplemental studies show variability between 7 and 292 days	1.0-1.7 days in Janesville, Iowa; 5.0-5.8 in York, Nebraska; 2.3-2.8 in Uvalde, Texas
Bioaccumulation in Fish	Not expected to be important, based on K_{OW}. In a supple-mental study BCF=5.8X in fillet, BCF=11X in whole, and BCF=15X in viscera	BCF=40X edible BCF=780X non-edible BCF=150X whole fish	BCF=15X edible BCF=69X whole fish	BCF=13X edible BCF=71X nonedible BCF=37X whole fish

The above table shows that alachlor, acetochlor, metolachlor, and propachlor are not only structurally related, but they also exhibit similar fate properties.

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Table 65: Comparison of Avian Acute Oral LD_{50} data (mg/kg) for Propachlor, Acetochlor, Alachlor and Metolachlor

Chemical	Avian LD_{50} (mg/kg)	Category	MRID No.	Classification
Propachlor	88	Moderately toxic	00132907	Core
Alachlor	1499	Slightly toxic	00079523	Core
	>2000	Slightly toxic	00160000	Core
	>2610	Slightly toxic	00107908	Core
Acetochlor	49	Highly toxic	41963303	Core
	1567	Slightly toxic	00079598	Core
	1788	Slightly toxic	41565129	Core
Metolachlor	4640	Slightly toxic	00015547	Core

* Technical Grade Material

Table 66: Comparison of Avian Subacute Dietary LC_{50} data (ppm) for Propachlor, Acetochlor, Alachlor and Metolachlor

Chemical	Avian LC_{50}	Category	MRID No.	Classification
Propachlor	>5000	Practically Non-toxic	00108087 00104335	Core
	>5423	Practically Non-toxic	00134006	Core
	>5620	Practically Non-toxic	00132908	Core
Alachlor	>5000	Practically Non-toxic	00093660	Core
	>5620	Practically Non-toxic	00106553	Core
	>5620	Practically Non-toxic	00106554	Core
Acetochlor	>4171	Slightly toxic	41565130	Core
	>4610	Slightly toxic	41565131	Core
	>5620	Practically Non-toxic	00064711	Core
	>5620	Practically Non-toxic	00064710	Core
Metolachlor	>10000	Practically Non-toxic	0016425	Core
	>10000	Practically Non-toxic	0016426	Core

*Technical Grade Material

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Table 67: Comparison of Freshwater Fish 96-hr LC_{50} data (ppm) for Propachlor, Acetochlor, Alachlor and Metolachlor.

Chemical	96-hr LC_{50}*	Category	MRID No.	Classification
Propachlor	0.23	Highly toxic	40098001	Core
	0.17	Highly toxic	00041335	Core
Alachlor	1.0	Highly toxic	00234628	Core
	5.6	Moderately toxic	00234628	Core
	2.8	Moderately toxic	00023615	Core
	4.3	Moderately toxic	40094602	Core
	2.4	Moderately toxic	40094602	Core
Acetochlor	1.2	Moderately toxic	41963306	Core
	1.5	Moderately toxic	41565133	Core
	0.38	Highly toxic	41565132	Core
	1.6	Moderately toxic	41565133	Core
Metolachlor	3.9	Moderately toxic	0018722	Core
	4.9	Moderately toxic	0015534	Core
	8.0	Moderately toxic	40098001	Core
	10.0	Moderately toxic	00018723	Core

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Table 68: Comparison of Aquatic Invertebrate 48-hour LC_{50} data (ppm) for Propachlor, Acetochlor, Alachlor and Metolachlor.

Chemical	48-hr LC_{50}*	Category	MRID No.	Classification
Propachlor	0.79	Highly toxic	40098001	Core
	7.8	Moderately toxic	00041336	Core
	6.9	Moderately toxic	40098001	Core
Alachlor	21.0	Slightly toxic	40098001	Core
	3.2	Moderately toxic	40098001	Core
Acetochlor	8.2	Moderately toxic	41565134	Core
	14.0	Slightly toxic	00064714	Core
Metolachlor	25.1	Slightly toxic	226955	Core
	23.5	Slightly toxic	40098001	Core
	3.8	Moderately toxic	40098001	Core

* Technical grade material

Table 69: Comparison of Estuarine Fish 48-hour LC_{50} data (ppm) for Propachlor, Acetochlor, Alachlor and Metolachlor

Chemical	48-hr LC_{50}*	Category	MRID No.	Classification
Propachlor	No Data			
Alachlor	3.9	Moderately toxic	44524301	Core
Acetochlor	2.1	Moderately toxic	42713102	Core
	3.9	Moderately toxic	41565137	Core
Metolachlor	9.8	Moderately toxic	43487101	Core

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Table 70: Comparison of Estuarine Invertebrate 96-hour LC_{50}/EC_{50} data (ppm) for Propachlor, Acetochlor, Alachlor and Metolachlor.

Chemical	48-hr LC_{50}*	Category	ID #	Classification
Propachlor	No Data			
Alachlor	2.4	Moderately toxic	44524302	Core
	1.6	Moderately toxic	44524303	Core
Acetochlor	2.2	Moderately toxic	42713101	Core
	8.0	Moderately toxic	41565136	Core
	5.3	Moderately toxic	41565135	Core
	3.82	Moderately toxic	42713103	Core
Metolachlor	4.9	Moderately toxic	43487103	Core
	1.6	Moderately toxic	43487102	Core

Table 71: Comparison of Mammalian Acute Oral LD_{50} data (mg/kg) for Propachlor, Acetochlor, Alachlor and Metolachlor

Chemical	96-hr LD_{50}*	Category	ID #	Classification
Propachlor	1800			NA
Alachlor	Not Required			
Acetochlor	2.2	Moderately toxic	42713101	Core
	8.0	Moderately toxic	41565136	Core
	5.3	Moderately toxic	41565135	Core
	3.82	Moderately toxic	42713103	Core
Metolachlor	4.9	Moderately toxic	43487103	Core
	1.6	Moderately toxic	43487102	Core

* Technical grade material

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11. Environmental Risk Assessment

a. Introduction

Risk Quotients (RQs) are used to evaluate the potential risk to nontarget organisms from the use of alachlor products. RQs are calculated by dividing an appropriate exposure estimate, (such as the estimated environmental concentration; EEC) by an appropriate toxicity test effect level. Typical acute effect levels are: EC_{25} for terrestrial plants, EC_{50} for aquatic plants and invertebrates, LC_{50} for fish and birds, and LD_{50} for birds and mammals. Typical chronic effect levels are: No Observed Effect Level (NOEL) for avian and mammal reproduction studies, and either the NOEL, or the Maximum Allowable Toxicant Concentration (MATC), (which is the geometric mean of the NOEL and the Low Observed Effect Level (LOEL), for chronic aquatic studies. The NOEL and LOEL are sometimes referred to as No Observed Effect Concentration (NOEC) or the Lowest Observed Effect Concentration (LOEC).

RQs are then compared to established levels of concern (LOC) for determination of potential ecorisk and the consideration of regulatory action. There are two general categories of LOCs: acute and chronic. The levels of concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms.

When the risk quotient exceeds the LOC for a particular category of organism, there is presumed to be risk to that particular category. Risk presumptions for particular categories of organisms are presented in Table 72 along with the corresponding LOC's.

Table 72: Levels of Concern and Associated Risk Presumptions:

Criterion	Presumption when Criterion Met
Mammals and Birds	
Acute RQ≥0.5	High acute risk.
Acute RQ≥0.2	Risk that may be mitigated through restricted use.
Acute RQ≥0.1	Endangered species may be affected acutely.
Chronic RQ≥1	Chronic risk, endangered species may be affected chronically.
Fish and Aquatic Invertebrates	
Acute RQ≥0.5	High acute risk
Acute RQ≥0.1	Risk that may be mitigated through restricted use.
Acute RQ≥0.05	Endangered species may be affected acutely.
Chronic RQ≥1	Chronic risk, endangered species may be affected chronically.
Plants	

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Table 72: Levels of Concern and Associated Risk Presumptions:	
Criterion	Presumption when Criterion Met
RQ≥1	High risk.
RQ>1	Endangered plants may be affected.

b. Risk to Nontarget Terrestrial Animals

Although available information does not indicate acute risk concerns for birds or mammals, an LC_{50} measurement for a small mammal would be required for a conclusive finding.

Birds

Alachlor emulsifiable concentrate at a maximum rate of 6 lbs a.i./A, would produce a maximum expected concentration of approximately 1440 ppm on range grasses. (Note that the maximum single application rate is now 4 lb a.i./A.) Alachlor is practically nontoxic to birds on a dietary basis: in the acute tests with two avian species, little or no mortality was observed at the highest measured concentration (5620 ppm). Therefore, no exceedances of Agency levels of concern for acute dietary risk are expected.

The avian acute oral data (LD_{50} = 1499 mg/kg) can be used to evaluate avian exposure to granules. The potential hazard to birds from exposure to granules should be slight. Granules are deposited typically in bands 6 inches wide, with 32 inches between band centers. This implies that the pesticide is applied to an area of 8,163 square feet in every acre. At the maximum label rate (for granular uses) of 4.0 lb ai per acre, there will be 222 mg ai/sq.ft. for the area within bands. If 85% of the granules are incorporated (Erbach and Tollefson, 1983) the potential surface residue is 33 mg/sq.ft. This value does not indicate an acute toxicity concern for non-endangered species (LOC=0.5). Exposures exceeding 150 mg/sq ft would exceed the endangered species LOC of a tenth of the LD_{50}. *Without incorporation, exposure could approach this level of concern.* However, the registrant has indicated that Lasso ®II is applied in 10 and 14-inch bands, reducing the level of exposure and attenuating the concern.

Assessment of chronic effects to terrestrial vertebrates is based on results of reproduction studies. Properties and use conditions of alachlor indicate a need for such studies. To date the Agency has not received or reviewed data on possible reproductive or growth effects to birds from exposure to alachlor. There is some certainty that the nesting and breeding seasons of many bird species will coincide with the usual preemergent application periods for alachlor. The persistence of the compound indicates that it will be available for a relatively long period of time on the application site, with an aerobic soil half life of 2-3 weeks and longer half lives for abiotic processes (photolysis, hydrolysis).

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Mammals

Available information for mammals is inconclusive regarding concerns for acute risk. LD_{50} values for laboratory rats indicate slight acute toxicity. An LC_{50} measurement would be required to calculate a risk quotient for non-target mammals. It is common for mammals to be somewhat less sensitive than birds, and risk quotients calculated above for birds do not indicate a concern for acute effects.

Regarding the possibility of chronic effects on mammals, three-generation rat studies produced a parental/offspring systemic toxicity NOEL of 10 mg/kg/day and an LOEC of 30 mg/kg/day. (MRID No. 00075062) Renal toxicity was observed in F_2 males. There were no effects on reproductive parameters. The rat developmental toxicity study showed maternal and developmental effects at dose levels of 400 mg/kg/day and a NOEC of 150 mg/kg/day. (MRID No. 00043645) Based on the computations for mg ai/sq ft for a granular application, the LOEC for a 1 kg mammal could be contained within a square foot of surface area. Higher exposure is expected for surface application with no incorporation. Ingestion of this amount of active ingredient for the extended periods represented in these studies would, however, seem unlikely as the herbicide would dissipate downward or laterally once irrigation or rainfall events occurred. In the absence of rainfall, irrigation is recommended within five days of planting to move the chemical to the root zone.

c. Risk to Nontarget Aquatic Animals

Freshwater Animals

The following features of alachlor use are relevant to the determination of aquatic exposures: (1) alachlor is a pre-emergent herbicide and is usually applied only once a year, (2) there are some postemergence uses that allow two applications, and (3) in the absence of rainfall, irrigation is recommended within five days of planting to move the chemical to the root zone.

Sufficient information is available to characterize the toxicity of alachlor to freshwater animals. Alachlor shows moderate acute toxicity to both coldwater fish and warmwater fish, based on measurement with TGAI or formulated EC 45. Alachlor TGAI and formulated products (42-45%EC) are slightly to moderately toxic to freshwater aquatic invertebrates on an acute basis.

Alachlor is highly toxic to freshwater fish and invertebrates chronically. The LOEC values for growth and reproductive effects are below 400 ppb. NOEC's are below 190 ppb.

Alachlor is not expected to cause freshwater fish or invertebrates to be at acute risk. Results of screening level modeling do not exclude the possibility of chronic effect threshold exceedance for fish and invertebrates through spray drift or runoff in areas close to application sites, particularly for smaller bodies of water with little inflow or outflow. Based on monitoring results, chronic thresholds in areas farther down the watershed from these smaller tributaries or ponds are not expected to exceed acute or chronic levels of concern for fish or invertebrates.

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Estuarine and Marine Animals

Sufficient data are available to characterize alachlor as being only moderately toxic to saltwater fish (sheepshead minnow), saltwater mysid and shellfish (Eastern oyster).

Bioaccumulation

Alachlor is not expected to bioaccumulate significantly in fish, based on high solubility (240 ppm), and relatively low octanol/water partition coefficient (434).

d. Risk to Nontarget Plants

Toxicity data for plants, though incomplete, are sufficient to characterize alachlor as highly toxic for both terrestrial and aquatic plants. Alachlor poses substantial risks to aquatic and terrestrial plants near use sites. Terrestrial plants may be exposed to alachlor via drift and runoff from areas of application, or via irrigation with contaminated ground water. Aquatic plants may be exposed via runoff or drift, or by discharge of contaminated ground water into surface water.

Aquatic Plants

Alachlor has an aquatic plant EC_{50} of 1.64 μg/L and NOEC of 0.35 µg/L, based on a green alga study. The risk quotients (based on screening models) using this EC_{50} range from 21 to 124, values that substantially exceed the level of concern (LOC=1). Based on monitoring results average detection levels often exceed levels of concern for aquatic plants.

Measurements of alachlor in surface and ground water were previously described in this document. The EC_{50} of 1.64 µg/L for aquatic plants approximately equals the alachlor MCL (2 µg/L); therefore the frequency of acute exposures exceeding the LOC for plants (LOC=1) approximately equals the frequency of exceeding the MCL.

Aquatic plants may be adversely affected by alachlor in ground water, in places where ground water discharges into surface water. Regarding ground water, the measured concentration of alachlor was higher than the MCL in 21% of wells (99 of 467 wells) that had detectable alachlor, as recorded in the Pesticides in Ground Water Database.

Terrestrial Plants

For terrestrial plants, the RQ is the ratio of the EEC to the EC_{25}, and RQ values 1 or larger indicate high risk. Based on calculations that follow, RQ values are equal to 5 or larger, which is indicative of high risk.

Typically alachlor is applied by ground equipment at rates of 4 lbs a.i./A. With 5% runoff the EEC is 0.2 lbs a.i./A. The EC_{25} for seedling emergence was 0.04 lbs a.i./A, based on a study that was

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found to be supplemental. The corresponding RQ is 5 (0.2/0.04). Alachlor is persistent, so additional applications would be additive, to some extent.

Semi-Aquatic Plants

Semi-aquatic plant species live for some part of a year in wet soil near freshwater wetlands or estuarine marshes. For these plants, the most appropriate toxicity measurements are those for terrestrial plants. Exposure scenarios are similar to those described previously for aquatic organisms.

Risk to semi-aquatic plants exceeds levels of concern. Risk is assessed using two different risk quotients, representing exposure by drift and runoff. Both are compared to an LOC of 1.

- A risk quotient based on exposure to aerial drift of alachlor is as follows: Alachlor is applied aerially at 4 lbs a.i./A, and drifts to a plot with area equal to that of the application plot. A loading of 0.2 lbs a.i./A (=5% drift) is calculated as for aquatic organisms. The most applicable toxicity data is that for vegetative vigor of terrestrial plants, with EC_{25} measurements as low as 0.044 lbs a.i./A. The value of the risk quotient is 0.2 / 0.044 = 5.

- A risk quotient based on exposure to runoff of water contaminated with alachlor is calculated as follows: If the pesticide is applied aerially at 4 lbs a.i./A to a 10-acre application plot and is transported to a 1-acre plot, a loading of 1.2 lbs a.i./A is calculated. The most applicable toxicity data is that for germination and growth of terrestrial plants, with EC_{25} measurements as low as 0.0067 lbs a.i./A. The value of the risk quotient is 1.2 / 0.0067 = 179.

e. Aquatic LOC Exceedances

For freshwater animals (fish or invertebrates) exposure estimates based on Tier I modeling (GENEEC) exceed LOCs (levels of concern) only for chronic effects, and only at application rates of 4 lb ai/A (invertebrates) without incorporation. For estuarine/marine organisms (fish, shrimp and shellfish), exposure estimates based on Tier 1 modeling (GENEEC) do not exceed concern levels for acute effects. (See Table 73)

Table 73: Alachlor Screening Level Aquatic EECs Generated by GENEEC, with LOC Exceedances.

Application Rate/Method/Incorporation	EEC Estimates Over Time (ppb)				Species with LOC exceedance, (risk quotient)
	Peak	4 Days	21 Days	56 Days	
1.0lb Granular/Ground/none	33	32.7	30.7	27.4	Aquatic Plant (21)
2.0lb Granular/Ground/none	66.3	65.5	61.5	58.9	Aquatic plant (41)

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Table 73: Alachlor Screening Level Aquatic EECs Generated by GENEEC, with LOC Exceedances.

Application Rate/Method/Incorporation	EEC Estimates Over Time (ppb)				Species with LOC exceedance, (risk quotient)
	Peak	4 Days	21 Days	56 Days	
4.0lb Granular/Ground/none	133	131	123	110	Daphnid Chronic NOEC (1) Aquatic Plant (83)
1.25lb ai/groundspray/none	39	38	36	32	Aquatic Plant (24)
2.5lb ai/groundspray/none	78	77	72	65	Aquatic Plant (49)
3.0 lb ai/groundspray/none	94	93	87	78	Daphnid Chronic (1) Aquatic Plant (57)
4.0lb ai/groundspray/none	125	124	116	104	Daphnid Chronic NOEC (1) Aquatic plant EC50 (76)
4.0 lb ai/groundspray/2.0 inch incorporation	64	63	59	53	Aquatic plant (40)
2.0 lb ai/A twice groundspray/no incorp./30 day interval	92	91	85	76	Daphnid Chronic NOEC (1) Aquatic Plant (57)

Alachlor concentration levels observed in monitoring studies do not indicate a risk for acute or chronic effects on aquatic animals. Thus, while a chronic risk cannot be dismissed for small, shallow, relatively static bodies of water (such as farm ponds or small freshwater marshes) from unincorporated applications of alachlor at 4 lbs ai/A (invertebrates), the information available suggests that impacts are not expected in larger water bodies such as rivers or large lakes. (See Tables 74, 75, and 76)

Table 74: USGS Mississippi River Basin Survey, 1991-1992[1]

Location Sampled (24 Samples per location)	Alachlor Concentration (µg/L)			LOC Exceedance-Organisms Affected
	Peak	Arithmetic average	Annual TWMC	
White River, Hazelton, In.	3.2	0.3	0.22	Aquatic Plants-(Peak only; based on EC_{50} (=1.64 ug/L)
Ohio River, Grain Chain, Il.	0.40	0.08	0.07	No

Table 74: USGS Mississippi River Basin Survey, 1991-1992[1]				
Location Sampled (24 Samples per location)	Alachlor Concentration (µg/L)			LOC Exceedance-Organisms Affected
	Peak	Arithmetic average	Annual TWMC	
Miss. River, near Clinton, IA.	0.85	0.16	0.10	No
Illinois River, Valley City, Il	3.00	0.40	0.22	Aquatic Plants-(Peak only, based on EC_{50})
Platte River, Louisville, NE	3.60	0.43	0.22	Aquatic Plants-(Peak only, based on EC_{50})
Missouri River, Hermann, Mo.	0.92	0.19	0.12	No
Miss. River, near Thebes, Il.	0.86	0.27	0.23	No
Miss. River, Baton Rouge, LA.	0.46	0.12	0.09	No

[1]Based on bi-weekly samples May to August and weekly samples Sept. to Dec. 1 (Coupe et. al. 1995).

Table 75: Illinois Surface Water Survey, 1986-1988[1]			
Site Type	Alachlor Concentration as a Range (over sites and years) (ug/L)		LOC Exceedance Organism Effected
	Range of Peak values	Range of annual TWMC	
Illinois Rivers (21 Sites-18 Rivers)	0.02- 8.5	0.02-0.65	Aquatic Plants based on EC_{50}
Illinois Creeks (9 Creeks)	0.02-18.0	0.02-2.0	

[1] Based on samples from 30 sites representing different streams and rivers, 4-7 samples per yr at each site (Moyer and Cross, 1990).

Table 76: Summary of Chesapeake Bay Fall Line Toxics Monitoring Program for Alachlor Detections in Major Streams.			
Location	Range detected µg/L	Mean µg/L	LOC Exceedances by Mean
Susquehanna River	<2.05-23.1	4.4	Aquatic Plants, based on EC_{50}

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Table 76: Summary of Chesapeake Bay Fall Line Toxics Monitoring Program for Alachlor Detections in Major Streams.			
Potomac River	2.5-20.9	4.1	
James River	7.5-20.2	2.9	

f. Environmental Risk Summary

An evaluation of the risk to nontarget organisms from the use of alachlor products, combining toxicity data with potential exposure, indicates that:

- Alachlor poses a potential risk to terrestrial animals on a chronic basis. Additional information must be submitted by the registrant to rule out risk.
- The granular formulations and high use rate pose the greatest risk to nontarget organisms.
- Alachlor levels observed in surface water monitoring studies could result in extensive adverse effects on aquatic plants.
- Aquatic animals are not at acute risk as a result of exposure to alachlor, but chronic effects may be observed under certain circumstances.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

a. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing alachlor as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing alachlor. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of alachlor, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of alachlor and to determine that alachlor can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing alachlor as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target database required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of alachlor are eligible for reregistration, it should be understood that the

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Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing alachlor, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

b. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient alachlor, the Agency has sufficient information on the health effects of alachlor and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that alachlor products, labeled and used as specified in this Reregistration Eligibility Decision Document (RED), will not pose unreasonable risks or adverse effects to humans or the environment. If the terms and conditions of registration for products containing the active ingredient alachlor are amended as specified in this RED, then the Agency concludes that products containing alachlor are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of alachlor are eligible for reregistration.

c. Regulatory Position

To lessen the risks posed by alachlor, EPA is requiring the following mitigation measures for alachlor-containing products.

To protect non-target species:

- Require labeling as specified in Section V.

To control surface water contamination:

- Require labeling as specified in Section V.
- Require labeling to implement spray drift best management practices

To control ground water contamination:

- Require labeling as specified in Section V.
- Classify alachlor as a Restricted Use Pesticide (RUP) for ground water concerns
- Add labeling language requiring a 50 ft setback of mixing and loading activities from wells, rivers, or lakes unless such activity is protected by an impervious pad.
- After promulgation of the Ground Water and Pesticides Management Plan Rule, require use in accordance with an approved State or Tribal Management Plan

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To protect workers:

- For liquid (emulsifiable concentrate) formulations for workers supporting groundboom application require that mixers, loaders, and persons cleaning equipment must wear long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.
- For dry flowable formulations for workers supporting groundboom application require that mixers, loaders, and persons cleaning equipment must wear long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.
- For liquid (emulsifiable concentrate) formulations for workers supporting aerial application require that mixers and loaders must wear long-sleeved shirt, long pants, and chemical resistant gloves, and the use of a closed transfer system.
- For dry flowable formulations for workers supporting aerial application require that mixers and loaders must wear long-sleeved shirt, long pants, and chemical resistant gloves, and the use of a closed transfer system.
-For mixers and loaders who impregnate dry bulk fertilizer require long-sleeved shirt, long pants, and chemical-resistant gloves, and the use of a closed transfer system.

To control the amount of alachlor present in rotated crops:

- Until the rotational crop data are received and reviewed, rotation to crops not specified on this label is prohibited.

1. Food Quality Protection Act Findings

The following is a summary of the Agency's regulatory position and rationale for managing the risks associated with uses of alachlor.

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for alachlor, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both chronic and carcinogenic) from food and drinking water.

The Agency has concluded that there are no alachlor products registered for home use, or use in or around schools, parks or other public areas. For this reason a residential assessment was not conducted and there is no residential assessment to aggregate with the total dietary assessment .

As previously discussed, available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route; therefore, an acute dietary assessment was not conducted.

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The Agency assessed the chronic (non-cancer) dietary risk using the chronic RfD of 0.01 mg/kg/day based a NOEL of 1 mg/kg/day from a one year chronic dog study (with an uncertainty factor of 100 to account for interspecies extrapolation and intraspecies variability). The Agency's aggregate chronic risk assessment was performed considering exposures from food and water. Values ranged from less than 1% to 4% of the RfD. The Agency concluded that the chronic dietary risk from food containing residues of alachlor and from consumption of water containing residues of alachlor and alachlor ESA is not of concern.

Using the MOE approach, the Agency calculated carcinogenic dietary risk using two endpoints of concern: the NOEL of 14 mg/kg/day for stomach tumors and 0.5 mg/kg/day for nasal tumors. The Agency's estimated MOEs for aggregate dietary carcinogenic risk considering exposures from food and water. The MOEs ranged from 29,000 to 1,400,000 indicating that the dietary cancer risk from the recommended uses of alachlor is not expected to be of concern.

Using the Q_1^* approach, the Agency calculated carcinogenic dietary risk using the Q_1^* of 0.08 $(mg/kg/day)^{-1}$. The Agency's estimated risks for aggregate dietary carcinogenic risk considering exposures from food and water. The risks ranged from 7.8×10^{-7} to 1.4×10^{-6} which is generally within the risk range considered to be negligible.

With regard to water monitoring data, sufficient analytical information on detections of all alachlor degradates were not available. The available information indicates that alachlor ESA is detected more often and in larger concentrations than alachlor, and that degradates of alachlor are probably more mobile and more persistent than alachlor per se. Toxicity information is available only for alachlor ESA. Due to the lack of available information on detections in ground and surface water of all degradates of alachlor (of which alachlor ESA is only one degradate) and on the toxicity of these degradates, the Agency is concerned about the exposure to drinking water containing alachlor and all alachlor degradates.

Alachlor, acetochlor, metolachlor, butachlor, and propachlor are structurally similar and therefore may share a common mechanism of toxicity. For the purpose of implementation of FQPA, common mechanism of toxicity is defined as pertaining to two or more pesticides that produce an adverse effect(s) to human health by the same, or essentially the same, sequence of major biochemical events. On August 6, 1998, the Notice of Availability for the "Guidance for Identifying Pesticide Chemicals that have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides" was published in the Federal Register. (Federal Register, Volume 63, No. 151). The Agency is proposing to use the following process for identifying those pesticides that share a common mechanism of toxicity: (1) identify pesticides that are likely to have a common mechanism of toxicity using available information on structural similarity, mechanism of pesticidal action, and common toxic effect, (2) identify the mechanism of toxicity of each pesticide, and (3) categorize pesticides according to mechanism of toxicity.

At this time the Agency has not yet made a final decision concerning a possible common mechanism of toxicity for alachlor, acetochlor, metolachlor, butachlor, and propachlor to

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scientifically apply that information to the tolerance decision. Therefore, for the purposes of this decision document, the tolerance decision will be reached based upon the best available and useful information for alachlor only. Thus, the alachlor risk assessment has been performed assuming that no common mechanism of toxicity exists.

However, the process for determining whether a common mechanism of toxicity exists has begun, but is not yet completed. Thus, the decisions made in this RED will be reexamined after the Agency (1) finalizes the process for determining whether a common mechanism of toxicity exists for these chemicals, (2) determines those chemicals with which alachlor does share a common mechanism of toxicity (cluster), (3) determines the potency equivalencies for each chemical of the cluster, (4) adds the potency equivalencies to determine the cumulative magnitude of the effect, and (5) after reviewing the use information/patterns, determines for which of the exposures/scenarios for which of the chemicals that cumulative exposure exists. Once the methodologies and procedures for integrating information concerning common mechanism of toxicity into risk assessments are developed, the Agency can determine the appropriateness of a cumulative assessment.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for alachlor, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of alachlor residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from alachlor residues, EPA considered the completeness of the database for developmental and reproductive effects, as well as other available information such as the nature of the effects observed. There is no evidence of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure. There are no data gaps for the assessment of the effects of alachlor following in utero and/or postnatal exposure.

Based on the current data requirements, alachlor has a complete database for developmental and reproductive toxicity. Reliable studies cited earlier in this document indicate no special sensitivity of young organisms to alachlor. Therefore, the Agency has concluded that the 10X FQPA safety factor for the protection of infants and children can be removed.

EPA estimates that the residues of alachlor in the diets of children (1 - 6 years) represent less than 1% of the chronic RfD and residues in drinking water, including residues of alachlor ESA, represent approximately 3% of the chronic RfD. The aggregate chronic dietary exposure for infants and children utilizes approximately 4% of the chronic RfD. Thus, the Agency concludes that aggregate risks for infants and children resulting from alachlor uses are not of concern.

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In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

c. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

2. Tolerance Reassessment

The tolerances listed in 40 CFR §180.249 are for the combined residues of alachlor and its metabolites (calculated as alachlor).

The Agency has determined that all alachlor metabolites which can be converted to 2,6-diethylaniline (DEA) and 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis are to be regulated and will be included in the tolerance expression. Therefore, the tolerance expression in 40 CFR §180.249 should be modified as follows: "Tolerances are established for the combined residues of the herbicide alachlor (2-chloro-2',6'-diethyl-N-(methoxymethyl) acetanilide) and its metabolites which can be converted to 2,6-diethylaniline or 2-ethyl-6-(1-hydroxyethyl)aniline upon basic hydrolysis, (calculated as alachlor), in or on the following raw agricultural commodities: ...".

Thus, for some commodities tolerance increases will be necessary. The more recent residue chemistry data reflect analysis for two classes of alachlor metabolites (DEA and HEEA); whereas some of the older data used to establish the existing tolerances reflect analysis for DEA metabolites only.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.249 for beans, dry; beans, lima(green); corn, sweet (K + CWHR); corn, grain; sorghum

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grain and fodder; eggs; milk; and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep. See Table 77 for modifications in commodity definitions.

Tolerances for the following commodities have been reassessed based on the available data: corn, field, forage, and stover; corn, pop, grain, and stover (translated from field corn grain); sweet corn, forage and stover; peanuts; and soybeans.

Field rotational crop studies are still required for a root crop and a leafy vegetable; rotational crop tolerances are needed. Monsanto plans to support cereal grains (except rice), and non-grass animal feeds as rotational crops.

Table 77: Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition/Comment
Beans, dry	0.1	0.1	
Beans, forage	0.2	5.0	*Cowpeas, forage*
Beans, hay	0.2	5.0	*Cowpeas, hay*
Beans, lima (green)	0.1	0.1	*Beans, succulent lima*
Cattle, fat	0.02	0.02	
Cattle, mbyp	0.02	0.02	
Cattle, meat	0.02	0.02	
Corn, fodder	0.2	2.0	*Corn, field, stover*
		2.0	*Corn, pop, stover*
		2.0	*Corn, sweet, stover*
Corn, forage	0.2	2.0	*Corn, field, forage*
		2.0	*Corn, sweet, forage*
Corn, fresh (inc. sweet K+CWHR)	0.05	0.05	*Corn, sweet (K+CWHR)*
Corn, grain	0.2	0.2	*Corn, field, grain*
		0.2	*Corn, field, pop*
Eggs	0.02	0.02	
Goats, fat	0.02	0.02	
Goats, mbyp	0.02	0.02	
Goats, meat	0.02	0.02	
Hogs, fat	0.02	0.02	
Hogs, mbyp	0.02	0.02	

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Table 77: Tolerance Reassessment Summary.			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition/Comment
Hogs, meat	0.02	0.02	
Horses, fat	0.02	0.02	
Horses, mbyp	0.02	0.02	
Horses, meat	0.02	0.02	
Milk	0.02	0.02	
Peanuts	0.05	0.5	
Peanuts, forage	3.0	Revoke	Feeding restrictions exist; not considered a major livestock feed.
Peanuts, hay	3.0	Revoke	Feeding restrictions exist.
Peanuts, hulls	1.5	Revoke	Based on Table II, peanut hulls are not considered to be a major livestock feed.
Poultry, fat	0.02	0.02	
Poultry, mbyp	0.02	0.02	
Poultry, meat	0.02	0.02	
Sheep, fat	0.02	0.02	
Sheep, mbyp	0.02	0.02	
Sheep, meat	0.02	0.02	
Sorghum, fodder	1.0	1.0	*Sorghum, grain, stover*
Sorghum, forage	2.0	2.0	*Sorghum, grain, forage*
Sorghum, grain (milo)	0.1	0.1	*Sorghum, grain, grain*
Soybeans	0.2	1	
Soybeans, forage	0.75	Revoke	All alachlor products with uses on soybeans have feeding restrictions or are in the process of being canceled.

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Table 77: Tolerance Reassessment Summary.			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition/Comment
Soybeans, hay	0.2	Revoke	All alachlor products with uses on soybeans have feeding restrictions or are in the process of being canceled.

Codex Harmonization

No maximum residue limits (MRLs) for alachlor have been established by CODEX for any agricultural commodity. Therefore, no questions of compatibility exist with respect to U.S. tolerances.

3. Ecological Risk Mitigation

For terrestrial animals there are concerns for acute effects. There is not an avian reproduction study for alachlor, but avian reproduction studies for other acetanilides (metolachlor, acetochlor) suggest high toxicity on a chronic basis. Based on this, and on consideration of the scope and seasonal pattern of use (including application at times when birds will be breeding) there is a concern that alachlor may adversely affect avian reproduction. The information available on persistence of alachlor is consistent with a chronic concern since alachlor is moderately persistent in soil. The major dissipation route in soil is microbially mediated, with half lives of 2-3 weeks under aerobic conditions. Avian reproduction studies are required.

Large scale use of a herbicide ordinarily poses concern for terrestrial plants at least in the vicinity of application sites. There are no special concerns for effects of alachlor on terrestrial plants, relative to other herbicides with extensive use. The evaluation of risk to terrestrial plants indicates high risk from exposure to alachlor drift and runoff. There is no information on toxicity of alachlor degradates to terrestrial plants.

Alachlor levels observed in surface water monitoring studies could result in extensive effects on aquatic plants. Such effects could in turn cause population level effects on aquatic animals (including fish and amphibians) via habitat modification or decreased food supply. Information is not available on the effects of degradates on aquatic plants.

For aquatic animals, risk quotients based on screening-level exposure estimates do exceed levels of concern for chronic effects. However, the monitoring information available does not suggest widespread effects by direct acute or chronic toxicity. The available information does not

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suggest high toxicity of alachlor degradates to aquatic animals. For estuarine/marine species, risk quotients, based on screening-level exposure estimates, do not exceed level of concerns for acute effects for saltwater fish, saltwater mysid or shellfish.

Based on the aquatic plant data, the Agency is confident that adverse effects on aquatic ecosystems, including potential for population level effects on aquatic animals, will occur.

Alachlor is expected to have some adverse effects on terrestrial plants, at least close to application sites. The greatest concern at present is for impacts on aquatic ecosystems, resulting from effects on aquatic plants, and perhaps occasionally from direct effects on aquatic animals.

Substantial reduction in the risk to aquatic species and ecosystems can only be obtained by a widespread reduction in use. The registrant has voluntarily reduced the maximum single application rate of alachlor from 6 to 4 lb ai/acre. New labels with the 4 lb ai/acre rate were approved by the Agency on June 30, 1998.

4. Surface Water Protection Measures

Alachlor levels observed in monitoring studies are sufficient to result in effects on aquatic plants and indirectly on aquatic animals. The available monitoring information indicate that drinking water supply systems usually comply with the Safe Drinking Water Act. Alachlor in the water sources (i.e., annual averages) will rarely exceed the current MCL of 2 µg/L. Particularly relevant sources of monitoring information are recent (1992-1996), extensive data collected by the Acetochlor Registration Partnership monitoring 175 surface water sites, and by the US Geological Survey in reconnaissance surveys of Midwestern streams and reservoirs. Such data may reflect reported substantial decreases in alachlor use. However, the concentration of alachlor ESA in surface water poses a potential human health risk. The concentration of alachlor ESA often greatly exceeds the concentration of parent alachlor and often occurs at concentrations of several ppb even in early spring before alachlor application.

At this time the toxicity of alachlor ESA to certain aquatic species cannot be fully assessed. Additional studies to characterize the potential ecological effects of alachlor ESA are required. There are concerns about the possible risk posed by exposure to other major degradates of alachlor such as alachlor DM-oxanilic acid, alachlor oxanilic acid, and alachlor sulfinylacetic acid.

Since available monitoring data show that alachlor degradates are more frequently found than the parent, validated analytical methods for these degradates (including alachlor ESA) are needed. These methods must have minimum detection limits of equal to or less than 0.1 µg/L in water. In addition to the parent alachlor, it is required that the registrant supply standards of alachlor degradates (alachlor ESA, alachlor DM-oxanilic acid, alachlor oxanilic acid, and alachlor sulfinylacetic acid) to the EPA Pesticide Repository.

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Labeling as specified in Section V will reduce the potential for incidents of contamination of surface water. Surface water monitoring, which will include some of the alachlor degradates, is being performed by the Acetochlor Registration Partnership (ARP), USGS National Water Quality Assessment Program (NAWQA), and various State Programs.

5. Ground Water Protection Measures

Several recent studies have found alachlor degradates in groundwater samples, including alachlor ESA and alachlor oxanilic acid. These degradates are more persistent than parent alachlor and appear to be widespread in groundwater. Alachlor ESA has been detected almost 10 times more frequently than alachlor, and is the most frequently reported pesticide related compound in ground water monitoring studies for pesticides in the midcontinent area. Alachlor ESA has been found up to a maximum concentration of 8.6 µg/L in 45 to 70 percent of Midwestern groundwater wells sampled in a study focused on near-surface aquifers in corn and soybean growing areas. Another study (Potter and Carpenter, 1995) sampled groundwater from a cornfield in Massachusetts. The last application of alachlor was three years prior to the sampling. Twenty alachlor degradation products as well as atrazine, metolachlor, carbofuran and their various degradation products were detected.

The Agency has significant concerns about the impact alachlor and its degradates may have on ground water quality. Consideration of environmental chemistry and fate properties indicates that alachlor and a number of alachlor degradates will leach to ground water. An extensive body of groundwater monitoring information has been reviewed which confirms that alachlor and alachlor degradates do in fact contaminate groundwater.

EPA will take additional measures for the protection of groundwater resources as follows:

- EPA will require labeling as specified in Section V to reduce the potential for incidents of contamination of groundwater.
- EPA will classify alachlor as a restricted use pesticide for groundwater concerns.
- EPA has included alachlor in its proposed Ground Water and Pesticides Management Plan Rule as one of the chemicals that would require an approved State or Tribal Management Plan to allow its use within the State or Tribe's jurisdiction.
- EPA will continue to consider results of monitoring by others such as the USGS National Water Quality Assessment program (NAWQA), and the Acetochlor Registration Partnership(ARP).

Additionally, once the Agency's Ground Water and Pesticides Management Plan Rule is final, the Agency will utilize as appropriate, sampling information that may be available as a result of State and Tribal Plans. If new information on the toxicity of the degradates or their cumulative or aggregate effects come to the Agency's attention, or if monitoring and sampling data demonstrate increased risk , then EPA may reassess its position relative to ground water concerns.

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6. Restricted Use Classification

Currently all alachlor labels contain the following statement "RESTRICTED USE PESTICIDE due to oncogenicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

This restriction is no longer required. However, the registrant, Monsanto, has voluntarily offered to classify alachlor as a Restricted Use Pesticide due to groundwater concerns. Thus, alachlor remains a Restricted Use Pesticide. See Section V Table 78 for labeling language.

7. Pesticides Management Plan (PMP) Candidate

In addition to classifying a pesticide for restricted use for or by a certfied applicator as discussed above, FIFRA section 3(d)(1)(C)(ii) gives EPA authority to classify a pesticide subject to such other restrictions, if EPA finds its use may cause unreasonable adverse effects on the environment. EPA is proposing to restrict the legal sale and use of several pesticides, one of which is alachlor, by requiring Pesticide Management Plans (PMPs) as an "other restriction" through the proposed Ground Water and Pesticides Management Plan Rule (formerly, State Management Plan Rule) (Federal Register, Volume 61, No. 124, June 26, 1996).

Once the Rule is finalized, the labels of these pesticides would be changed to require use in accordance with an EPA-approved PMP. All products subject to a PMP would bear the following statement "For use only in accordance with an EPA-approved Pesticide Management Plan (PMP) for groundwater protection. Sale and use are prohibited in States and Indian Nations that do not have an EPA-approved PMP." Once the Rule becomes effective, use of the chemicals subject to the rule will not be allowed unless an approved Plan is in place.

PMPs will provide States and Tribes with the flexibility to protect the groundwater in the most appropriate way for local conditions. To help States and Tribes achieve the ability to protect their groundwater, EPA strongly encourages the alachlor registrants to cooperate with States and Tribes, particularly with monitoring and vulnerability assessments. Registrants are also encouraged to help with other requirements as outlined in the EPA "Guidance for Pesticides and Ground Water State Management Plans" EPA 735-B-93-005a, December 1993. Without this cooperation, State and Tribal lead agencies must assume the major burden for Plan development to address potential ground water concerns related to the continued use of alachlor.

The eligibility determination made at this time is based upon a presumption that registrations will conform to all applicable requirements of the final regulation addressing this issue.

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8. Endangered Species Statement

Currently, the Agency is developing "The Endangered Species Protection Program" to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

9. Labeling Rationale

Occupational Labeling Rationale/Risk Mitigation

Alachlor is a restricted use pesticide; therefore, alachlor can be used only by certified applicators and cannot be purchased or used by the general public. The Agency has not identified any alachlor products that are intended for home use, or uses in/around schools, parks, or other public areas. No registered use is likely to involve applications at residential sites.

Restricted Use Classification

Alachlor will be classified as a RUP due to groundwater concerns.

The Worker Protection Standard (WPS)

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. At this time all registered uses of alachlor are within the scope of the WPS.

In general, WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

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For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or certain other adverse effects, such as allergic effects or systemic effects (cancer, developmental toxicity, reproductive effects, etc.):
   - # In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
   - # These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
   - # The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA is establishing ai specific requirements for some occupational handlers for certain formulations of alachlor. The MOE's for short- and intermediate-term exposure were a concern for some occupational mixers, loaders, applicators, and flaggers. Since the NOELs for estimating short- and intermediate-term occupational risks are different, the resultant MOEs are also different. EPA is regulating on the intermediate-term endpoint, since (1) the risks resulting from intermediate-term exposures are greater, and (2) the available information for pre-plant herbicide and fertilizer applications indicate that a window of approximately 28 days is available once weather and field conditions are right and equipment can enter the fields.

For the ***granular*** formulations, (for mixer/loader/applicators) the estimated risks were greater than 100 at baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks). Therefore, no ai specific requirements are being established for the granular formulations of alachlor.

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For the ***liquid (emulsifiable concentrate)*** formulations, the risks were greater than 100 at baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks) for applicators using groundboom equipment, and for flaggers.

However, for mixers and loaders supporting groundboom application, the MOEs estimated for intermediate term risk are acceptable (i.e., 250 at 4.0 pounds active ingredient per acre and 300 at 3.0 pounds active ingredient per acre) only with the addition of personal protective equipment. Instead of requiring mixers and loaders to wear a coverall, over their long-sleeve shirts and long pants, EPA will require the addition of a chemical-resistant apron and chemical-resistant footwear (plus chemical-resistant gloves). Although EPA has no data to specifically assess the exposure reduction to mixers and loaders afforded by a chemical-resistant apron, the Agency is persuaded that the exposure reduction would be significant. Available data indicate that the preponderance of non-hand exposure to mixers and loaders is to the front torso. Therefore, for mixers and loaders the use of a chemical-resistant apron is probably approximately equivalent to double-layer body protection. The chemical-resistant footwear will provide an additional, although not quantifiable, reduction in exposure.

For mixers and loaders supporting aerial application, the MOEs estimated for intermediate-term risk are 93 at 4.0 pounds active ingredient per acre and 130 at 3.0 pounds active ingredient per acre) only with the addition of personal protective equipment (i.e., double-layers of body protection and chemical-resistant gloves). Current labels require the use of a closed (mechanical transfer) system for all mixer/loaders and/or applicators who treat 300 acres or more annually with pesticides containing alachlor. Thus, due to the existence of these systems, the Agency does not believe that requiring closed (mechanical transfer) systems for mixer/loaders supporting aerial application and chemigation will create an undue hardship. Therefore, for liquid (EC) formulations for workers supporting aerial applications, EPA will require the use of a closed (mechanical transfer) system. Workers will be required to wear long pants, long-sleeved shirts, and chemical resistant gloves.

For the ***dry flowable*** formulations, the estimated risks from both the short- and intermediate-term endpoint were greater than 100 at baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks) for mixers and loaders supporting groundboom application, applicators using groundboom equipment, and for flaggers. EPA will require the addition of a chemical-resistant apron and chemical-resistant footwear (plus chemical-resistant gloves).

However, for mixers and loaders supporting aerial application, the MOEs estimated for intermediate-term risk endpoint are marginal (i.e., 61 at 4.0 pounds active ingredient per acre and 82 at 3.0 pounds active ingredient per acre) even with the addition of personal protective equipment (i.e., double-layers of body protection and chemical-resistant gloves). To mitigate the risks Monsanto may develop water soluble packaging (WSP) for the dry flowable formulations. However, if the WSP is not practicable, then this use will be voluntarily canceled by Monsanto.

For applicators using fixed- and rotary-wing aircraft to apply the liquid or dry flowable formulations, the risks are acceptable (i.e., ranging from 500 to 1,600) when enclosed cockpits are

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assumed. Since the Pesticide Handlers Exposure Database does not contain sufficient data to estimate exposure to applicators using aircraft with open cockpits, only exposure for aerial applicators using engineering controls, (i.e., enclosed cockpits) was estimated. Since the MOEs are acceptable at baseline attire for applicators using groundboom equipment and for flaggers, and the MOEs are high for applicators using enclosed cockpits, the Agency does not have concerns for handlers who may apply alachlor using aircraft with open cockpits. Additionally, the Agency does not believe that open cockpits are being used extensively.

For mixers and loaders who impregnate dry bulk fertilizer with alachlor, the estimated risks are acceptable (ranging from110-220) for short-term exposures with the use of baseline attire plus chemical-resistant gloves and a closed transfer system; however the risks are unacceptable (ranging from 10-20) for intermediate-term exposures even with the use of baseline attire, chemical-resistant gloves, and a closed transfer system. EPA notes that many assumptions were made in performing this assessment and acknowledges that many of the assumptions were deliberately intended toward performing an upper-end assessment. For example, one high-end assumption is that the mixing tower would run at full capacity for 8 hours a day and thus generate 960 tons of alachlor impregnated fertilizer. EPA also notes that these estimates are based on using dermal unit exposure data from PHED V1.1. for a closed mixing/loading system (i.e., mechanical transfer) from individual containers into mix tanks typically used in agricultural field conditions. The amount of alachlor necessary to impregnate the tons of fertilizer processed in a day probably involves transfer from huge containers such as tanker trucks or railroad tank cars, rather than from individual containers. Therefore, using unit exposure from the available PHED data is likely to result in an over-estimate. EPA currently does not have data for bulk transfer/loading. Given these and other uncertainties, EPA has determined that additional data are necessary to appropriately assess this use pattern. Therefore, the Agency is calling in data on dermal and inhalation exposure to handlers who are engaged in impregnating fertilizer with alachlor. In the interim, EPA is requiring such handlers to wear long pants, long sleeved shirts, and chemical-resistant gloves, and to use closed (e.g., mechanical transfer) systems. This exposure scenario will be reevaluated upon receipt of the requested data.

For handlers who apply dry bulk fertilizer impregnated with alachlor, the estimated risks were acceptable (ranging from 98 to 1300) at baseline attire using open cabs. Therefore, no ai specific requirements are being established for the application of dry bulk fertilizer impregnated with alachlor.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval: Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of

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the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

During the reregistration process, EPA determined that the restricted-entry interval for all occupational-use products that contain alachlor and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 12 hours.

Alachlor is not a candidate for the 4-hour REI, since both the acute oral and acute inhalation toxicity studies are category III.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS. The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

During the reregistration process, EPA determined that the early-entry personal protective equipment for all occupational-use products that contain alachlor and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) are: coverall, chemical-resistant gloves, and shoes plus socks.

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WPS Double Notification Statement:

"Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. During the reregistration process, EPA determined that for alachlor double notification is not required.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing alachlor. For the specific labeling statements, refer to Section V of this document.

10. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products containing alachlor as an active ingredient..

a. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of alachlor for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required and considered confirmatory to our conclusion of Eligibility for reregistration:

- 71-4 Avian reproduction (two species)
- 122-2 Aquatic plant studies with the parent alachlor with an aquatic macrophyte, a marine diatom, a blue-green algae and a freshwater diatom (These studies were recently submitted to the Agency and are now under review.)
- 122-2 Aquatic plant studies with alachlor ESA with 5 aquatic plant species

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- 171-4 Validated analytical method for degradates, methods must have minimum detection limits equal to or less than 0.1 ug/L in water
- 231, 232, 233, and 234 (now 875.2400 and 875.2500) Handler exposure studies are required for impregnating dry bulk fertilizer with alachlor (including use of mini-bulk containers) and distribution-to-field application exposure scenarios. Samples for dermal and inhalation exposure should be taken concurrently. Both outdoor and indoor (at least partially enclosed) sites are required.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained in Table 78 at the end of this section.

b. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

All end-use products should have clear, concise and complete labeling instructions. Proper labels can improve reader understanding, thereby reducing misuse and the potential for incidents. Towards this end, the Agency is requiring the following:

Directions for Use:

Directions for Use must be stated in terms that can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. It must be presented in a format that is easy to understand and follow. The Directions for Use section of a pesticide label must provide the necessary information to answer four major categories regarding the use of the pesticide. These four questions are:

1) Why is the pesticide being used? For what pest(s) or problem?

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2) Where is the pesticide applied? (Where should it not be applied?)
3) How is the pesticide applied? (What special precautions must the user take? How much should they use?)
4) When should the pesticide be applied?

In addition, the Agency encourages the use of clearly understood, widely recognized graphic symbols whenever possible, to clarify the written label.

National Pesticide Telecommunications (NPTN) Hotline Number

All alachlor labels must refer consumers to the NPTN number for additional information. This reference must bear the labeling contained in Table 78 at the end of this section.

First Aid (Statement of Practical Treatment)

The Agency is requiring that all labels with Statement of Practical Treatment sections be amended so that these sections are entitled, "First Aid." First aid statements must be brief, clear, simple and in straightforward language (conforming to the labeling required by the Agency) so that the average person can easily and quickly understand the instructions. These statements should be appropriate for all ages or, when necessary, should include distinctions between the treatments for different ages.

Labeling Requirements

Table 78 summarizes the labeling requirements being imposed by this RED for all alachlor products. Any use instructions on current labels that conflict with those listed in Table 78 should be removed.

For **sole-active-ingredient** end-use products that contain alachlor:

- Revise the product labeling to adopt the handler personal protective equipment/engineering control requirements set forth in Table 78, and .
- Revise the product labeling to adopt the entry restrictions set forth in Table 78.

For **multiple-active-ingredient** end-use products that contain alachlor:

- Compare the handler personal protective equipment/engineering control requirements set forth in Table 78 to the requirements on the current labeling, then
- Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7).
- Compare the entry restrictions set forth in Table 78 to the entry restrictions on the current labeling, then
- Retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

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The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

EPA is not establishing active-ingredient-specific PPE for WPS occupational uses of alachlor end-use products formulated as a **granular**, or for the application of dry bulk fertilizer impregnated with alachlor.

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
Manufacturing Use		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	"This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
End-Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE due to groundwater concerns. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."	Top of Front Panel and Beginning of Directions for Use

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
Notice to Users	While alachlor has produced tumors in laboratory animals, extensive studies have established that alachlor is unlikely to be a human carcinogen at low levels of exposure. However, even when used according to label directions, some exposure will result. Therefore, users must read and follow all Precautionary Statements, Environmental Hazards, and Directions for Use to minimize exposure to this product.	Beginning of Directions for Use
Precautionary Labeling	"For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1-800-858-7378."	Precautionary Statements: Hazards to Humans and Domestic Animals
Precautionary Labeling	"This product may cause skin sensitization reactions in some people."	Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements: Liquid (emulsifiable concentrate) and dry flowable formulations	"Mixers, loaders, and persons cleaning equipment in support of groundboom application must wear: -long-sleeved shirt and long pants, -chemical-resistant gloves,* -chemical-resistant footwear, and -chemical-resistant apron." *For the glove statement, use the statement established for alachlor through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following the PPE Requirements)

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
Engineering Controls	"Engineering Controls" "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR 170.240(d)(4.6), the handler PPE requirements may be reduced or modified as specified in the WPS." "Mixers and loaders supporting aerial applications, chemigation, or impregnation of dry bulk fertilizer are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS for agricultural pesticides (40CFR 170.240(d)(4))."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and user Safety Statements
Engineering Controls for all Dry Flowable Formulations	In addition to the above Engineering Controls statement, dry flowable formulations must also have the following statement: "Water soluble packaging when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packaging are permitted to wear long-sleeved shirt, long pants, shoes and socks, and chemical resistant gloves."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements)
Engineering Controls for all Liquid (emusifiable concentrate) Formulations	In addition to the above Engineering Controls statement, liquid formulations must also have the following statement: "Mixers and loaders are required to use closed (mechanical transfer) systems. Handlers using closed systems are permitted to wear long-sleeved shirt, long pants, shoes and socks, and chemical resistant gloves."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements)

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals (Must be placed in a box.) (Immediately following Engineering Controls)
Environmental Hazards for liquid (emulsifiable concentrate) or dry flowable formulations	"This chemical is toxic to terrestrial and aquatic plants, fish, and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas."	Precautionary Statements under Environmental Hazards Section
Environmental Hazards for granular product formulations	"This chemical is toxic to fish, and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. "	Precautionary Statements under Environmental Hazards Section
Ground and Surface Water Statements	"Alachlor can contaminate surface water through spray drift. Under some conditions, alachlor may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water. Do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark."	Environmental Hazards Section
Ground and Surface Water Statements	"Do not contaminate water when disposing of equipment wash water or rinsate."	Environmental Hazards Section

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
Ground and Surface Water Statements	"This chemical and/or its metabolites are known to leach through soil into ground water under certain conditions as a result of registered uses. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."	Environmental Hazards Section
Ground and Surface Water Statements	"Do not apply to highly permeable soils (as classified by the USDA Natural Resources Conservation Service) where the depth to ground water is 30 feet or less."	Environmental Hazards Section
Restricted-Entry Interval (required by Supplement Three of PR Notice 93-7)	"A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all alachlor end-use products. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."	Directions for Use, Agricultural Use Requirements Box
Personal protective equipment required for early entry	"The PPE required for early entry is: -coveralls, -chemical-resistant gloves, and -shoes plus socks."	Directions for Use, Agricultural Use Requirements Box
Application Restrictions	"Do not apply this product by any method not specified on this label." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
The following language must be placed on each product that can be applied aerially:	**"CONTROLLING DROPLET SIZE"** "**!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
The following language must be placed on each product that can be applied aerially:	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE AND HUMIDITY"** "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE INVERSIONS"** "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use
Application Rate Limit for All End-Use Products	If any alachlor end-use products have application rates that are greater than 4lb ai/acre/year, then the label must be amended to be no more than 4 lb ai/acre/year.	Directions for Use Directions for Application

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Table 78: Summary of Required Labeling Changes for Alachlor Products		
Description	**Required Labeling**	**Placement**
Application Restrictions: Mixing/Loading Setbacks	"This product may not be mixed or loaded within 50 feet of perennial or intermittent streams and rivers, natural or impounded lakes and reservoirs. This product may not be mixed/loaded or used within 50 feet of all wells, including abandoned wells (unless the well has been properly capped or plugged), drainage wells, and sink holes. Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or wash-water, and rain water that my fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self-contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above-specified minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site."	Directions for Use
Application Restriction	"Do not apply to highly permeable soils (as classified by the USDA Natural Resources Conservation Service) where the depth to ground water is 30 feet or less."	Directions for Use (Under Use Precautions and Restrictions)
Rotational Crop Restriction	"Rotation to crops not specified on this label is prohibited"	Directions for Use (Under Use Precautions and Restrictions)

c. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell alachlor products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

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VI. APPENDICES

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Appendix A - Table of Use Patterns Subject to this RED

Appendix A is 52 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

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GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case alachlor covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to alachlor in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 605-6000.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

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APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Alachlor

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
830.1550	Product Identity	All	00146114
830.1600 830.1620 830.1650	Starting Material & Mnfg. Process	All	00146114, 40396301
830.1670	Formation of Impurities	All	00146114, 00152206
830.1700	Preliminary Analysis	All	00146114, 00152206
830.1750	Certification of limits	All	00146114
830.1800	Analytical Method	All	00146114, 00147476, 00152206, 40396301
830.6302	Color	All	00146114
830.6303	Physical State	All	00146114
830.6304	Odor	All	00146114
830.6313	Stability	All	00146114
830.7000	pH	All	00146114
830.7050	UV		44492301
830.7200	Melting Point	All	00146114
830.7220	Boiling Point		N/A
830.7300	Density	All	00146114
830.7550	Dissociation Constant		N/A

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REQUIREMENT		USE PATTERN	CITATION(S)
830.7550 830.7560 830.7570	Octanol/Water Partition	All	00146114, 00152209, 00152210, 40396301
830.7840 830.7860	Solubility	All	00146114, 00152209, 40396301
830.7950	Vapor Pressure	All	00146114, 00152209
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	AB	00079523
71-2A	Avian Dietary - Quail	AB	43087101
71-2B	Avian Dietary - Duck	AB	43087001
71-4A	Avian Reproduction - Quail	AB	Data Gap
71-4B	Avian Reproduction - Duck	AB	Data Gap
72-1	Fish Toxicity Bluegill	AB	00023615, 00028551, 00028554, 00031525, 40098001, 43774706
72-1	Fish Toxicity Rainbow Trout	AB	00023616, 00028550, 00028553, 00031524, 40098001, 43774704
72-2	Invertebrate Toxicity	AB	00028549, 00028555, 00031526, 40098001, 43774703(2), 43774705(2)
72-3	Estuarine/Marine Toxicity - Fish	AB	44524301
72-3	Estuarine/Marine Toxicity - Mollusk	AB	44524303
72-3	Estuarine/Marine Toxicity - Shrimp	AB	44524302
72-4A	Early Life Stage Fish	AB	43862601

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REQUIREMENT		USE PATTERN	CITATION(S)
72-4B	Life Cycle Invertebrate	AB	43774707
122-2	Aquatic Plant Phytotoxicity	AB	Data Gap for alachlor (data in review) for alachlor ESA
123-1A	Seed Germination/Seedling Emergence	AB	42468701
123-1B	Vegetative Vigor	AB	42468601
123-2	Aquatic Plant Growth	AB	42763801
141-1	Honey Bee Acute Contact	AB	00074486, 00028772
TOXICOLOGY			
870.1100	Acute Oral Toxicity - Rat	all	00139383, 42701501(1)
870.1200	Acute Dermal Toxicity - Rabbit/Rat	all	00139384
870.1300	Acute Inhalation Toxicity - Rat	all	00109561
870.2400	Primary Eye Irritation - Rabbit	all	00139385
870.2500	Primary Dermal Irritation - Rabbit	all	00139386
870.2600	Dermal Sensitization - Guinea Pig	all	00161728
870.3100	90-Day Feeding - Rodent	AB	00023658, 42863701(1)
870.3150	90-Day Feeding - Non-rodent	AB	00087479
870.3200	21-Day Dermal - Rabbit/Rat	AB	00147328
870.4100 870.4200 870.4300	Chronic Toxicity and Carcinogenicity - Rodent	AB	00139021, 00075709, 00091050, 00141060, 43507601

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REQUIREMENT		USE PATTERN	CITATION(S)
870.4100	Chronic Toxicity and Carcinogenicity - Non-Rodent	AB	00148923
870.3700	Developmental Toxicity - Rat	AB	00043645, 43908101(1)
870.3700	Developmental Toxicity - Rabbit	AB	40579402
870.3800	2-Generation Reproduction - Rat	AB	00075062
870.5300 870.5385 870.5500 870.5550 870.5575	Mutagenicity	AB	00109563, 00141061, 00141062, 00148921, 00155389(2), 00155391(2), 00155392(2), 00155393(2), 00151394(2), 0015395(2), 00151396(2), 00151397(2), 00151398(1),00151399(2), 42651301, 42651301(2), 42651302, 42651303, 43889403(1), 44032103
870.7485	General Metabolism	AB	000132045, 43889404(1), 40000901, 42651306, 42852107, 42651308, 42852108, 42651305, 42852106
870.7600	Dermal Penetration	AB	00149403, 00149404, 00149405
	Special Studies	AB	00023611, 00023612, 00149402, 00149403, 00149404, 00149405, 00150089, 00154238, 00159365, 00159364, 42852102, 43590002, 43889401(1), 43889402(1), 42651307, 42651310, 42852109, 42931101, 42651304, 42651309, 42651311, 42651312, 42651314, 42651318, 42852103, 42852104, 42852105, 42852110, 42852111, 42957201, 43267501, 43369201, 43482301, 43504101, 43507401, 43641603, 43706001, 43590001, 43641604, 43641602, 43729502, 43750801, 43729503, 43729501, 43878501

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REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation		
132-1B	Soil Residue Dissipation		
133-3	Dermal Passive Dosimetry Exposure		
133-4	Inhalation Passive Dosimetry Exposure		
231	Estimation of Dermal Exposure at Outdoor Sites	AB	Data Gap - Impregnation of Dry Bulk Fertilizer
232	Estimation of Inhalation Exposure at Outdoor Sites	AB	Data Gap - Impregnation of Dry Bulk Fertilizer
233	Estimation of Dermal Exposure at Indoor Sites	AB	Data Gap - Impregnation of Dry Bulk Fertilizer
234	Estimation of Inhalation Exposure at Indoor Sites	AB	Data Gap - Impregnation of Dry Bulk Fertilizer
ENVIRONMENTAL FATE			
161-1	Hydrolysis	AB	00134327
161-2	Photodegradation - Water	AB	00023012
162-1	Aerobic Soil Metabolism	AB	00023014, 00101531, 00134327
163-1	Leaching/Adsorption and Desorption	AB	00027139, 00027140, 00078301, 00134327, 42485703[3], 42485704[3], 44405301[1]
164-1	Terrestrial Field Dissipation	AB	42528001, 42528002, 42528003, 42528004, 43774701

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REQUIREMENT		USE PATTERN	CITATION(S)
201-1	Droplet Size Spectrum	AB	Reserved - Spray Drift Task Force (data in review)
202-1	Drift Field Evaluation	AB	Reserved - Spray Drift Task Force (data in review)
	Special Studies Monitoring Data	AB	41400001, 41400002, 41400003, 41400004, 44592401, 40265901, 00158911, 41065205, 441095503
RESIDUE CHEMISTRY			
165-1	Rotational Crop (Confined)	AB	42395301, 42395302
165-2	Rotational Crop (Field)	AB	43442001 Data Gap (Data in Review)
171-4A	Nature of Residue - Plants	AB	00026221, 00081314, 00131424
171-4B	Nature of Residue - Livestock	AB	00137777, 00137778, 00147472, 00147473, 40393901, 40394001, 42594901, 42594902, 42594903, 42594904
171-4C/D	Residue Analytical Method - Plants and Animals	AB	00023663, PP#9F0740, 00093160, 00148285, 00149999, 00152197, 00154237, 00154332, 00155732, 00159793, 00159796, 00162939, 40039901, 40040301, 40040401, 40271801, 40271802, 40529201, 40558001, 40820601, 41916001, 41949601, 42086001, 42192501, 42286701, 42286702, 42308701, 42349101, 43140001
171-4C/D	Residue Analytical Method - Water	AB	Data Gap

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Data Supporting Guideline Requirements for the Reregistration of Alachlor

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	Storage Stability	AB	00149406, 00150090, 00152198, 00152868, 00154237, 40491101, 40628301, 40946901, 42239501
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	AB	00149406, 00150090, 00152198, 00152868
171-4K	Crop Field Trials		
	Root and Tuber Vegetable Group		
	Potatoes		tolerance revoked
	Legume Vegetables (Dry Succulent) Group		
	-Beans, succulent and dry	AB	00022988, 00026995, 00035389, 00035390, 00035391, PP#3F1406, 00147475, 40039901, 40040301, 40189701, 40341201, 41083801
	-Peas, succulent and dried		tolerance revoked
	-soybeans	AB	00023664, 00025262, 00148285, 00152197, 40511901, 41862901, 41916301, 42309001, 42313301, 42348901, 42349101, PP#3F2313
	Foliage of Legume Vegetables Group		
	-beans, vines and hay	AB	00022988, 00026995, 00035389, 00035390, 00035391, PP#3F1406, 00147475, 40039901, 40040301, 40189701, 40341201, 41083801, PP#3F4179
	-peas, vines and hay		tolerance revoked
	-soybeans, forage and hay	AB	00023664, 00025262, 00152197, 41140801, 42348901, 42349101, PP#9F3776

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REQUIREMENT	USE PATTERN	CITATION(S)
Cereal Grains Group		
-corn, field, grain	**AB**	**00023665, 00035395, 00035399, PP#9F0740, 00152197, 00155732, 00159793, 40502101, 42348902, 42349101, 42741601**
-corn, sweet	**AB**	**00023665, 00035395, 00035399, PP#9F0470, 00152197, 00155732, 00159793, 40502101, 40662601, 42929901, 42934401**
-sorghum, grain	**AB**	**00028556, 00028557, 00028558, 00068044, 00068045, PP#0F2338, 00159796, 40271801, PP#8F3671**
Forage, Fodder and Straw of Cereal Grains Group		
-corn, field, forage and fodder	**AB**	**00023665, 00035395, 00035399, PP#9F0740, 00152197, 00159793, 40502101, 42348902, 42349101, PP#0F2348**
-corn, sweet, forage	**AB**	**00023665, 00035395, 00035399, PP#9F0740, 00152197, 00159793, 40502101, 40662601, 42741601, 42929901, PP#0F2348**
-sorghum, forage and fodder	**AB**	**00068044, 00068045, 00159796, 40271801, 40511201, PP#8F3671**
Miscelllaneous Commodities		
-Cotton	**AB**	**tolerance revoked**
-peanuts	**AB**	**00024526, 00081311, PP#7G2002, 00152199, 00159936, 40511301, 40820601, 42971701, PP#0F2313, FAP#1H5612**
-sunflower	**AB**	**tolerance revoked**

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Data Supporting Guideline Requirements for the Reregistration of Alachlor

REQUIREMENT		USE PATTERN	CITATION(S)
171-4L	Processed Food		
	-corn, field	AB	00162939, 40788201
	-peanuts	AB	PP#0F2313/FAP#1H5612, 00162937, 40040401, 41856301, 42302001
	-sorghum	AB	40271802
	-soybeans	AB	00148285, 00152197, 00154239, 00154240, 40947101, 41862901, 41916301
	-sunflower	AB	00147471, 40040101, 40314601, 40529201
171-5	Reduction of Residues	AB	40330301, 40820601, 40820701, 42158601, 42276701, 42300701, 42309001
	Footnotes:		
	(1). test material alachlor ESA		
	(2). test material other metabolites of alachlor		
	(3). Test material metabolites of propachlor		

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GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

      (1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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BIBLIOGRAPHY

MRID	CITATION
00022998	Monsanto Company (1968) Full Reports of Investigations Made with Respect to the Safety of the Pesticide Chemical: [Lasso]. Summary of studies 004026-C through 004026-E. (Unpublished study received Dec 20, 1968 under 524-287; CDL:004026-B)
00023012	Sutherland, M.L.; Curtis, T.G.; Darlington, W.A.; et al. (1972) Final Report on Lasso and the Environment: Part 4: Photolysis of Lasso on Soil and in Water: Agricultural Research Report No. 262. (Unpublished study received Jun 29, 1973 under 3F1372; submitted by Monsanto Co., Washington, D.C.; CDL:093660-L)
00023014	Sutherland, M.L.; Curtis, T.G.; Darlington, W.A.; et al. (1972) Final Report on Lasso and the Environment: Part 6: Soil Dissipation of Lasso: Agricultural Research Report No. 264. (Unpublished study received Jun 29, 1973 under 3F1372; submitted by Monsanto Co., Washington, D.C.; CDL:093660-N)
00023611	Shelanski, M.V. (1968) To Determine Whether or Not Repeated Contact with the Test Material under Controlled Conditions Presents a Hazard to the Skin of Human Volunteers: Project No. SH-67-9. (Unpublished study received Aug 16, 1978 under 524-285; prepared by Industrial Biology Research and Testing Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:234629-B)
00023612	Shelanski, M.V. (1968) To Determine If the Test Material Is Capable of Irritating the Skin of Humans under Controlled Test Conditions: IBT: 1978 under 524-285; prepared by Industrial Biology Research and Testing Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:234629-C)
00023615	Thompson, C.M.; Forbis, A.D.; McAllister, W.A. (1978) Acute Toxicity of Technical Alachlor (AB-78-166) to Bluegill Sunfish (Lepomis macrochirus). (Unpublished study received Aug 16, 1978 under 524-285; prepared by Analytical Biochemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL: 234628-C)
00023616	Forbis, A.D.; McAllister, W.A. (1978) Acute Toxicity of Technical Alachlor to Rainbow Trout (Salmo gairdneri). (Unpublished study received Aug 16, 1978 under 524-285; prepared by Analytical Biochemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:234628-D)
00023658	Wolf, C. (1966) Report to Monsanto Company: 90-Day Subacute Oral Toxicity of CP50144--Albino Rats: IBT No. B4477. (Unpublished study received Dec 1, 1966; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:090813-C)
00023663	Monsanto Company (19??) Chemical Analytical Residue Methods. Three undated methods. (Unpublished study received Dec 1, 1966 under 7F0622; CDL:090813-H)

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MRID	CITATION
00023664	Monsanto Company (1966) Results of Analysis of Field Treated Soybeans. (Unpublished study received Dec 1, 1966 under 7F0622; CDL:090813-I)
00023665	Monsanto Company (1966) Results of Analysis of Field Treated Corn. (Unpublished study received Dec 1, 1966 under 7F0622; CDL: 090813-J)
00024526	Monsanto Company (1971) Chemical Residue Studies on Peanuts, Peanut Hulls and Peanut Vines. (Unpublished study received Mar 5, 1975 under 3F1334; CDL:093569-B)
00025262	Monsanto Company (1966) Results of Analysis of Field Treated Soybeans: [Alachlor]. (Unpublished study received Sep 11, 1968 under 9F0740; CDL:091280-B)
00026221	Monsanto Company (19??) Summary on Metabolism of CP 50144 in Soybeans and Corn. (Unpublished study received Dec 1, 1966 under 7F0622; CDL:090813-M)
00026995	Monsanto Company (1969) Reasonable Grounds in Support of the Petition for Residue Tolerance: [Lasso]. (Unpublished study received on unknown date under 2G1176; CDL:095433-F)
00027139	Weidner, C.W. (1974) Degradation in Groundwater and Mobility of Herbicides. Master's thesis, Univ. of Nebraska, Dept. of Agronomy. (Unpublished study received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234472-O)
00027140	Lavy, T.L. (1974) Mobility and Deactivation of Herbicides in SoilWater Systems: Project A-024-NEB. (Available from: National Technical Information Service, Springfield, VA: PB-238 632; unpublished study received Jul 19, 1978 under 201-403; prepared by Univ. of Nebraska, Water Resources Research Institute, submitted by Shell Chemical Co., Washington, D.C.; CDL:234472-P)
00028549	McAllister, W.A.; Forbis, A.D. (1978) Acute Toxicity of Technical Alachlor (AB-78-200) to Daphnia magna. (Unpublished study received Dec 28, 1979 under 524-285; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241535-A)
00028550	Thompson, C.M.; Forbis, A.D. (1978) Acute Toxicity of Lasso (MCB/ Cg) (AB-78-111) to Rainbow Trout (Salmo gairdneri). (Unpublished study received Dec 28, 1979 under 524-285; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241535-B)
00028551	Thompson, C.M.; Forbis, A.D. (1978) Acute Toxicity of Lasso (MCB/ Cg) (AB-78-111) to Bluegill Sunfish (Lepomis macrochirus). (Unpublished study received Dec 28, 1979 under 524-285; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL: 241535-C)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms(Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms (Insert B) (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

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You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice.

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Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form((Insert B).

The Data Call-In Response Forms(Insert A) must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms(Insert B) also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms(Insert A) and the Requirements Status and Registrant's Response Forms(Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms(Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms (Insert B). You must also complete a Data Call-In Response Form(Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form(Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form(Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response

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Form (Insert A). Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B) and item 6b on the Data Call-In Response Form (Insert A). If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form(Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be submitted as

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part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form(Insert B) also must be submitted for each product listed on the Data Call-In Response Form(Insert A) unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form(Insert A) and Requirements Status and Registrant's Response Form (Insert B) (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form(Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms(Insert B). If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant’s Response Form(Insert B) and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form(Insert A). Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B). If you choose this option, you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

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III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form(Insert A) that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form(Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for

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studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form(Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request

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EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

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a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both documents available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA".

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA."

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form(Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

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Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B), and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form(Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume/minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume/minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume/minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas,

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cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

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b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form(Insert B). Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

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1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B).

   b. Fulfill the commitment to develop and submit the data as required by this Notice; or

   c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

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IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell,

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distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Insert A)and completed Requirements Status and Registrant's Response Forms (Insert B), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms(Insert A) need be submitted.

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The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

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ALACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing alachlor.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of alachlor. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this alachlor Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for alachlor are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on alachlor are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible alachlor products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 308-8585.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Veronica Dutch
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **alachlor**

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ALACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing alachlor.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of alachlor. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this alachlor Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for alachlor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on alachlor are needed. These data are needed to fully complete the reregistration of all eligible alachlor products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Kathryn Boyle at (703) 305-6304.

All responses to this Notice for the generic data requirements should be submitted to:

Kathryn Boyle, Chemical Review Manager
Reregistration Branch III
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: alachlor

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Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" (Insert A) and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms."(Insert A) Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

INSERT A

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms (Insert B)

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

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Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

INSERT B
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form(Insert B) that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

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If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

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INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

INSERT B CONTINUED
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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Instructions For Completing The "Requirements Status and Registrant's Response Forms" (Insert B) For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form(Insert B).

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INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B) continued

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled

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PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

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Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

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Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" (Insert B) for generic data.

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Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" (Insert B) for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the

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option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

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EPA'S BATCHING OF ALACHLOR PRODUCTS FOR MEETING ACUTE MAMMALIAN TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing Alachlor as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

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In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twelve active products were found which contain Alachlor as the active ingredient. These products have been placed into the "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling.

The following product(s) may cite acute data as follows:

- EPA Reg. No. 524-344 may be supported by acute oral, acute dermal and/or acute inhalation data generated with EPA Reg. Nos. 524-403 or 524-316.

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	241-311	Alachlor 34.5 Imazaquin 2.2	Liquid
	241-329	Alachlor 32.4 Imazaquin 1.9	Liquid
	524-296	15.0	Solid
	524-314	45.1	Liquid

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No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	524-315	60.0	Liquid
	524-316	90.0	Liquid
	524-329	Alachlor 27.2 Atrazine 15.5	Liquid
	524-341	Alachlor 27.6 Glyphosate 14.8	Liquid
	524-344	41.5	Microencap Liquid
	524-403	65.0	Microencap Solid
	524-418	Alachlor 25.2 Atrazine 14.3 Related atrazine compounds 0.8	Microencap Liquid
	524-422	Alachlor 31.7 Trifluralin 3.9	Liquid

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This page has been inserted as a place marker and is replaced by an electronically generated PDCI List of Registrants page number 1 in the actual Printed version of the Red document

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.
   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.

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8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

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4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   b. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   c. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   d. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   e. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:
   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site at ace.orst.edu/info/nptn/.

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The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

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List of Available Related Documents

The following is a list of available documents for Dicofol that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDs, or contact Kathryn Boyle at (703) 305-6304.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Alachlor

The following documents are part of the Administrative Record for Alachlor and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria

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