United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA 738-R-015 November 1998

Reregistration Eligibility Decision (RED)

Propachlor

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 propachlor. 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 propachlor 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 Anne Overstreet at (703) 308-8068.

Sincerely,

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

Enclosures

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 or 800-553-6847).

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 Data Compensation Requirements**. Complete and sign EPA form 8570-31 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.

REREGISTRATION ELIGIBILITY DECISION

PROPACHLOR

LIST A

CASE 0177

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GLOSSARY OF TERMS AND ABBREVIATIONS

PROPACHLOR REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Alan Halvorson	Economic Analysis Branch
James Saulmon	Herbicide and Insecticide Branch

Environmental Fate and Effects Risk Assessment

Jose Melendez	Environmental Risk Branch IV
Nelson Thurman	Environmental Risk Branch IV
Richard Felthousen	Environmental Risk Branch IV
Sid Abel	Environmental Risk Branch IV
Mike Rexrode	Environmental Risk Branch IV

Health Effects Risk Assessment

Kathryn Boyle	Risk Characterization and Analysis Branch
William Hazel	Chemistry and Exposure Branch I
Linda Taylor	Toxicology Branch II
Christina Swartz	Chemistry and Exposure Branch II

Registration Support Risk Assessment

Jim Tompkins	Herbicide Branch

Risk Management

J. Anne Overstreet	Reregistration Branch III

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
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
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

GLOSSARY OF TERMS AND ABBREVIATIONS

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 © 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.
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide propachlor and determined that most 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.

Propachlor is a pre-emergent herbicide used to control grasses and broadleaf weeds in sorghum, corn and onion seed (registered for use only in Washington and Oregon). The pesticide can be applied with a groundboom sprayer, tractor-drawn broadcast spreader and granular row planter. Propachlor was first registered as a pesticide in the U.S. in 1964. Propachlor is produced by the Monsanto Company, which currently holds most registrations.

Registration Eligibility

The Agency has concluded under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that most uses, as prescribed in this document, will not cause unreasonable adverse effects on human health or the environment and therefore most products are eligible for reregistration. In developing this decision, the registrant has agreed to various risk mitigation measures and to voluntarily cancel the registrations of dry flowable formulations. Among other labeling changes, the registrant has agreed to require a closed mixing/loading system for liquid applications on corn and sorghum; an enclosed cab for goundboom spraying operations; and a double layer body covering ensemble for mixing/loading and applying the granular formulation to corn and sorghum. Workers who re-enter treated fields within the 48 hour restricted entry interval (REI) must wear eye protection. In addition, the registrant has agreed to limit the rotation of crops on propachlor-treated fields to those crops for which there are registered propachlor uses. To address uncertainties associated with the environmental fate profile and certain ecological hazards of propachlor, the Agency is calling-in additional aerobic soil and aquatic metabolism studies, and some acute toxicity studies.

Tolerance Reassessment

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 a pesticide and other compounds with a common mechanism of toxicity. The FQPA further directs the Agency 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.

Although propachlor is structurally similar to the following acetanilides: acetochlor, butachlor, metolachlor, and alachlor, 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 propachlor only. The risk assessment has been performed for propachlor 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.

The Agency has reassessed propachlor food tolerances under the standards of FQPA and determined, based on available information, that there is a reasonable certainty of no harm will result to infants and children or to the general population from aggregate exposure to propachlor residues. Propachlor is not registered for residential uses. Thus, for the purposes of tolerance reassessment the only routes of exposure to humans are through food and water residues. Combining the exposure to propachlor in food and water, the Agency found that the aggregate risk did not exceed the Agency's level of concern. In addition, as a result of new data on the concentrations of propachlor residues in food and because of the existence of certain obsolete tolerances, some existing tolerances have been refined and the unsupported tolerances will be revoked in conjunction with this action.

Toxicology of Propachlor

The Agency has reviewed the available toxicology data and found the information sufficient for assessing the acute, sub-chronic, chronic toxicity and carcinogenic potential of propachlor. Propachlor has been classified as a "Likely" human carcinogen (or B2), based on the (1) rare stomach tumor in male Fischer 344 rats; (2) thyroid tumors in male and ovarian granulosa/theca cell tumors in female Sprague-Dawley rats at doses that were not adequate to assess carcinogenicity; (3) hepatocellular tumors in male CD-1 mice; (4) in vitro clastogenic activity; and (5) tumors observed at one or more of the same sites with three structurally-related chloroacetanilide compounds. Because propachlor is highly toxic to the eye, the Agency has placed propachlor in Toxicity Category I (the highest of four categories) for this effect.

The Agency has found the database for developmental and reproductive toxicity of propachlor to be complete at this time. A developmental neurotoxicity study was not required. Nor is there a unique or special sensitivity for pre- or post-natal exposure. Based on these factors, the Agency has concluded that there is not a basis for retaining the additional 10X safety factor from FQPA. An uncertainty factor of 100 will adequately protect infants and children.

The Agency has decided to use a Q_1* approach for assessing the carcinogenic risk of chronic exposure to propachlor. The Reference Dose (RfD) for propachlor was determined by the Agency

to be 0.054 mg/kg/day, based on the rat chronic toxicity study (NOEL = 5.4 mg/kg/day) and a standard uncertainty factor of 100.

Human Health Risk (Dietary Risk)

The general public may be exposed to residues of propachlor through the diet because propachlor is used on number of food and/or feed crops and the pesticide has the potential to reach ground and surface waters. The Agency, however, has determined that neither the parent propachlor nor its degradates pose a significant threat to ground-water quality under most conditions.

Three acid degradates of propachlor have the potential to leach and to persist in ground water. Detections of propachlor and/or its metabolites have been reported (0.02-3.5 ppb) in some wells, suggesting that this chemical or its degradates reach ground water under certain conditions. Propachlor is most likely to reach ground water in soils which have little microbiological activity, high permeability, and a shallow water table. In addition, based upon limited fate data, the three major acid degradates of propachlor appear to be available for runoff longer than the parent, moving primarily by dissolution in runoff water. Thus, in some cases propachlor residues are detectable in surface waters. To address uncertainties associated with the environmental fate profile of propachlor, the Agency is calling-in additional aerobic soil and aquatic metabolism studies.

For the purposes of conducting dietary risk assessments, the Agency estimated the dietary exposure to propachlor residues on the bases of acute and chronic exposure scenarios.
The Agency assessed the acute dietary risk posed by propachlor and found Margins of Exposure (MOE) for food residues within acceptable ranges. In addition, when combining food residues and anticipated drinking water exposure, the Agency calculated the MOE's for acute dietary risk for adult males and females in the range of 17,000 to 53,000.

The chronic dietary risk is also within acceptable limits, even when using conservative assumptions. For the overall U.S. population, chronic (non-cancer) risk from all current propachlor tolerances represents less than 1% of the Reference Dose (RfD), or an amount believed not to cause adverse effects if propachlor residues are consumed daily over a 70-year lifetime. In addition, the Agency calculated the lifetime cancer risk from exposure to dietary residues of propachlor (combined food and water sources) to be 9.3×10^{-7} for females and 9.0×10^{-7} for males.

The Agency was also concerned about potential exposure to propachlor from residues taken up by rotational food and/or feed crops grown on propachlor-treated fields. The Agency concluded that it would be prudent to limit the rotation of crops on propachlor-treated fields to only those crops for which there are registered propachlor uses.

Human Health Risk (Occupational)

The Agency is concerned about the risk posed to propachlor handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated areas following

application of this herbicide. In accordance with this decision, exposure and risk to workers will be mitigated by the use of Personal Protective Equipment (PPE) as required by the Worket Protection Standards, and supplemented by requiring the use of additional PPE, enclosed cabs and closed mixing/loading systems. The Agency is also requiring that post-application reentry workers observe a 48-hour Restricted Entry Interval based on propachlor's classification as a toxicity category I (severe) for eye irritant and strong dermal sensitizer.

Based on current use patterns, the Agency determined that propachlor has the potential to expose handlers (mixers, loaders, and applicators) in agricultural settings during and after normal use of the pesticide. The Agency assessed the following major exposure scenarios for propachlor: (1) mixing/loading liquids for groundboom application; (2) mixing/loading dry flowables for groundboom application; (3) loading granulars for tractor-drawn spreader application; (4) applying sprays with groundboom equipment; and (5) applying granulars with a tractor-drawn spreader. The Agency found that some of these scenarios resulted in high exposure without taking additional exposure reduction measures.

In developing this decision document, the registrant has agreed to various risk mitigation measures to address those scenarios with the potential to expose workers. Regarding the highest occupational risk calculated by the Agency, the registrant agreed to voluntarily cancel the dry flowable formulation. Among other labeling changes, the registrant has agreed to require a closed mixing/loading system for liquid applications on corn and sorghum; an enclosed cab for goundboom spraying operations; and a double layer body covering ensemble for mixing/loading and applying the granular formulation to corn and sorghum. Workers who re-enter treated fields within the 48 hour restricted entry interval (REI) must wear eye protection.

Environmental Fate and Ecological Risk

Propachlor poses some risk to non-target organisms, but is generally considered to be a low to moderate concern in the environment. The Agency has no reported incidences of adverse impacts on non-target organisms from the use of propachlor. The available toxicity date on propachlor suggests that the compound is (1) moderately toxic to birds on both an acute oral and chronic basis; (2) practically non-toxic to mammals on an acute oral basis; (3) practically non-toxic to bees on an acute oral basis and a subacute dietary basis; and (4) moderately to highly toxic to freshwater fish on an acute basis. Although no aquatic invertebrate studies have been performed, a comparative analysis yielded a Risk Quotient (RQ) factor which does not trigger a need for any further testing on freshwater fish.

The granular formulations of propachlor pose the greatest risk to non-target organisms. The potential for chronic (long-term) exposure of propachlor to non-target organisms, however, is tempered because the pesticide is not persistent under most conditions and because the pesticide is only applied once per growing season.

The Agency is requiring the submission of additional environmental fate and ecological effects data, including the following guideline (GLN) studies:

II. GLN 72-3 (a): Acute toxicity to estuarine and marine fish
- GLN 72-3 (b): Acute toxicity to estuarine and marine mollusks
- GLN 72-3 (c): Acute toxicity to esturarine and marine shrimp
- GLN 123-2: Aquatic Plant Growth on four of the five required species is still outstanding: *Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom.
- GLN 162-1: Aerobic Soil Metabolism. An additional study is needed to better characterize the rate of dissipation of propachlor.
- GLN 162-4: Aerobic Aquatic Metabolism
- GLN 165-1: Limited Field rotational Crop

Product Reregistration

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

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 is embarking 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 will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. Therefore, 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 propachlor, 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 propachlor, 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 propachlor. Section V discusses the reregistration requirements for propachlor. 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.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Propachlor
- **Chemical Name:** 2-chloro-N-isopropylacetanilide
- **Chemical Family:** Acetanilide
- **CAS Registry Number:** 1918-16-7
- **OPP Chemical Code:** 019101
- **Empirical Formula:** $C_{11}H_{14}ClNO$
- **Trade and Other Names:** n/a
- **Basic Manufacturers:** Monsanto Agricultural Company

Chemical Profile

Physical state: solid
Color: light brown (TGAI)
Odor: pungent
Solubility: water (613 ppm at 25°C)
At 20°C the following solubilities in g/100 mL

acetone	30.9	benzene	50.0
Ccl_4	14.8	ethanol	29.0
xylene	19.3	chloroform	soluble
toluene	soluble	ethyl ether	soluble

Vapor pressure: 7.9×10^{-5} mm Hg
Calc. Henry's Law Constant: 3.59×10^{-8} atm m^3/mol
Octanol/water partition coefficient: 201

Nomenclature for the parent propachlor and its major degradation products:

Propachlor = 2-chloro-N-isopropylacetanilide

propachlor oxanilic acid = [(1-methylethyl)phenylamino]oxoacetic acid

propachlor sulfonic acid = 2-[(1-methylethyl)phenylamino]-2-oxoethanesulfonic acid

propachlor sulfinylacetic acid = (([(1-methylethyl)phenylamino]acetyl)sulfinyl)acetic acid

hydroxypropachlor (sometimes called propachlor alcohol) = 2-hydroxy-N-(1-methyl-ethyl)-N-phenylacetamide

propachlor methylsulfone = N-(1-methylethyl)-2-(methylsulfonyl)-N-phenylacetamide

norchloropropachlor = N-(1-methylethyl)-N-phenylacetamide

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods.

For propachlor:

Type of Pesticide: Herbicide

Use Sites: Corn, Sorghum, and Onions grown for seed in Washington and Oregon (non-food)

Target Organisms: According to the labels, the formulated products control or reduce competition from the following weeds:

Broadleaf Weeds: wild buckwheat; buttonweed; carpetweed; cocklebur; groundsel; jimsonweed; kochia; ladysthumb; lambsquarters; annual morningglory; mustard; nightshade, black, hairy; pigweed; purslane; Florida pusley; smartweed, Pennsylvania; and velvet.
Grasses: barnyardgrass; crabgrass; foxtail, giant, green, and yellow; goosegrass; wild millet; fall panicum; sandbur; and broadleaf signalgrass.

Formulation Types Registered: manufacturing product (93% and 96.5% A.I.); a flowable concentrate (31.5% and 42% A.I.); a dry flowable (48.1% A.I. formulated with atrizine) and a granular (20% A.I.)

Method and Rates of Application:

Equipment - Propachlor can be applied with groundboom sprayers, tractor drawn broadcast spreaders, and granular row planters.

Method and Rate -Application rates vary from 3.0 to 6.0 pounds active ingredient per acre depending upon the application scenario.

Timing - pre-emergent

Use Practice Limitations: All labels include hazard statements for humans and domestic animals requiring that the product be kept away from humans, domestic animals, and pets.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of propachlor. These estimates are derived from a variety of published and proprietary sources 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.

Based on available pesticide usage information for 1987 through 1996, average annual domestic usage of propachlor is approximately 2.1 million pounds active ingredient (a.i.). In terms of pounds a.i., total usage is allocated primarily to sorghum (75%) and field corn (24%). On average, 6% of sorghum acreage is treated, while less than 1% of field corn, and bulb crops (including onions) were treated. Except for sorghum, usage generally has been declining over the past few years based on the raw usage data.

Table 1: Various U.S. Crops Treated Annually with Propachlor

		Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Application Rates			States of Most Usage
Site	(000) Acres Grown	Weighted Average	Est Max	Weighted Average	Est Max	Weighted Average	Est Max	lb ai/ acre/yr	# appl /year	lb ai/A/ appl	% of Total lb/ai used at these sites
AG SITES											
Bulb Crops [1]	194	1	1	0.4%	1%	1	2	1.5	1.0	1.5	OH (100%)
Corn, Sweet	805	3	4	0.4%	0.5%	6	8	1.9	1.0	1.9	MN OR (92%)
Sorghum	10,932	693	878	6%	8%	1,584	2,283	2.3	1.0	2.3	NE KS AR MO (80%)
TOTAL		948	1,548			2,115	3,765				

1 Bulb crops consist of garlic, leeks, and onions

COLUMN HEADINGS

-Weighted averages: the most recent years and more reliable data are weighted more heavily.
-Average application rates are calculated by dividing average pounds a.i. by average acre-treatments or acres treated.

NOTES ON TABLE DATA

-Usage data cover 1987 -1996.
-Calculations of some of the above numbers may not appear to agree because of rounding.
-A dash (-) indicates that information is NOT available in EPA sources or is insufficient for estimation.
-Any crops not included in the table receive little or no treatment (<1% of crop treated) according to data sources.

SOURCES: EPA data, USDA, and National Center for Food and Agricultural Policy.

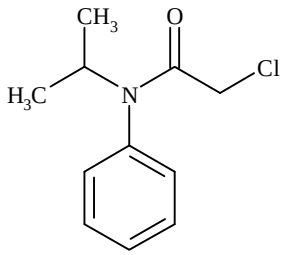
D. Data Requirements and Regulatory History

Propachlor was registered in the United States in 1964 for use as a herbicide. A Data Call-In was issued for propachlor requiring additional data to complete the risk assessment. A Registration Standard for propachlor was issued in December 1984. These documents summarized the regulatory conclusions based on the available residue chemistry data, and specified the additional data required for reregistration purposes. Data submitted and evaluated following the Update are incorporated into this Reregistration Eligibility Decision, which outlines the Residue Chemistry Science Assessments with respect to the reregistration of propachlor. The conclusions are based on the use patterns supported by the basic producer, Monsanto Agricultural Company.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Propachlor [2-chloro-N-isopropylacetanilide] is a selective herbicide used for the preemergence control of grasses and certain broadleaf weeds in corn and sorghum.



Empirical Formula:	$C_{11}H_{14}ClNO$
Molecular Weight:	211.69
CAS Registry No.:	1918-16-7
PC Code No.:	019101

1. Identification of Active Ingredient

Propachlor is a light tan/brown solid with a melting point of 67-76 C. Propachlor is practically insoluble in water (0.058 g/100 g at 20 C) and readily soluble in organic solvents including acetone, benzene, chloroform, carbonteterachloride, ethanol, ethyl ether, toluene, and xylene.

2. Manufacturing-use Products

A search of the Reference Files System (REFS) conducted 2/27/97 identified two manufacturing-use products (MPs): the Monsanto Agricultural Company 96.5% technical product (T; EPA Reg. No. 524-310) and the Drexel Chemical Company 93% T (EPA Reg. No. 19713-163).

3. Regulatory Background

The Propachlor Guidance Document (dated 12/84) required additional generic and product-specific product chemistry data for the Monsanto 96.5% T. The Propachlor Reregistration Standard Update (dated 4/10/90) reviewed data submitted in response to the Guidance Document and summarized the product chemistry database for the Monsanto 96.5% T; data for the Drexel 93% T were not reviewed in the Update because this product was registered subsequent to issuance of the Guidance Document. Additional data were required concerning GLNs 61-3, 62-2, and 63-20 (now OPPTS 830.1670, 830.1750, and 830.6320) for the Monsanto 96.5% T.

4. Conclusions

All pertinent data requirements are satisfied for the Monsanto and Drexel propachlor Ts, except for a new data requirement concerning UV/visible absorption for the PAI (OPPTS 830.7050), which applies to the Monsanto 96.5% T. Provided that Monsanto submits the data required in the attached data summary table for the 96.5% T and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Agency has no objections to the reregistration of propachlor with respect to product chemistry data requirements.

B. Human Health Risk Assessment

1. Toxicology Assessment

Toxicology data are used by the Agency 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 toxicology profile for propachlor is summarized below. The toxicology database on propachlor is complete and will support reregistration eligibility.

Table 2: Toxicology Profile

Guideline	OPPTS #	Study Type	MRID #	Required	Satisfied
81-1	870.1100	acute oral - rats	00104350	yes	yes
81-2	870.1200	acute dermal - rabbits	00104351	yes	yes
81-3	870.1300	acute inhalation - rats	41986001	yes	yes
81-4	870.2400	primary eye irritation	00151787	no	yes
81-5	870.2500	primary dermal irritation	00104353	no	yes
81-6	870.2600	dermal sensitization	00151789	no	yes
81-7	870.6100	acute delayed neurotoxicity - hen	-	no	no
81-8	870.6200	acute neurotoxicity - rat	42584702	yes	yes
82-1	870.3100	subchronic feeding - rats subchronic feeding - mice	00152151 00152865	yes no	no[1] no[2]

Guideline	OPPTS #	Study Type	MRID #	Required	Satisfied
82-1	870.3150	subchronic feeding - dog	00157852	yes	yes
82-2	870.3200	21-day dermal - rats	44590801	yes	no[4]
82-5	870.6100	subchronic neurotoxicity - rats	43575701	yes	yes
83-1(a)	870.4100	chronic toxicity - rats	44168301	yes	yes
83-1(b)	870.4100	chronic toxicity - dog	40081601	yes	yes
83-2	870.4200	carcinogenicity - mice	40162501 40248701 44069801 44158001	yes	yes
83-3(a)	870.3700	developmental toxicity - rat	00115136	yes	yes
83-3(b)	870.3700	developmental toxicity - rabbits	00150936 40113801 40398301 42348002 42584701	yes	yes
83-4	870.3800	2-generation reproduction - rats	00157168 43226701 43862901	yes	yes
83-5	870.4300	chronic toxicity/carcinogenicity - rat	40473101 44168301	yes	yes
84-2	870.5140	gene mutation	00153939	yes	yes
84-2	870.5385	chromosomal aberration	00153940 40312701	yes	yes
84-2	870.5500	other genotoxic effects	00144512 40068401 43221801	yes	yes
85-1	870.7485	metabolism	00157496- 00157500 00157502- 00157507	yes	yes
85-2	870.7600	dermal penetration	-	no[3]	no
86-1	870.7200	domestic animal safety	-	waived	no

1 Classified unacceptable, but there is a chronic toxicity study available and a repeat of the subchronic study is not required.
2 Classified unacceptable, but there is a carcinogenicity study available and a repeat of the subchronic study is not required

3 Generally, a dermal penetration study is required for a chemical with a significant route of human exposure for which the assumption of 100% absorption does not produce an adequate margin of exposure. For propachlor additional information, such as a dermal absorption factor is necessary to refine the occupational assessment.
4 The 21-day sermal toxicity study is classified as unacceptable but upgradeable. It does not satisfy the guideline requirement for a repeated dose [21-day] dermal toxicity study in rats. This study can be upgraded with the submission of an examination of the spleens in the rats of both sexes at the two lower dose levels.

a. Acute Toxicity

Sufficient data are available on the acute toxicity of propachlor. Acute toxicity values and categories for propachlor are summarized in Table 3. The acute toxicity data requirements [§81-1 through §81-8] are satisfied.

Table 3: Acute Toxicity of Propachlor

Guideline/ OPPTS # Study Type	MRID	Results	Toxicity Category
81-1 870.1100 Acute Oral - rat	00104350	LD_{50} = 1.8 g/kg	III
81-2 870.1200 Acute Dermal - rabbit	00104351	LD_{50} > 20 g/kg	IV
81-3 870.1300 Acute Inhalation - rat	41986001	LC_{50} = > 1.2 mg/L	III
81-4 870.2400 Primary Eye Irritation - rabbit	00151787	severe irritant	I
81-5 870.2500 Primary Skin Irritation - rabbit	00104353	slight irritant	IV
81-6 870.2600 Dermal Sensitization - guinea pig	00151789	strong dermal sensitizer	-
81-8 870.6200 Acute Neurotoxicity - rat	42584702	systemic NOEL = 175 mg/kg, systemic LOEL = 350 mg/kg, based on an increase in landing foot splay at 7 hours [peak effect time]	-

Propachlor is highly toxic via the ocular route of exposure. In a primary eye irritation study with rabbits, the test material was a severe irritant. This is toxicity category I. In a dermal sensitization study in guinea pigs, propachlor was found to be a strong dermal sensitizer. The acute oral neurotoxicity study in the rat is discussed in the section on Neurotoxicity Studies.

b. Subchronic Toxicity

Although the mouse and rat studies were classified as unacceptable, sufficient data for the purposes of reregistration are available on the chronic toxicity of propachlor.

In a 21-day dermal toxicity study (MRID 44590801), propachlor [98.25% a.i.] was administered to 10 rats/sex/dose via the skin [=10% of the body surface area] at dose levels of 0, 40, 150, and 500 mg/kg/day for 21 days [five days per week for three consecutive weeks]. All rats survived until study termination. There was a dose-related increase in the frequency of the dermal response [very slight erythema, very slight edema, focal/pinpoint eschar, and slight to moderate disquamation], and the males displayed a greater response than did the females. Body-weight gain fluctuated throughout the study, with the high-dose males and the mid-dose females displaying a significant decrease during the last week of dosing, and the high-dose females displaying a significant decrease during the first week of dosing. The overall body-weight gain for the high-dose males was 91% of the control value. The overall body-weight gain for the females was 82% of control for the mid-dose females and 81% of control for the high-dose females. There was no adverse effects on body weight, food consumption, hematology, clinical chemistry, and organ weights, and gross microscopic findings were comparable among the groups for both sexes, although both sexes displayed congestion of the spleen at the high-dose level. This 21-day dermal study is classified as unacceptable but upgradeable, and it does not satisfy the guideline for a repeated dose [21-day] dermal toxicity study [OPPTS 870.3200] in rats.

In a subchronic feeding study [MRID 00152151], 30 Sprague-Dawley rats/sex/group were administered propachlor [96.1%] via the diet at dose levels of 0, 300 ppm [≈15 mg/kg/day], 1500 ppm [75 mg/kg/day], and 7500 ppm [375 mg/kg/day] for 90 days [standard conversion ratio]. There were no deaths. During the first month only, hyperactivity was displayed by the high-dose rats. There was a dose-related decrease in body weight throughout the study [terminal sacrifice: males 90% and 39% of control/females 92% and 63% of control for the mid- and high-dose, respectively]. There was a negative body-weight gain during the first week in both sexes at the high-dose level, and overall [males 13% of control/females 31% of control]. Food consumption was decreased during the first 4-5 weeks at the high-dose level [both sexes]. Effects [increasing cholesterol, decreasing glucose, decreasing protein, decreasing organ weights] observed at the high dose are attributed to poor nutrition, due to the poor palatability of the test material and not to a toxic effect. No adverse effects were observed at the mid- and low-dose levels in either sex. **The NOEL is 1500 ppm [≈75 mg/kg/day].** This guideline [§82-1] study is classified **Unacceptable** due to the lack of effects at dose levels that were palatable and the lack of pair-fed controls for comparison with the dose level that was not palatable. Since sufficient data from a chronic toxicity study in rats are available, an additional subchronic feeding study in rats is not required.

In a subchronic feeding study [MRID 00157852], 6 Beagle dogs/sex/group were administered propachlor [96.1%] via the diet at dose levels of 0, 100 ppm [≈2.5 mg/kg/day; standard conversion factor used], 500 ppm [≈12.5 mg/kg/day], and 1500 ppm [≈37.5 mg/kg/day] for 90 days. There were no deaths. Throughout the study, decreased body weight was observed at all dose levels in both

sexes, although there was no dose-response. The mid-dose level of both sexes displayed the lowest terminal body weight [males 85%/females 87% of control]. Overall, decreased body-weight gain was observed at all dose levels of both sexes [males: 46%, 26%, and 37%/females: 91%, 18%, and 27% of control at the low-, mid-, and high-dose levels, respectively]. At the high-dose level in both sexes, food consumption was decreased throughout the study. There were no dose-related effects observed in hematology, clinical chemistry, urinalysis, ophthalmoscopic, gross, or microscopic examinations in either sex. **The NOEL is 37.5 mg/kg/day, the highest dose tested (HDT).** This guideline [§82-1] subchronic toxicity study in dogs is classified Acceptable.

In a subchronic feeding study [MRID 00152865], 30 Crl:CD®-1 (ICR)BR mice/sex/group were administered Propachlor [96.1%] via the diet at dose levels of 0, 500 ppm [≈75 mg/kg/day], 1500 ppm [≈225 mg/kg/day], and 5000 ppm [≈750 mg/kg/day] for 90 days. There were no deaths. There was a dose-related decrease in body weight of the males throughout the study [week 13: 95.6% and 91.1% of control for the mid- and high-dose, respectively]. In females, there was a dose-related decrease in body weight during the first 6 weeks [week 6: 93.3% and 91.6% of control at the mid- and high-dose levels, respectively], but during the last half of the study, the mid-dose females displayed the lowest body weight compared to the control [week 13: 92.2% and 95.8% of control at the mid- and high-dose levels, respectively]. Food consumption was decreased mainly in females at the high dose. There was a dose-related decrease in leukocytes in both sexes at week 7, and a decrease was observed in the mid- and high-dose males at study termination. There was a dose-related decrease in kidney weight in males that was statistically significant at all dose levels and relative kidney weight was significantly decreased in the high-dose males. Liver weight was increased in the mid- and high-dose males and in the high-dose females. There was a dose-related increase in relative liver weights in both sexes. Centrilobular hepatocyte enlargement was observed at all dose levels in the males [dose-related] and in the high-dose females.

There is no NOEL for this study. This guideline [§82-1] subchronic feeding study in the mouse is classified Unacceptable, because a NOEL could not be set due to questions regarding liver effects raised during a data audit that were not addressed by the study author. Since there are sufficient data available on long-term exposure [mouse carcinogenicity study] in the mouse, an additional mouse subchronic study is not required at this time.

c. Chronic Toxicity and Carcinogenicity

Sufficient data are available to assess the chronic toxicity and carcinogenic potential of propachlor. Propachlor has been classified as a "**Likely**" human carcinogen, based on the (a) rare stomach tumor in male Fischer 344 rats; (b) thyroid tumors in male and ovarian granulosa/theca cell tumors in female Sprague-Dawley rats at doses that were not adequate to assess carcinogenicity; (c) hepatocellular tumors in male CD-1 mice; (d) in vitro clastogenic activity; and (e) tumors observed at one or more of the same sites with three structurally-related chloroacetanilide compounds.

GLN 83-5: Combined Chronic Toxicity/Carcinogenicity Study in Rats

In the combined chronic toxicity/carcinogenicity study in rats [MRID 44168301], Propachlor [97.83% a.i.] was administered to 60 F-344 rats/sex/dose via the diet at dose levels of 0, 100, 300, 1000, and 2500 [males]/5000 [females] ppm [males 0, 5.4, 16.1, 53.6, and 125.3/females 0, 6.4, 19.3, 65.5, and 292.1 mg/kg/day, respectively] for 24 months. Due to palatability problems, the high dose level was attained by ramping the dose from 1000 ppm initially to the desired level by increasing by 500 ppm each week.

There were no adverse effects on survival or clinical signs in either sex. Both sexes at the highest dose level displayed decreased body weight throughout most of the study [males 93%/females 72% of control value at study termination], which was accompanied by a decreased food intake [attributable to poor palatability of the test material]. Small decreases in body weight [males 96-97%/females 93-97% of control] and food consumption were observed in both sexes at the 1000 ppm dose level also. Body-weight gains at the two highest dose levels of both sexes were significantly decreased throughout much of the study, with the deficit for the first 3-month interval being 93%/89% of the control for males/females at 1000 ppm and 82%/79% of the control for males/females at the highest dose level, respectively. Several clinical pathology findings [initial decrease in red cell indices suggesting a mild anemia, increases in platelets/WBC in females, decreases in serum enzymes, increased GGT levels] may be treatment-related, although wide variability occurred in both sexes. At both the 12-month and terminal sacrifices, increased liver weight [absolute and relative-to-brain] was observed in females at the highest dose level, but males at the highest dose level displayed increased liver weight only at the interim sacrifice. At the highest dose level, kidney weights [absolute and relative-to-brain] were decreased in both sexes at the terminal sacrifice. At study termination, increased testicular weight was observed in males at the highest dose level and decreased thyroid weight was observed in females at the highest dose level. In the stomach, herniated mucosal glands [submucosa/tunica muscularis], mucosal hyperplasia of the pylorus, and pyloric cyst(s) were observed only in treated rats of both sexes, and the incidence and severity increased with dose in males. Females at the 65.5 mg/kg/daydose level and both sexes at the highest dose level also displayed erosion/ulceration of the glandular mucosa of the stomach. The incidence and severity of hepatocellular hypertrophy (centrilobular/midzonal) were increased in a dose-related manner in both sexes. There was no increase in the incidence of hepatocellular tumors in either sex. One male at the highest dose level displayed a glandular stomach carcinoma and, because of the other lesions observed in this organ, it could not be ruled out and appeared to be treatment related. At the doses tested, with the exception of the uncommon stomach tumor in one high-dose male, there was no apparent treatment-related increase in tumors in the treated rats when compared to the control rats. Dosing was considered adequate, based on the known poor palatability of propachlor and the demonstrated decrease in food consumption and a concomitant decrease in body-weight gain.

The NOEL in males is 5.4 mg/kg/day and in females is 6.4 mg/kg/day. The LOEL in males is 16.1 mg/kg/day and in females is 19.3 mg/kg/day, based on stomach lesions in males and liver lesions in both sexes. This guideline [§83-5] chronic toxicity/carcinogenicity study in the rat is Acceptable.

In another 2-year feeding study [MRID 40473101], 60 Sprague-Dawley CD®-Crl:CD(SD)BR rats/sex/group were administered propachlor [96.1%] via the diet at dose levels of 0, 10 ppm [males 0.48/females 0.60 mg/kg/day], 50 ppm [males 2.39/females 3.04 mg/kg/day], and 500 ppm [males 23.88/females 30.05 mg/kg/day] for 104 weeks. Survival was comparable among the groups of both sexes, and there were no adverse effects observed on any parameter monitored, with the exception of a slight increase in the incidence of thyroid and ovarian tumors. It was concluded that the dose levels were not adequate, and a repeat study [cited above] was performed. This study was considered in the weight of evidence considerations on propachlor.

GLN 83-1(b): Chronic Toxicity Study in Dogs

In a chronic feeding study [MRID 40081601], 6 Beagle dogs/sex/ group were administered Propachlor [97.1%] via the diet at dose levels of 0, 25 ppm [≈0.025 mg/kg/day], 250 ppm [≈6.25 mg/kg/day], and 1000 ppm [≈25 mg/kg/day] for 12 months. There were no deaths. Estrus occurred more frequently in the treated females than in the controls. Throughout the study, decreased body weight was observed at the mid- and high-dose levels in males and at the high-dose level in females. At termination, the decreases in body weight were 94% of control for the mid-dose males and high-dose females and 84% of control for the high-dose males. At the high-dose level in both sexes, food consumption was decreased throughout the study. Low-dose females and mid-dose males consumed less food than the controls from week 6 on, and the mid-dose females consumed less food from week 13 on. There was a dose-related decrease in body-weight gain in both sexes [high-dose males were 37% of control during the 1-92 day interval; high-dose females were 47% of control for the same interval]. There were no dose-related effects observed in hematology, clinical chemistry, urinalysis, ophthalmoscopic, gross, or microscopic examinations in either sex. **The NOEL is 6.25 mg/kg/day. The LOEL is 25 mg/kg/day, based on decreased body weight, body-weight gain, and food consumption.** This guideline [§83-1(b)] chronic dog study is classified Acceptable.

GLN 83-2: Carcinogenicity Study in Mice

In a carcinogenicity study (MRID 44069801), propachlor [97.8% a.i.] was administered in the diet to 60 CD-1 mice/sex/dose for 18 months at dose levels of 0, 100, 500, 1500, or 6000 ppm (0, 14.6, 75.0, 222.9, or 847.3 mg/kg/day, respectively, in males; 0, 19.3, 100.0, 276.7, or 1006.9 mg/kg/day, respectively, in females). Due to palatability problems, the high-dose level was attained by ramping the dose from 1500 initially to the desired level of 6000 ppm by increasing by 500 ppm each week.

There were no adverse effects on survival or clinical signs in either sex. Decreased body weight [males 89%/females 86% of control value at study termination] and body-weight gains [overall gain males 72%/females 68% of control] were observed in males at 276.7 mg/kg/day and in both sexes at the highest dose level throughout most of the study following the ramping phase of the dosing procedure. These decreases were accompanied by decreases in food consumption. This latter effect can be attributed to the known poor palatability of the test material. Comparable increases in platelet counts were observed in both sexes at the highest dose level compared to the controls. At both the

12-month and terminal sacrifices in both sexes, there was a dose-related increase in liver weight. At the highest dose level, kidney weights [absolute and relative-to-brain] were decreased in males at both the 12-month and terminal sacrifices and in females at the terminal sacrifice. In the stomach, herniated mucosal glands into the submucosa/tunica muscularis were observed in both sexes at the highest dose level and in some males at the next highest dose level. Males at the highest dose level also displayed erosion/ulceration of the glandular mucosa of the stomach. Several non-neoplastic lesions indicative of liver toxicity were observed in the liver in both sexes at the highest dose level and in males at the next highest dose level. These included hepatocellular hypertrophy (centrilobular/midzonal), necrosis of individual hepatocytes, eosinophilic foci, telangiectasis, and pigment deposition in Kupffer cells in the males and hepatocellular hypertrophy (periportal), mononuclear cell infiltrate, and pigment deposition in Kupffer cells in the females. Treatment-related increases in liver tumors [hepatocellular adenomas, carcinomas, adenomas and/or carcinomas combined]. There were no treatment-related tumors in female mice. Dosing was considered adequate, based on the known poor palatability of propachlor and the demonstrated decrease in food consumption and a concomitant decrease in body-weight gain. **The NOEL in males is 14.6 mg/kg/day and in females is 19.3 mg/kg/day. The LOEL in males is 75 mg/kg/day and in females is 100 mg/kg/day, based on increased liver weights and microscopic lesions in the liver.** This guideline [§83-2] carcinogenicity study in the mouse is Acceptable.

In another mouse study [MRID 40162501], 60 CD-1 mice/sex/group were administered propachlor [96.1%] via the diet at dose levels of 0 ppm, 10 ppm [males 1.62/females 2.01 mg/kg/day], 50 ppm [males 8.12/females 10.03 mg/kg/day], and 500 ppm [males 81.25/females 104.89 mg/kg/day] for 78 weeks. There were no treatment-related effects observed on survival, body weight/gain, food consumption, hematology, gross pathology, or histopathology in either sex, and there were no apparent treatment-related increases in tumors in either sex compared to the controls. The dose levels were determined to be inadequate for assessing the carcinogenic potential of propachlor. A repeat study [cited above] was performed. This study was considered in the weight of evidence considerations on propachlor.

d. Other Carcinogenic Issues

Propachlor induced tumors in rats at the same sites [stomach and thyroids] as structurally-related acetanilides; alachlor [stomach/thyroids], acetochlor [thyroids], and butachlor [stomach/thyroids]. In rats, propachlor did not induce tumors in the liver, as observed with metolachlor and SAN 582H, or nose/ turbinates, as seen with acetochlor, alachlor, and butachlor. The hepatocellular tumors seen with propachlor in mice were observed only with acetochlor.

e. Developmental Toxicity Studies

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.

GLN 83-3(a): Developmental Toxicity in Rats

Under the conditions of the study [MRID 00115136], 25 pregnant Charles River COBS CD rats [mated 1:1] were administered propachlor [technical] at dose levels of 0 [corn oil], 20, 60, and 200 mg/kg/day via gavage from day 6 through 19 of gestation. On day 20 of gestation, the dams were sacrificed via CO_2 inhalation. The one death that occurred [at 200 mg/kg/day] was attributed to intubation error. Body weights were comparable among the groups. There were no significant differences observed in the mean number of viable fetuses, postimplantation loss, total implantations, corpora lutea, fetal body weights, or sex ratio. Soft tissue and skeletal malformations were comparable among the groups, and the occurrence of unossified sternebrae, 14th rudimentary ribs, and renal papillae not developed and/or distended ureter were comparable among the groups also. Although no effects were observed in this study, it was determined that a repeat rat study was not required in light of the fact that maternal toxic effects were observed in the rabbit developmental toxicity study at 100 mg/kg/ day and the rabbit developmental NOEL was 58.3 mg/kg/day compared to the rat NOEL for maternal and developmental toxicity in this study was equal to or greater than 200 mg/kg/day. Additionally, severe maternal toxicity [moribund appearance, loss of righting reflex,, inactivity, dilated pupils,cool to touch] was observed in a range-finding study in rats at 600 mg/kg/day. **The NOEL is 200 mg/kg/day, the highest dose tested.** This guideline [§83-3(a)] rat developmental toxicity study is classified Acceptable.

GLN 83-3(b): Developmental Toxicity Study in Rabbits

In the range-finding study [MRID 42348002] in rabbits, dose levels of 0, 25, 75, 125, 175, and 225 mg/kg/day propachlor [96.8%]/kg body weight/day to 7 artificially inseminated New Zealand rabbits/group during days 7 through 19 of gestation via gavage resulted in (1) death and gross pathological lesions of the stomach and liver at dose levels of 125 mg/kg/day and greater; (2) reduced defecation and soft stool at doses of 125 mg/kg/day and greater; and (3) decreased body-weight gain and, corrected body weight at 175 mg/kg/day and above. Pregnancy rate was 57.1% at 175 and 225 mg/kg/day. There were no differences observed in any Cesarean section parameter monitored among groups with gravid does at the scheduled sacrifice. No external malformation or developmental variation was observed in any of the fetuses. Maternal toxicity was observed at 125 mg/kg/day and above, expressed mainly as deaths. Developmental toxicity was not observed at any dose level with available animals [25, 75, and 125 mg/kg/day]. From these results, dose levels of 5, 50, and 100 mg/kg/day were chosen for the definitive study [cited below].

Under the conditions of the study [MRID 00150936], 16 artificially inseminated New Zealand female rabbits were administered Propachlor [96.5%] at dose levels of 0 [corn oil], 5, 15, and 50 mg/kg/day via gavage from day 7 through 19 of gestation. On day 29 of gestation, the does were sacrificed. There were numerous deaths [all groups], apparently due to disease. There were no maternal toxic effects reported at any dose level, and the clinical observations and necropsy findings [nasal and ocular discharge, lung congestion, foci] suggest a possible infection [or dosing problem]. There was no adverse effect on body weight due to treatment, and in fact the control group showed a negative body-weight gain compared to positive gains in the treated groups. There was no apparent adverse effect on pregnancy rate, although due to deaths and abortions, the low-dose group had only 8 litters. The number of corpora lutea were comparable among the groups, but the number of

implantation sites/doe and live fetuses/doe were decreased at the mid- and high-dose levels. Preimplantation loss was increased at all dose levels, and the incidence exceeded historical control. Postimplantation loss was also increased, with the incidence being the highest at the mid-dose level. Because there was an insufficient number of litters at the low-dose level, no developmental toxicity NOEL could be set. The rabbit developmental toxicity study was repeated [cited below].

Under the conditions of the study [MRID 42348002 and 42584701], 20 artificially inseminated New Zealand female rabbits were administered propachlor [96.8%] at dose levels of 0 [0.5% aqueous methylcellulose], 5, 50, and 100 mg/kg/day [analytical doses of 5.8, 58.3, and 116.7 mg/kg/day] via gavage from day 7 through 19 of gestation. On day 29 of gestation, the does were sacrificed via an i.v. injection of T-61®. There were 2 deaths at the high-dose level [on day 10], and both were considered treatment-related. One control doe died on day 12, and this was attributed to intubation error. Salivation was displayed immediately after dosing in several high-dose does, and reduced defecation occurred in the majority of these does during the treatment period. Thrashing, vocalization, prostration, labored breathing, and convulsions were displayed prior to death by the two does that died at the high dose. Negative body-weight gain occurred at the high-dose level throughout the dosing period, and the corrected overall gain was ≈27% of the control value. The high-dose does displayed decreased food consumption throughout the dosing period and for 5 days thereafter [77% of control]. Gravid uterine weight was decreased at the high-dose level [86% of control] compared to the control. There were no significant differences observed in the pregnancy rate among the groups. One low- and one high-dose does aborted [day 24], but only the abortion at the high dose was considered treatment-related, since none of the mid-dose does aborted and the high-dose doe displayed considerable weight loss and reduced food intake during treatment. One high-dose doe delivered prematurely on day 29. The number of corpora lutea were comparable among the groups, but the number of implantation sites and live fetuses were decreased at the high-dose level, and the mid- and high-dose does displayed an increased number [dose related] of resorptions [total and per doe] compared to the control. Postimplantation loss was increased in a dose-related manner, but statistical significance was not attained. A subsequent assessment of the data with respect to resorptions/postimplantation losses determined that the apparent increase was due to total litter resorption in one mid-dose doe and two high-dose does, which was within the historical control incidence. Although the number of fetuses per litter and fetal body weight were comparable among the groups, the high dose displayed the smallest number and weight. There were no statistically significant increases in the incidence of any external, visceral, or skeletal malformation or variation at any dose level that could be attributed to treatment. **The developmental toxicity NOEL is 58.3 mg/kg/day. The developmental toxicity LOEL is 116.7 mg/kg/day, based on the slightly reduced mean fetal body weight. The maternal NOEL is 58.3 mg/kg/day. The maternal LOEL is 116.7 mg/kg/day, based on decreased body-weight gain and food consumption.** This guideline [§83-3(b)] developmental toxicity study is classified Acceptable.

f. Reproduction Toxicity Studies

Reproduction studies are 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.

GLN 83-4: Two-Generation Reproduction Study in Rats

In a two-generation reproduction study [MRID 43862901], propachlor [97.83%] was administered to Sprague-Dawley (CD) rats [30 rats/sex/group] via the diet during pre-mating [F_0 10 weeks/F_{1A} 11 weeks] and through gestation and lactation [one litter/generation] at dose levels of 0, 100 ppm [males 7.1/females 8.2 mg/kg/day], 1000 ppm [males 69.6/females 80.1 mg/kg/day], and males 2500 ppm/females 5000 ppm [males 140.7/females 315.1 mg/kg/day]. Maternal toxicity was observed at the high-dose level, as evidenced by (1) decreased body weight [86% of control at mating; 75% of control at day 21 of gestation; 72% of control at day 21 of lactation], (2) decreased body-weight gain (60% of control for premating period; 48% of control during gestation; 56% of control during lactation), (3) decreased food consumption, and (4) decreased litter size at birth. This dose level was discontinued after the first generation due to severe toxicity. Reproductive effects occurred at the high-dose level, as evidenced by decreased (1) litter size at birth, (2) F_{1A} pup body weight, and (3) pup viability. Offspring viability and growth were adversely affected at the highest dose level, as evidenced by the fact that at day 21, the pups were too small [body weight ≈32% of the control] to be weaned, and the majority [11/14] of those weaned at day 21 died within one day. At the 1000 ppm dose level, slight maternal toxicity was observed, as evidenced by a decrease in body weight [90% of control] in the F_{1A} females at mating and a decrease in body-weight gain in both the F_0 [86% of control] and F_{1A} [82% of control] females during the mating period. No consistent decrease in body weight or body-weight gain was displayed by the F_0 and F_{1A} dams at 1000 ppm during gestation or lactation. At 1000 ppm in both generations, decreased pup body weight was observed at weaning [88% of control]. There were no adverse effects on mating or fertility at any dose level. At terminal sacrifice, centrilobular hepatocellular hypertrophy was observed in the liver of the adults in both sexes in both generations at the 69.6 mg/kg/day dose level. **The NOEL for maternal/paternal toxicity in males is 7.1 mg/kg/day and in females is 8.2 mg/kg/day. The LOEL in males is 69.6 mg/kg/day and in females is 80.1 mg/kg/day based on decreased body weight/gain and food consumption. The NOEL for effects on the offspring in males is 7.1 mg/kg/day and in females is 8.2 mg/kg/day. The LOEL in males is 69.6 mg/kg/day and in females is 80.1 mg/kg/day based on decreased body weight at weaning. The NOEL for reproductive/ developmental effects in males is 69.6 mg/kg/day and in females is 80.1 mg/kg/day. The LOEL for reproductive/developmental effects in males is 140.7 mg/kg/day and in females is 315.1 mg/kg/day based on reduced litter size, decreased offspring growth, and decreased pup viability at the highest dose level in the first generation.**

In another 2-generation reproduction study [MRID 00157168], Fischer 344 rats [30 rats/sex/group] were administered propachlor via the diet [F_0 for 100 days/F_1 for 120 days premating; through gestation and lactation] at dose levels of 0.3, 3.0, and 30 mg/kg/day for two generations [1 litter for F_0; 2 litters for F_1 due to low fertility at the 2 highest dose levels]. Propachlor did not produce any adverse effects on the ability of the rats to mate, reproduce, and nurse their offspring. Although initially it was concluded that the rats had not been challenged adequately to assess the potential of propachlor to produce reproductive effects, a subsequent assessment of the data

determined that the absolute and relative liver weight decreases and the increased centrilobular hepatocyte eosinophilia accompanied by very slight hypertrophy in the females demonstrated an effect level. **The maternal/systemic NOEL is 3.0 mg/kg/day. The LOEL is 30 mg/kg/day, based on liver toxicity. The reproductive NOEL is equal to or greater than 30 mg/kg/day, the highest dose tested.**

g. Mutagenicity Studies

Sufficient data are available to satisfy data requirements for mutagenicity testing. There is evidence that propachlor has genotoxic activity and analogue data are supportive of a mutagenicity concern for propachlor.

GLN 84-2: Gene Mutation

In a Chinese hamster ovary [CHO] cells HGPRT forward gene mutation assay [MRID 00153939], propachlor induced a concentration-dependent increase in mutant frequency to over a doubling of ethanol control frequency at the HGPRT locus of CHO cells at 50 µg/mL with metabolic activation only. This was supported by appropriate toxicity (14% relative survival)at this concentration, an increase in absolute colony numbers, and the relatively tight spontaneous background reported in the testing lab. There was no apparent increase without metabolic activation (dose levels of 10 - 60 ug/mL).

GLN 84-2: Chromosomal Aberration Assay

In a Chinese hamster ovary [CHO] cell/chromosomal aberration assay [MRID 40312701], propachlor was found to induce a clastogenic effect under metabolic activation conditions at the highest dose tested, 15 ug/mL, and was negative for aberrations in this in vitro assay in CHO cells without metabolic activation, dose levels of 5 - 15 ug/mL.

In an in vivo rat bone marrow cytogenetic assay [MRID 00153940], Propachlor was not shown to be clastogenic in bone marrow cells of Fischer 344 rats. Cytotoxicity was not observed at the i.p. doses tested (0.05, 0.2, or 1.0 mg/kg), and slightly higher dosing may have been appropriate. In other studies [open literature], propachlor was positive for aberrations in mouse bone marrow.

h. Other Genotoxic Effects

In an in vitro unscheduled DNA assay [MRID 00257647], propachlor was not shown to be genotoxic at doses up to 25 µg/mL; higher doses were cytotoxic.

In an in vivo-in vitro rat hepatocyte DNA repair assay [MRID 40068401], propachlor was not shown to be genotoxic at the concentrations [25-1000 mg/kg] tested.

In a dominant lethal assay [MRID 43221801] in Sprague-Dawley rats, there was no indication of a dominant lethal effect associated with dietary exposure to propachlor at dose levels up to 2500 ppm for approximately 10 weeks, an acceptably high dose.

i. Metabolism

Sufficient data are available on the metabolism of propachlor in the rat.

In a metabolism study in rats in which single doses of 25 mg propachlor/kg of body weight were administered orally, 91% of the dose was recovered in 56 hours, with 68% of the dose being excreted in urine, 10% in the feces, and 4% was found in the carcass. Eleven metabolites were identified. The metabolic fate of propachlor depends to a large extent on the presence of the intestinal microflora. Propachlor metabolites can make 3 or more cycles in the enterohepatic circulation. In the first cycle, propachlor is metabolized via the mercapturic acid pathway and the conjugates are excreted in the bile. The second cycle is initiated when the biliary mercapturic acid pathway metabolites are metabolized by a microflora C-S lyase to reabsorbable metabolites, which are then metabolized to glucuronides that are secreted with the bile. Subsequent cycles result from microfloral β-glucuronidase activity. Propachlor appears to undergo rapid absorption, distribution, metabolism, and excretion with little, if any, tissue retention in rats. From the studies available [MRID 00157496-00157500, 00157501-00157507], it can be stated that, following initial glutathione conjugation, metabolism proceeds primarily via the mercapturic acid pathway with concurrent oxidative reactions and glucuronic acid conjugation. Initially-formed metabolites undergo extensive excretion and enterohepatic circulation.

j. Neurotoxicity Studies

GLN 81-8: Acute Neurotoxicity Study

In an acute neurotoxicity study [MRID 42584702], 10 Sprague-Dawley CD rats/sex/ group were administered a single dose of propachlor via gavage at dose levels of 0, 175, 350, and 700 mg/kg. At the 700 mg/kg dose level, deaths occurred in both sexes, and several clinical signs suggestive of general systemic toxicity and/or neurological involvement [increased foot splay, myoclonic jerks, slightly abnormal gait, and decreased forelimb grip strength] were observed at the mid- and/or high-dose levels. **The NOEL is 175 mg/kg, and the LOEL is 350 mg/kg, based on an increase in landing foot splay at 7 hours [peak effect time] in females.** This guideline [§81-8] acute neurotoxicity study in rats is classified Acceptable.

GLN 82-5: Subchronic Neurotoxicity Study

In a subchronic neurotoxicity study [MRID 43575701], 10 Sprague-Dawley CD rats/sex/group were administered propachlor at dose levels of 100 ppm [males 5.5/females 6.8 mg/kg/day], 1000 ppm [males 55.8/females 6.3 mg/kg/day], and 2500 ppm [males 120.6 mg/kg/day]/5000 ppm [females 316.4 mg/kg/day] for at least 13 weeks. There were decreases in (1) body weight of both sexes

[males 86%/females 77% of control] at their respective high-dose levels, (2) overall body-weight gain in both sexes at the same dose levels [males 76%/females 57% of control], and (3) food consumption in both sexes [males 79-91%/females 75-93% of control], which are likely to be related to the poor palatability of propachlor. None of the neurotoxicity parameters examined was affected by treatment in either sex. **The NOEL in males is 55.8 mg/kg/day and in females is 66.3 mg/kg/day. The LOEL in males is 120.6mg/kg/day and in females is 316.4 mg/kg/day based on decreased body weight/gain and food consumption. Propachlor does not appear to be a neurotoxin.** This guideline [§82-5] subchronic neurotoxicity study in rats is classified Acceptable.

2. Dose/Response Assessment

a. Consideration of FQPA Issues for Propachlor

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 the toxicity and exposure data bases, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

OPP's Health Effects Division RfD Committee met on May 7, 1997, (1) to evaluate the reproductive, developmental, and neurotoxicity data for propachlor, and (2) to address the sensitivity of infants and children from exposure to propachlor as required by FQPA.

Adequacy of data: An acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits have been submitted to the Agency, meeting basic data requirements, as defined for a food-use chemical by 40 CFR Part 158. Based upon a weight-of-the-evidence evaluation, the Committee determined that a developmental neurotoxicity study would not be required for propachlor. The following information was utilized in the decision. No structural anomalies of the developing central nervous system were observed in the prenatal developmental toxicity studies in rats and rabbits. No structural anomalies of the central nervous system were reported in the two-generation reproduction study in rats. There were no effects of propachlor administration on the organ weight and/or histopathology data of the nervous system in any of the long term studies in rats, mice, or dogs. Although relative brain weight was increased (due to body

weight losses) in the subchronic toxicity studies in rats and mice, the subchronic neurotoxicity study in rats was negative for neurotoxic effects. In the acute neurotoxicity study in rats, an increase in landing foot splay was noted for females at 7 hours posttreatment; this was the only indication of neurotoxic potential. Therefore, based upon consideration of the toxicity profile for propachlor, a developmental neurotoxicity study in rats was not recommended. The Committee concluded that there are no data gaps for the assessment of the effects of propachlor following *in utero* or early postnatal exposure.

Susceptibility issues: The data demonstrated no indication of increased sensitivity of rats to *in utero* and/or postnatal exposure to propachlor. In the two-generation reproduction study in rats (MRID 43862901), the parental and offspring systemic NOELs and LOELs were equivalent at 100 ppm (7.1/8.2 mg/kg/day in M/F) and 1000 ppm (69.6/80.1 mg/kg/day in M/F), respectively. In the prenatal developmental toxicity study in rats with propachlor (MRID 00115136), no maternal or developmental toxicity was noted up to the highest dose tested of 200 mg/kg/day. However, data from the 2-generation reproduction study indicate that the developmental NOEL in rats is estimated to be within the range of 200 to 315 mg/kg/day, with the caveat that this is an extrapolation from two separately conducted studies in the same strain of rats, with different routes (gavage vs. dietary) and different durations of *in utero* exposure.

The data demonstrated no indication of increased sensitivity of rabbits to *in utero* exposure to propachlor. In the prenatal developmental toxicity study in rabbits, the maternal and developmental NOELs and LOELs were equivalent at 58.3 mg/kg/day and 116.7 mg/kg/day, respectively.

Uncertainty factor: The RfD Committee determined that for propachlor, the 10-fold uncertainty factor required by FQPA for the protection of infants and children could be removed, based upon the following information: (1) The data base was complete for the evaluation of potential hazard to perinatal animals following pre- and/or postnatal exposure to propachlor. (2) Based upon a weight of the evidence determination, as described previously in this document, there was no concern regarding the potential for effects on functional development following in utero exposure to propachlor, and a developmental neurotoxicity study was not required. (3) The studies demonstrated no indication of increased sensitivity of rats to *in utero* and/or postnatal exposure to propachlor and rabbits to *in utero* exposure to propachlor.

Therefore, an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for intraspecies variability) is appropriate, and will adequately protect infants and children.

b. Reference Dose [RfD]

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 propachlor was first established in 1986 based on a 90 day feeding study in rats that was conducted with the 65% wettable powder. The NOEL was 13.3 mg/kg/day. The LOEL

was 133.3 mg/kg/day based on decreased weight gain, food consumption, and increased relative liver weights. An uncertainty factor of 1000 (10 x 10 x 10) was used to account for inter- and intraspecies differences, and the insufficient duration of the study to fully assess chronic effects. The Agency's Integrated Risk Information System (IRIS) gave the 1986 propachlor data base a low confidence rating. Therefore, there was low confidence in the 1986 RfD of 0.013 mg/kg/day.

On May 7, 1997, after reviewing chronic studies in rats, mice, and dogs, the RfD for propachlor was determined to be 0.054 mg/kg/day, based on the rat chronic toxicity study [MRID 44168301] with a NOEL of 5.4 mg/kg/day. (The LOEL was 16.1 mg/kg/day, based on stomach lesions in males and liver lesions in both sexes.) An uncertainty factor of 100 (previously determined appropriate by the HED RfD Committee) was applied to account for both inter-species extrapolation and intra-species variability.

c. FAO/WHO

Propachlor has not been reviewed by the FAO/WHO Joint Committee Meeting on Pesticide Residues (JMPR) or the International Agency for Research on Cancer (IARC).

d. Carcinogenicity Classification and Risk Quantification

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased tumor incidence is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship.

The carcinogenic potential of propachlor was evaluated by the HED Cancer Assessment Review Committee on July 30, 1997. The Committee determined that propachlor be classified as a "**Likely**" human carcinogen, based on (a) the observance of multiple tumors at multiple sites, including the rare stomach tumor in a male Fischer 344 rat, thyroid tumors in male and ovarian granulosa/theca cell tumors in female Sprague-Dawley rats, and hepatocellular tumors in CD-1 mice; (b) in vitro clastogenic activity; (c) tumors observed at one or more of the same sites with three structurally-related chloroacetanilide compounds (alachlor, acetochlor, and butachlor); (d) lack of data on mode of action; and (e) the relevance of the observed tumors to human exposure.

The Committee also recommended a linear low-dose approach for human risk assessment with extrapolation being based on both the neoplastic [ovarian tumors in rats and liver tumors in male mice] and non-neoplastic [liver hypertrophy in mice] lesions.

Since a linear low-dose approach for human risk assessment was recommended, cancer potency factors for propachlor were calculated for 2 tumor types and a combined tumor/ hyperplasia finding. These cancer potency factors were calculated using the Tox_Risk 4.0_K. Crump model and converted from animals to humans by the use of the 3/4's scaling factor.

For male mouse liver tumors the Q_1^* was estimated to be 5.0×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents.

For male mouse liver tumors and liver hyperplasia the Q_1^* was estimated to be 1.4×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

For female rat ovarian tumors the Q_1^* was estimated to be 3.2×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

For risk assessment, the largest Q_1^* (based on female rat ovarian tumors) of 3.2×10^{-2} $(mg/kg/day)^{-1}$ will be used. Note that this Q_1^* will also be used for the adult male population even though the Q_1^* is based on female rat ovarian tumors.

e. Assessment of Reproductive/Developmental Toxicity

The database for developmental toxicity and reproductive toxicity is considered to be complete at this time. There was no indication of reproductive or developmental effects. The data demonstrated no indication of increased sensitivity of rats to in utero and/or postnatal exposure to propachlor. The data demonstrated no indication of increased sensitivity of rabbits to in utero exposure to propachlor. Therefore, the RfD Committee did not refer propachlor to the Developmental/Reproductive SARC.

f. Dermal Absorption Factor

Two dermal studies were reviewed to determine if either study was appropriate for use in this assessment. One of the studies is an IBT study which was performed using a combination of propachlor and atrazine. This study was classified INVALID.

A 21-day dermal study conducted on rats (MRID No. 44590801) was submitted to the Agency and found to be unacceptable but upgradeable. A NOEL could not be determined due to the lack of an examination of the spleens at the low and mid-dose levels despite the spleen congestion observed in the high-dose rats of both sexes which was considered to be treatment-related. The NOEL for minor dermal changes was 40 mg/kg/day, and the LOEL was 150 mg/kg/day. This study could not be used in an assessment of dermal absorption because no common endpoint was observed between this dermal exposure study and any of the rat oral studies. The registrant is currently working towards submitting an upgraded study for the 21-day dermal study to refine the risk assessment.

Another study [MRID No. 104299], performed using a 65% wettable powder formulation of propachlor, was determined to be inadequate for use in estimating the dermal absorption of propachlor. This was a 1963 study that was performed using only two dose levels. The percent of the body surface area exposed was not provided, no stability/ homogeneity/dose preparation data were provided, no hematology or clinical chemistry parameters were monitored, eye examinations were not performed, and the age of the rabbits at study initiation was not provided. Only 5

rabbits/sex/group were tested [although 10/sex were exposed to the high-dose level, 5/sex of these were held for two weeks after exposure ended before they were sacrificed and examined histologically]. No toxic effects were produced at either dose level; however, the limit dose was not tested, and there was no discussion as to how the dose levels were chosen.

Given the deficiencies in the 21-day dermal toxicity study, the repeated dose dermal study on the 65% wettable powder and the lack of acute data in the same species with which to estimate dermal absorption, the default estimate of 100% must be utilized pending submission of the upgraded 21-day dermal toxicity study which Monsanto is expected to submit.

g. Toxicological Endpoints of Concern for Use in Human Risk Assessment

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 should be done to assure that the public is adequately protected from any pesticide exposure scenario. Exposure scenarios can be dietary or non-dietary. Both short and long durations of exposure as well as routes 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 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.

The Agency's Toxicity Endpoint Selection Committee met on May 7, 1997 and the Hazard Identification Committee (HIARC) on December 5, 1997, to determine the endpoints for use in the propachlor risk assessment.

3. Toxicological Endpoints for Risk Assessment

a. Acute Dietary Risk Assessment

An acute dietary risk assessment is required. The NOEL of 175 mg/kg from a single dose acute neurotoxicity study in rats will be used in estimating the MOE. The LOEL was 350 mg/kg, based on an increase in landing foot splay at 7 hours [peak effect time] in female rats. An acute neurotoxicity study is pertinent for an acute dietary assessment because the test animals receive a single oral administration of the pesticide, and therefore all toxicological effects can be attributed to that one dose. This effect, landing foot splay, is appropriate for all population sub-groups, including infants and children. An MOE of 100 will adequately protect all population sub-groups including infants and children.

b. Chronic (non-cancer) Dietary Risk Assessment

The RfD is the traditionally accepted endpoint for a chronic (non-cancer) dietary risk assessment. The RfD of 0.054 mg/kg/day will be used for estimating chronic (non-cancer) dietary risk for all population sub-groups from exposure through both food and water. A percent RfD of less than 100 is considered protective.

c. Carcinogenic Dietary Risk

The Q_1^* of 3.2×10^{-2} $(mg/kg/day)^{-1}$ based on female rat ovarian tumors will be used for estimating carcinogenic dietary risk from exposure through both food and water. Carcinogenic risk is estimated for adults only. A risk of less than 1×10^{-6} is considered protective for dietary exposures.

d. Dermal Absorption

A dermal penetration study has not been submitted. (See discussion on dermal absorption factor.) No acceptable data were available to estimate a dermal absorption factor. Therefore, 100% dermal absorption is assumed.

e. Occupational and Residential

Residential

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

Short-Term (1 - 7 days) Occupational Risk Assessment

A short-term occupational risk assessment is required. Generally end-point selection should be made using toxicity generated by the same route as the likely exposure - in this case dermal. However, the upgraded results from the 21-day dermal study have yet to be submitted to the Agency for review. Therefore, an acceptable dermal study was not available for selecting a NOEL. The NOEL of 175 mg/kg from a single dose acute neurotoxicity study in rats will be used in estimating the MOE. The LOEL was 350 mg/kg, based on an increase in landing foot splay at 7 hours [peak effect time] in female rats. This effect is appropriate for all population sub-groups. An MOE of 100 will adequately protect adult workers. Since the NOEL is from an oral study and dermal absorption data are not available, a dermal absorption factor of 100% must be used in estimating the risk until which time Monsanto submits an upgraded 21-day dermal study.

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

An intermediate term occupational risk assessment is required. Generally end-point selection should be made using toxicity generated by the same route as the likely exposure - in this case dermal. However, no dermal study was available for selecting a NOEL. The subchronic (90 day) feeding study in the dog, the subchronic neurotoxicity study in rats, and the 2-generation reproduction study in rats were considered. All of these studies exhibit decreased body weight gain and food consumption. As noted previously there are palatibility problem with propachlor; therefore, the HIARC concluded that the decreased body weight gain and food consumption should not be used for regulatory purposes.

In the 2-generation reproduction study liver lesions, characterized as contrilobular hepatocellular hypertrophy were observed in both the F_o and F_{1a} generation in both sexes at 69.6 mg/kg/day. The NOEL for this effect was 7.1 mg/kg/day. This was supported by the 2 year rat study at the interim (1 year) sacrifice in which liver lesions, characterized as hepatocellular hypertropy were observed. The observance of liver lesions in both studies at approximately the same time period (i.e., after several months of exposure) and therefore was deemed appropriate for the intermediate-term exposure (i.e., 7 days to several months). Therefore, the maternal/paternal NOEL of 7.1 mg/kg/day from the 2-generation reproduction study in rats will be used in estimating the MOE. The effect (liver lesions) is appropriate for all population sub-groups. An MOE of 100 will adequately protect adult

workers. Since the NOEL is from an oral study and dermal absorption data are not available, a dermal absorption factor of 100% must be used in estimating the risk.

Chronic (non-cancer)(several months to lifetime) Occupational Risk 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 propachlor 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 chronic occupational assessment is not appropriate.

If a chronic scenario can be identified, then this assessment is required. No chronic dermal toxicity studies are available. The NOEL of 5.4 mg/kg/day from the combined oral chronic toxicity/carcinogenicity study in rats will be used in estimating the MOE. (Note that this study was used to establish the RfD.) The LOEL is 16.1 mg/kg/day, based on stomach lesions in males and liver lesions in both sexes. This effect is appropriate for all population sub-groups. An MOE of 100 will adequately protect adult workers. Since the NOEL is from an oral study and dermal absorption data are not available, a dermal absorption factor of 100% must be used in estimating the risk.

Carcinogenic Occupational Risk Assessment

Since a linear low-dose approach for carcinogenic risk assessment was recommended, the assumption is made that any exposure to propachlor during a 70 year lifetime leads to an increase in the carcinogenic risk that is linearly proportional to the exposure level, regardless of the pattern (frequency and level of dosing). All exposures even those of an intermittent nature should be assessed. Therefore, a carcinogenic risk assessment for workers is appropriate. The Q_1^* of 3.2×10^{-2} $(mg/kg/day)^{-1}$ will be used for estimating carcinogenic occupational risk. A risk within the ranges of 10^{-4} to 10^{-6} (or lower) per the Non-Dietary Cancer Risk Policy (8/14/96) is considered protective for adult workers.

Inhalation

The inhalation exposure will be added to the dermal exposure for all occupational risk assessments.

Table 4: Summary of Toxicological Endpoints for Propachlor

Exposure Duration	Exposure Route	Dose (mg/kg/day)	Endpoint	Level of Concern
Acute	Dietary (food and water)	NOEL =175	Increase in landing foot splay at 7 hours post treatment (based on a rat acute neurotoxicity study)	MOE equal to or greater than 100 is protective
Chronic	Dietary (food and water)	RfD = 0.054 (calculated from NOEL = 5.4 using UF = 100)	Stomach lesions and liver lesions (based on a rat chronic toxicity study)	less than 100% of the RfD is protective
Carcinogenic	Dietary (food and water)	$Q_1^* = 3.2 \times 10^{-2}$	Based on female rat ovarian tumors (based on a 2-year oral rat study)	Less than 1×10^{-6} is protective
Short-Term Occupational	Dermal and Inhalation	NOEL = 175	Increase in landing foot splay at 7 hours post treatment (based on a rat acute neurotoxicity study)	MOE equal to or greater than 100 is protective
Intermediate-Term Occupational	Dermal and Inhalation	NOEL = 7.1	Liver lesions in F_o and F_{1a} generations supported by liver lesions at the interim sacrifice in the 2-year rat study (based on a 2-generation rat reproduction study)	MOE equal to or greater than 100 is protective
Chronic-Term Occupational (only if scenario identified)	Dermal and Inhalation	NOEL = 5.4	Based on the use pattern (pre-plant) chronic exposure is not anticipated, therefore, this risk assessment will not be performed	
Carcinogenic Occupational (adult only)	Dermal and Inhalation	$Q_1^* = 3.2 \times 10^{-2}$	Based on female rat ovarian tumors	Within the ranges of 10^{-4} to 10^{-6} (or lower) is protective

4. Risk Assessment

a. Dietary

Propachlor [2-chloro-N-isopropylacetanilide] is a selective herbicide manufactured by Monsanto Agricultural Company under the trade name Ramrod®. A search of the Reference Files System (REFS) conducted on 02/27/97 indicated that propachlor is federally registered for uses on corn and sorghum. The granular (G), flowable concentrate (FlC), and dry flowable (DF) are the propachlor formulation classes registered for use on these crops. These formulations are applied preemergence to the soil using ground equipment.

There are also SLNs (Special Local Needs) for the use of propachlor on onions grown for seed (non-food use) in Oregon and Washington.

Propachlor was the subject of a Reregistration Standard Guidance Document dated 12/84. The Residue Chemistry Chapter Update of the Propachlor Reregistration Standard was issued on 4/10/90. These documents summarized the regulatory conclusions based on available residue chemistry data, and specified the additional data required for reregistration purposes. Data submitted and evaluated following the Update are incorporated into this document, which outlines the Residue Chemistry Science Assessments with respect to the reregistration of propachlor. The conclusions are based on the use patterns supported by the basic producer, Monsanto Agricultural Company.

a. Dietary Exposure (Food Source)

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 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.

The residue chemistry database for propachlor is adequate and will support reregistration eligibility, provided the necessary label changes are made.

(1) Directions for Use

Four propachlor end-use products (EPs) are registered under FIFRA Section 3 to Monsanto. These EPs, including the associated Special Local Need (SLN) registrations under FIFRA Section 24 (c), are listed in the table below.

Table 5: Propachlor EPs with Food/Feed Uses Registered to Monsanto.

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
524-152	11/16/94	20% G	Granular Ramrod® 20 Selective Herbicide
524-328	4/26/94	3 lb/gal FlC	Ramrod® and Atrazine Flowable Herbicide Mixture
524-331 [1]	10/2/96	4 lb/gal FlC	Ramrod® Flowable Herbicide
524-423	6/16/96	48.1% DF [2]	Ramrod® + Atrazine Dry Flowable Herbicide

[1] Including SLN Nos. OR950022 and WA950031.

[2] REFs lists EPA Reg. No. 524-423 as an FlC formulation; however, upon examination of the product label, it was determined that the formulation is more correctly described as a DF.

(2) Nature of the Residue - Plants

The qualitative nature of the residue in plants is adequately understood, based on an acceptable [^{14}C]propachlor metabolism study in sorghum. The sorghum study results have shown that propachlor was not detectable in any edible sorghum commodity. The principal metabolite in sorghum grain and foliage was propachlor oxanilic acid; in addition, all of the propachlor metabolites identified in sorghum commodities contained the N-isopropylaniline (NIPA) moiety.

Radiotracer studies on corn, sorghum, soybeans, and sugar beets conducted using [^{3}H]propachlor, indicated that degradation of propachlor was rapid. In these studies, no intact propachlor was observed 5-7 days following application. Based on the available metabolism data, the Agency has determined that the residues of concern (i.e. those to be regulated in the tolerance expression) in plant commodities are propachlor and all metabolites containing the N-isopropylaniline (NIPA) moiety. (MRID numbers: 40068601, 42140301)

(3) Nature of the Residue - Livestock

The qualitative nature of the residue in livestock is adequately understood. The Agency has determined that ruminant, swine, and poultry metabolism studies in which animals were fed a mixture of radiolabeled metabolites (rather than radiolabeled propachlor) are acceptable since no radiolabeled propachlor was detected in the sorghum metabolism study. (See Meat, Milk, Poultry, Eggs Section for a description of the studies) The residues of concern in livestock commodities are propachlor and its metabolites containing the NIPA moiety. (MRID numbers: 40123101, 401293014)

(4) Residue Analytical Methods

Adequate methods are available for data collection and tolerance enforcement in plant and livestock commodities. The Pesticide Analytical Manual (PAM) Vol. II lists two GC methods, using flame ionization detection, for the determination of propachlor and its metabolites containing the N-isopropylaniline moiety in animal tissues and milk (Method I) and in plant commodities and eggs (Method A). The registrant has proposed a GC method using thermionic specific detection for

tolerance enforcement in plant and livestock commodities. This method is a modification of current enforcement methods and has successfully undergone Agency method validation. The Agency has concluded that the proposed method is adequate for tolerance enforcement provided the registrant incorporates the comments made by BEAD/ACB. The methods used for data collection were GC methods similar to the current enforcement methods. (MRID numbers: 40584004, 43028601, 430286026, 43251801, 40584004, 430286026, 432518017)

(5) Multiresidue Methods

The 1/94 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that propachlor is completely recovered (>80%) using Multiresidue Method Section 302 (Luke method; Protocol D) but is not recovered using Multiresidue Methods Section 303 (Mills, Onley, Gaither method; Protocol E, non-fatty foods) and Section 304 (Mills method; Protocol E, fatty foods). The registrant has submitted the results of multiresidue methods testing of the acid metabolites of propachlor (propachlor oxanilic acid, propachlor sulfinyl lactic acid, propachlor sulfonic acid, and propachlor acetic acid) which have been forwarded to FDA for review; the acid metabolites of propachlor were not adequately recovered by any of the multiresidue method protocols. (MRID number: 43028501)

(6) Storage Stability Data

Adequate storage stability data are available to support reregistration. Storage stability data indicate that residues of propachlor oxanilic acid are stable in corn and sorghum matrices for up to 29-32 months of frozen storage, and residues of propachlor oxanilic acid, propachlor sulfinyl lactic acid, and propachlor sulfonic acid are stable for up to ~28 months of frozen storage in eggs and the kidney, liver, muscle, and fat of swine, poultry, and cattle. Residues of propachlor oxanilic acid, propachlor sulfinyl lactic acid, and propachlor sulfonic acid are stable for up to ~18 months of frozen storage in milk and residues of 4-hydroxyacetanilide are stable for up to 26 months in milk. Storage stability data for propachlor *per se* were not required because propachlor was not detected in the sorghum metabolism study. (MRID numbers: 40081701, 40085301, 40584005, 42121302, 421213039, 421403023)

(7) Crop Field Trials

Crop field trials are used to assess the magnitude of the pesticide residue in/on a commodity at the time of harvest. These studies usually involve application of the pesticide to a crop in accordance with label directions in a manner which would expose the crop to the maximum legal amount of the pesticide. This information is used to set pesticide tolerances.

The Agency has received adequate field trial data depicting propachlor residues of concern in field corn and sorghum commodities following applications made in accordance with the maximum registered use patterns.

Corn: Following treatment at 1X, residues were < 0.02 - 0.04 ppm in grain and < 0.02 - 0.52 in forage except for one grain sample in which residues were 0.19 ppm, and three forage samples in which residues were 1.53 - 2.12 ppm (One sample was from the same trial that yielded the 0.19 ppm grain sample.).

Sorghum: Following treatment at 0.8X or 1.2 X, residues were 0.08 - 3.77 ppm in forage and 0.05 - 2.78 ppm in fodder except for one forage sample at 7.67 ppm, and one fodder sample at 10.59 ppm. The Agency has determined based on available data for supported use patterns, that no tolerances are required for resides in processed commodities of field corn and sorghum. Processing was required to support the previously registered uses on barley, oats, soybean, and wheat grown for seed. Since these uses have not been supported through reregistration, these processing studies are no longer required.

Label revisions are required for sorghum in order to reflect current Agency policies.

Requirements for residue data in aspirated grain fractions were waived because propachlor applications are made preemergence; thus, there is little likelihood that grain will contain surface residues of this chemical.

Although tolerances are listed at 40 CFR §180.211, there are no registered uses on cotton, flax, peas, pumpkins, sweet corn, and sugar beets. Therefore, no field trial data are required for these crops. (MRID numbers: 40085301, 40081701, 40085301, 40081701)

(8) Processed Food/Feed

Adequate corn and sorghum processing studies have been submitted. Residues of propachlor and its NIPA-containing metabolites, calculated as propachlor, did not concentrate in starch, crude oil(dry- and wet-milled), refined oil (dry- and wet-milled), and concentrated insignificantly in flour (1.1x), grits (1.2x), and meal (1.3x) processed from field corn grain bearing detectable propachlor residues following treatment with a single preemergence application of the 4 lb./gal FlC formulation at 3.3x.

The Agency has determined that no tolerances are required for residues in the processed commodities of field corn or sorghum. There are no federally registered uses on crops grown for seed; therefore, no processing study data are required for these crops. (MRID numbers: 40085302, 42962501, 40081702).

(9) Meat, Milk, Poultry, Eggs

Acceptable ruminant and swine feeding studies are available to reassess the established tolerances for residues in milk and in the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. An acceptable poultry feeding study is available to determine the need for tolerances for

residues in eggs and the fat, meat, and meat byproducts of poultry. A summary of the required tolerances for residues in livestock commodities is presented below.

Milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep: The maximum theoretical dietary burdens of propachlor to beef and dairy cattle are 11.99 and 12.91 ppm, respectively (see Table below). The maximum theoretical dietary burden of propachlor to swine is 0.25 ppm based on a diet consisting of 90% sorghum grain and 10% corn milled byproducts.

Table 6: Calculation of Maximum Ruminant Dietary Burden for Propachlor.

	Reassessed		Beef Cattle		Dairy Cattle	
Feed Commodity	Tolerance (ppm)	% Dry Matter	% of Diet	Burden[1] (ppm)	% of Diet	Burden[1] (ppm)
Sorghum grain	0.25	86	40	0.116	40	0.116
Sorghum forage	8.0	35	40	9.143	50	11.429
Sorghum stover	12.0	88	20	2.727	10	1.364
		TOTAL	100	11.986	100	12.909

1 Burden (ppm) = (% of diet)(reassessed tolerance)/(%dry matter)

An adequate dairy cattle feeding study was reviewed in the Propachlor Reregistration Standard Update; this study reflected dosing with a mixture of propachlor metabolites (oxanilic acid, sulfinyl lactic acid, and sulfonic acid at a 6:3:1 ratio) at ~0.4X, 1.3X, and 4X (5, 15, and 50 ppm, respectively) for 28 days. The 15 ppm (1.3X) most closely approximates the estimated total dietary burden. Propachlor metabolite residues were <0.02-0.02 ppm in milk samples from both the 1.3X and 4X dosing levels. In tissues, residues were <0.02-0.04 ppm in liver, 0.09-0.12 ppm in kidney, <0.02 ppm in muscle, and <0.02-0.04 ppm in fat at the 1.3X dosing level.

Based on the maximum theoretical dietary burden, and based on residues in milk and ruminant tissues, the following revised tolerances are proposed: 0.05 ppm for residues in the meat byproducts (except kidney) and fat and 0.2 ppm for residues in the kidney of cattle, horses, goats and sheep. Existing tolerances for residues in milk and in the meat of cattle, horses, goats and sheep are adequate.

An adequate swine feeding study was reviewed in the Propachlor Reregistration Standard Update; this study reflected dosing with a mixture of propachlor metabolites at ~20X, 60X, and 200X (5, 15, and 50 ppm, respectively) for 28 days. At the 20X dosing level, propachlor metabolite residues were 0.02-0.04 ppm in liver, 0.04-0.06 ppm in kidney, <0.02 ppm in muscle, and <0.02 ppm in fat. Based on these data, the existing tolerances of 0.02 ppm for propachlor residues in hog meat, fat, and meat by-products are adequate.

Eggs and the fat, meat, and meat byproducts of poultry: The maximum theoretical dietary burden of propachlor to poultry is 0.24 ppm.

Table 7: Calculation of Maximum Poultry Dietary Burden for Propachlor

Poultry Feed Commodity	Reassessed Tolerance (ppm)	% of Diet	Burden[1] (ppm)
Field corn grain	0.20	20	0.040
Sorghum grain	0.25	80	0.200
	TOTAL	100	0.240

1 Burden (ppm) = (%of diet) (reassessed tolerance)

An adequate poultry feeding study was reviewed in the Propachlor Reregistration Standard Update; the study reflected dosing with a mixture of propachlor metabolites at ~20X, 60X, and 200X (5, 15, and 50 ppm, respectively) for 28 days. At the 20X and 60X dosing levels, propachlor metabolite residues were <0.02 ppm in eggs, and <0.02-0.02 ppm in fat, kidney, liver, and muscle. Based on this study, HED concludes residues in poultry commodities can be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues; therefore, no tolerances are needed for residues in poultry commodities. (MRID numbers: 40584001, 40584003)

(10) Water, Fish, and Irrigated Crops

Propachlor is not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic. (MRID number: 43064501)

(11) Food Handling

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

(12) Confined Accumulation in Rotational Crops

The nature of the residue in rotational crops is adequately understood, based on an acceptable confined rotational crop study. Following application of [^{14}C]propachlor to sandy loam soil at 6.0 lb ai/A (1X the maximum rate), lettuce, radishes, and wheat planted were planted at 30-, 120-, and 365- day plantback intervals (PBIs). Lettuce, and radishes (roots and tops), as well as immature and mature wheat, were harvested and analyzed for total radioactive residues (TRR). Accumulation of radioactive residues was highest in samples planted 30 and 120 days after treatment (DAT) and decreased at the 365-DAT planting interval. Radioactive residues (expressed as [^{14}C]propachlor equivalents) were highest in wheat straw at 9.630, 5.281, and 1.704 ppm at the 30-, and 120-, and 365-DAT intervals, respectively, and lowest in lettuce at 0.124, 0.161, and 0.049 ppm, respectively. Propachlor residues of concern were present in rotational crops at 30-, 120-, and 365-day plantback intervals (PBIs).

The confined rotational crop study indicates that the metabolism of propachlor in rotational crops is similar to that in primary plants; metabolites containing the NIPA moiety were observed in

both studies. Propachlor residues of concern are the parent and all metabolites containing the N-isopropyl aniline (NIPA) moiety. Parent propachlor was not detected in any rotational crop commodity at any rotational interval. The major metabolite identified in all matrices at all three plantback intervals was oxanilic acid. Based on identification of NIPA-containing residues at 68% TRR in grain, and 43% TRR in straw of wheat from the 365-day plantback interval, residues of concern in rotational crops were 0.48, 0.39, and 0.73 ppm in forage, grain and straw, respectively. Given that the residues in rotational grain were 0.48 ppm, and given that tolerances for residues in primary crops are 0.1 ppm in corn grain and 0.25 ppm in grain sorghum, the Agency believes that residues of concern above 0.01 ppm could be present in rotational grains at plantback intervals of up to 365 days. In addition, residues of concern above 0.01 ppm were identified in all rotational crop matrices at the 365-day PBI. Therefore, the Agency will not support unrestricted crop rotation; only crops for which there are registered propachlor uses may be rotated to treated fields.

(13) Field Accumulation in Rotational Crops

The reregistration requirement for data pertaining to field accumulation in rotational crops is not fulfilled. The confined rotational crop data indicate that limited field rotational crop studies must be conducted. The limited field trials must be conducted on representative crops of the root and tuber vegetables, leafy vegetables, and small grains at two sites per crop for a total of six trials.

This requirement should not affect the reregistration eligibility decision for propachlor; however, the registrant must amend the product labels to add a rotational crop restriction stating that only crops for which there are registered propachlor uses may be rotated to treated fields.

b. Dietary Risk Assessment (Food Source)

Analyses were performed to estimate acute and chronic dietary risk for propachlor. The Agency uses the Dietary Risk Evaluation System (DRES) to combine the pesticide residue data with food consumption data. Thus, dietary (food source) exposure is equal to pesticide residues present in food multiplied by consumption data for the food item.

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 becoming dated. However, at this time, the data are the best information available to the Agency.

Note that a tiered approach is used for dietary risk assessment. The pesticide residue component is progressively refined proceeding from worst-case assumptions (such as tolerance level

residues) to more realistic assumptions (such as use of monitoring data). Refinement of pesticide residues continues until no risk concern is indicated or a determination is made that mitigation is required. This tiering approach conserves Agency resources.

Acute - Tier 1 - Point Estimates

A Tier 1 acute assessment was performed to estimate the risk of consuming a large amount of propachlor residues in the food consumed on a single day. The assessment uses a single high-end residue estimate, which is usually the tolerance, together with a distribution of individual food consumption values as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey. Thus, exposure to the chemical is accumulated for each commodity to estimate a worst-case single-day's exposure. It is assumed that propachlor is uniformly distributed in the food supply at the tolerance level. Note that a Tier 1 acute dietary asessment does not account for blended commodities or percent crop treated data.

As previously discussed the appropriate endpoint for an acute dietary assessment is 175 mg/kg/day.

Acute Dietary Risk = 175 mg/kg/day/ high-end exposure = MOE

The Margin of Exposure (MOE) is a measure of how close the high-end exposure comes to the NOEL. An MOE greater than 100 will adequately protect all population sub-groups including infants and children. The acute dietary MOEs (rounded to two significant figures) for food source exposure to propachlor for various population sub-groups are given below.

Table 8: Acute MOE's

Population Sub-Groups	High-End Exposure (mg/kg/day)	MOE
Infants < 1 year	0.01	18,000
Child (1 - 6 years)	0.004	44,000
Females (13+ years)	0.0012	150,000
Males (13+ years)	0.001	180,000
General Population	0.003	58,000

The MOE's for all population sub-groups greatly exceed 100. Therefore, the Agency has no concerns for acute dietary (food) exposure for all population sub-groups.

Chronic Dietary (food source)

A chronic (non-carcinogenic) dietary assessment is performed to estimate the lifetime risk of consuming an average amount of propachlor residues. The assessment uses 3 day average

consumption values from USDA's 1977-1978 Nationwide Food Consumption Survey. Chronic dietary risk is calculated for the U.S. population and 22 population sub-groups using DRES (Dietary Risk Evaluation System). As previously discussed, the appropriate endpoint for the chronic assessment is the RfD, 0.054 mg/kg/day. Chronic risk is reported as the percent of the RfD that is taken up by the estimated exposure.

Tolerance level residues were used for corn and sorghum. However, the agency refined its assessment by using percent crop treated (%CT) information for these two commodities. OPP's Biological and Economic Analysis Division supplied the %CT information, which was obtained from various public and proprietary sources. The following values were used: corn 2%, and sorghum 8%. This analysis assumes that propachlor is uniformly distributed in the food supply at the tolerance level adjusted for the percent crop treated.

Section 408(b)(2)(F) requires that if a tolerance relies on percent crop-treated data, that the Agency make a determination as to the reliability of the data. Percent crop-treated estimates are derived from federal and private market survey data. Typically, a range is assumed for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not understated for any significant population sub-group. Additionally, the DRES (Dietary Risk Evaluation System) modeling used in estimating chronic dietary risk uses regional consumption information to estimate exposure for four population sub-groups that are geographically based regions of the United States. To provide for the periodic evaluation of these estimates of percent crop treated, the Agency will require under Section 408(b)(2)(F) for periodic re-evaluation of the percent crop treated data as long as the tolerances remain in force.

Anticipated residues were estimated for meat and milk by re-estimating the dietary burden using the percent crop treated data.

Table 9: Re-Estimation of Ruminant Dietary Burden for Propachlor Using Percent Crop Treated Data

Feed Item	Reassessed Tolerance (mg/kg)	% Dry Matter	% Crop Treated	Beef Cattle		Dairy Cattle	
				% of Diet	Burden[1] (mg/kg)	% of Diet	Burden[1] (mg/kg)
Sorghum grain	0.25	86	8	40	0.0093	40	0.0093
Sorghum forage	8.0	35	8	40	0.731	50	0.914
Sorghum stover	12.0	88	8	20	0.218	10	0.109
TOTAL				100	0.958	100	1.03

1 Burden (ppm) = (%of diet)(reassessed tolerance)(%CT) / % dry matter

The dietary burden for ruminants is now 1.0 mg/kg, as compared to the previous estimation of 13 mg/kg. In the previously described feeding studies, at the mg/kg feeding level (5X), residues were not detected (<0.02 mg/kg) in milk, muscle, fat, and liver. Residues were 0.03 - 0.05 mg/kg in kidney. At the 15X feeding level, residues were detected in kidney (0.12 mg/kg), fat (0.04 mg/kg), and liver (0.04 mg/kg), but not in milk or muscle (<0.02 mg/kg). Thus, the anticipated residues are for use in dietary risk estimation are: milk 0.001 mg/kg, meat 0.001 mg/kg, fat 0.003 mg/kg, liver 0.003 mg/kg, and kidney 0.01 mg/kg. These anticipated residues are based on the finite residues or limits of quantitation found at the exaggerated feeding levels. Note that the residues in kidney, the only commodity with finite residues at three feeding concentrations, were approximately linear with feeding level: 0.05 mg/kg at 5X; 0.12 mg/kg at 15X; and 0.53 mg/kg at 50X.

Section 408(b)(2)(E) requires that if a tolerance relies on anticipated or actual residue levels, that the Agency make a determination every five years as to the reliability of the data, i.e. that the current residue levels are not above the levels relied on. For anticipated residues for meat and milk, instead of using tolerances as the level of propachlor present in the feed items, anticipated residues as estimated for food /feed crops were used in the calculation. To provide for the periodic evaluation of these anticipated residues, the Agency will require under Section 408(b)(2)(E) residue data to be evaluated after the first five years.

Table 10: Chronic (Non-Carcinogenic) Dietary Risk

Subgroup	Exposure(mg/kg/day)	%Reference dose
U.S. population	0.000018	0.03
Children (1-6 years)	0.000045	0.08
Non-nursing infants	0.000073	0.1
Adult Females (20+ years)	0.000009	0.02
Adult Males (20+ years)	0.000011	0.02

The %RfDs for all population sub-groups are less than 1%, which is much less than the Agency's level of concern of 100%.

Carcinogenic Dietary (Food Source)

A carcinogenic dietary assessment is performed to estimate the lifetime carcinogenic risk from consuming an average amount of propachlor residues. The assessment uses 3 day average consumption values from USDA's 1977-1978 Nationwide Food Consumption Survey. The exposure (mg/kg/day) is the same as that estimated by DRES for the chronic dietary assessment. Carcinogenic dietary risk is calculated for the adult U.S. population. As previously discussed, the appropriate endpoint for the carcinogenic assessment is the Q_1^*, 0.032 $(mg/kg/day)^{-1}$. This analysis also assumes that propachlor residues are uniformly distributed in the food supply.

Carcinogenic dietary risk is estimated by:

Exposure (mg/kg/day) x Q_1^* (0.032 $(mg/kg/day)^{-1}$) = Risk

For propachlor, carcinogenic risk for adult females is:

(0.000009 mg/kg/day)((0.032 $(mg/kg/day)^{-1}$) = 2.9×10^{-7}

For propachlor, carcinogenic risk for adult males is:

(0.000011 mg/kg/day)((0.032 $(mg/kg/day)^{-1}$) = 3.5×10^{-7}

These estimates of carcinogenic dietary risk are less than 1×10^{-6}.

Data for Use in Risk Assessment

Surface water monitoring data are primarily limited by the lack of correlation between sampling date and the use patterns of the pesticide within the study's drainage basin. Additionally, the sample locations were not associated with actual drinking water intakes for surface water.

The monitored wells were not associated with known groundwater drinking water sources.

The monitoring data presented in this document provides verification that propachlor is found in surface and ground waters of the U.S. However, the lack of correlation between use and sampling and sampling and mitigation measures that may have occurred over time make it difficult to rely on the data for quantitative risk assessment purposes without further analysis. Review of the data did not provide evidence as to whether the data were representative of vulnerable areas, peaks, long term means, or other important factor in determining the extent of impact on an aquatic environment.

The Agency believes that the monitoring data should be used only for illustrative purposes; while still acknowledging that the monitoring data and the model-derived estimated values were within the same order of magnitude. For quantifying risks to the general population, including infants and children, SCI-GROW and PRZM2.3/EXAM2 Estimated Environmental Concentrations (EEC's) are recommended.

Since all surface water numbers exceed the groundwater estimate of 0.027 ppb, only the surface water estimates will be used in the risk assessment. For propachlor, the acute exposure will be estimated using the highest of the estimated values which is 64 ppb estimated by PRZM2.3/EXAMS2 for grain sorghum. The chronic and carcinogenic exposure will be estimated using the highest of the estimated values which is 0.6 ppb estimated by PRZM2.3/EXAMS2 for grain sorghum.

c. Tier II EEC Estimations

Tier II EEC's were estimated using environmental models (PRZM2.3/EXAMS2.97) for use in drinking water exposure estimates. A ten-hectare drainage basin with a 1 hectare pond 2 meters deep does not adequately reflect the dynamics in a watershed which is large enough to support a drinking water utility. A drinking water utility with a basin of adequate size would not be planted entirely in a single crop nor would it be treated entirely with the pesticide being modeled. Additionally, the pesticide would more than likely be applied over several days to weeks rather than on a single day within a given basin. This would in effect reduce the magnitude of the peak concentrations, but would broaden them, reducing the acute exposure but perhaps increasing the chronic exposure. The final overriding concern with the use of estimates derived from PRZM/EXAMS is that the simulated pond has no outlet where as any water body capable of supporting a drinking water utility would have some flow through (rivers) or turnover (reservoirs). See section 6 for a full discussion of modeling and monitoring results.

d. Dietary Exposure (Drinking Water)

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 Office of Water. The 10 kilograms is an assumption per memo of D. Edwards.

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 nor drink 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.

Acute Exposures

For propachlor, acute exposure for adult females is:

(64 ug/L)(0.001)(2 L) / 60 kg = 0.002133 mg/kg/day

For propachlor, acute exposure for adult males is:

(64 ug/L)(0.001)(2 L) / 70 kg = 0.001829 mg/kg/day

For propachlor, acute exposure for children (1 - 6 years) is:

(64 ug/L)(0.001)(1 L) / 10 kg = 0.0064 mg/kg/day

Chronic/Carcinogenic Exposures

For propachlor, chronic/carcinogenic exposure for adult females is:

(0.6 ug/L)(0.001)(2 L) / 60 kg = 0.00002 mg/kg/day

For propachlor, chronic/carcinogenic exposure for adult males is:

(0.6 ug/L)(0.001)(2 L) / 70 kg = 0.000017 mg/kg/day

For propachlor, chronic/carcinogenic exposure for children (1 - 6 years) is:

(0.6 ug/L)(0.001)(1 L) / 10 kg = 0.00006 mg/kg/day

e. Dietary Drinking Water Risk

Acute Risk

As previously stated, the NOEL for use in estimating acute dietary risk is 175 mg/kg/day.

MOE = NOEL/exposure

For propachlor, acute risk for adult females is:

175 mg/kg/day / 0.002133 mg/kg/day = 82,000

For propachlor, acute risk for adult males is:

175 mg/kg/day / 0.001829 mg/kg/day = 96,000

For propachlor, acute risk for children (1 - 6 years) is:

175 mg/kg/day / 0.0064 mg/kg/day = 27,000

All MOEs greatly exceed 100. Therefore, the Agency has no concerns for acute drinking water dietary exposure.

Chronic Risk

As previously stated, the RfD of 0.054 mg/kg/day will be used in estimating chronic (non-cancer) dietary risk.

Exposure/RfD x 100 = % RfD

For propachlor, chronic risk for adult females is:

0.00002 mg/kg/day / 0.054 mg/kg/day x 100 = 0.04%

For propachlor, chronic risk for adult males is:

0.000017 mg/kg/day / 0.054 mg/kg/day x 100 = 0.03%

For propachlor, chronic risk for children (1 - 6 years) is:

0.00006 mg/kg/day / 0.054 mg/kg/day x 100 = 0.1%

All %RfDs are less than 1%, which is much less than the Agency's level of concern of 100%.

Carcinogenic Risk

As previously stated, the Q_1^* of 0.032 $(mg/kg/day)^{-1}$ will be used in estimating carcinogenic dietary risk. By concentration, the carcinogenic risk is estimated for the adult population only.

$(Exposure)(Q_1^*)$ = risk

For propachlor, carcinogenic risk for adult females is:

$(0.00002\ mg/kg/day)(0.032\ (mg/kg/day)^{-1}) = 6.3 \times 10^{-7}$

For propachlor, carcinogenic risk for adult males is:

$(0.000017\ mg/kg/day)(0.032\ (mg/kg/day)^{-1}) = 5.4 \times 10^{-7}$

These risks are less than 1×10^{-6}, the Agency's level of carcinogenic concern.

f. Total Dietary (Food and Water) Assessment

Propachlor residues can be consumed in both food and drinking water. Therefore, a total dietary assessment that accounts for both is appropriate. Conservative estimates of acute dietary risk,

chronic dietary risk, and carcinogenic dietary risk from consumption of propachlor residues in food and in water were estimated previously in this document.

Per current EPA policy, dietary drinking water risk can be estimated only for adult females, adult males, and child (1 - 6 years). Therefore, only aggregate risk pertaining to these population sub-groups are assessed. MOEs and carcinogenic risk are rounded to two significant figures. Chronic risk is rounded to one significant figure.

Table 11: Total Dietary Acute MOEs

Population Sub-Group	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	Total Dietary Exposure (mg/kg/day)	Total Dietary Acute MOEs
adult female	0.0012	0.002133	0.003333	53,000
Population Sub-Group	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	Total Dietary Exposure (mg/kg/day)	Total Dietary Acute MOEs
adult male	0.001	0.001829	0.002829	62,000
child (1 - 6 years)	0.004	0.0064	0.0104	17,000

All total dietary MOEs greatly exceed 100. Therefore, the Agency has no concerns for total acute dietary exposure.

Table 12: Total Chronic (non-carcinogenic) Dietary %RfD

Population Sub-Group	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	Total Dietary Exposure (mg/kg/day)	Total Dietary RfD
adult female	0.000009	0.00002	0.000029	0.05
adult male	0.000011	0.000017	0.000028	0.05
child (1 - 6 years)	0.000045	0.00006	0.000105	0.2

All total dietary RfDs are much less than the Agency's level of concern of 100%.

Table 13: Total Dietary Carcinogenic Risk

Population Sub-Group	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	Total Dietary Exposure (mg/kg/day)	Total Dietary Carcinogenic Risk
adult female	0.000009	0.00002	0.000029	9.3×10^{-7}
adult male	0.000011	0.000017	0.000028	9.0×10^{-7}

The carcinogenic risk is less than HED's level of concern of 1×10^{-6}.

There are no registered residential uses of propachlor. Therefore, an aggregate assessment due to exposure from residues of propachlor in food and water, and from residential uses is not meaningful. Therefore, these total dietary (food and water) assessments are the aggregate assessments for the purposes of FQPA.

g. Dietary Risk Characterization

The acute dietary food source assessment was performed at tolerance level and did not consider any blended commodities, anticipated residues, or percent crop treated data. Therefore, actual residues are likely to be lower, which would correspondingly increase the MOEs (decreasing risk).

The chronic/carcinogenic food source assessments were performed at tolerance level with percent crop treated data for corn and sorghum. Anticipated residues were estimated for meat and milk. These assessments are more refined than Tier 1 (tolerance level assessments), and therefore are a more realistic assessment, however, further refinement could occur.

The drinking water assessments are considered to be over-estimates since surface water modeling numbers are from PRZM2.3/EXAMs2 which is an ecological model. It does not necessarily represent drinking water that would be obtained from a treatment plant.

The Agency considers that the data used to perform these assessments were adequate. Overall, the Agency does not consider any of these estimates to under-represent residue levels and corresponding risk estimates.

b. Occupational and Residential

Occupational Exposure Assessment

An occupational and/or residential 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) during use or to persons entering treated sites after application is complete. In the case of propachlor, the above indicators have been met. The toxicological criterion

is triggered by the determination that propachlor is a "likely" human carcinogen and the potential for exposure exists.

Use Patterns

Propachlor, 2-chloro-N-isopropylacetanilide, is a selective herbicide used in commercial settings for the preemergence weed control of annual grasses and broadleaf weeds in grain sorghum (milo), field corn, hybrid seed corn, and silage corn, and for weed control "in the first season, growth-establishment phase" for onion seed use in Washington and Oregon. Propachlor is formulated as a manufacturing product (93 and 96.5 percent active ingredient), a flowable concentrate liquid (31.5 and 42 percent active ingredient), a dry flowable (48.1 percent active ingredient), and as a granular (20 percent active ingredient).

Propachlor can be applied with groundboom sprayers, tractor drawn granular broadcast spreaders, and granular row planters. Application rates vary from 3.0 to 6.0 pounds active ingredient per acre depending upon the application scenario. Propachlor can be applied to the following crops/ areas: field corn, hybrid seed corn, silage corn, grain sorghum (milo), and onions grown for seed.

Occupational-use Products and Homeowner Use Products

Currently registered products containing propachlor are intended for occupational uses. Due to the absence of residential uses, a residential assessment has not been performed.

Acute Toxicology Categories

Guideline studies for acute toxicity indicate that the technical grade of propachlor is classified as category I for primary eye irritation and category IV for primary skin irritation.

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The WPS requires a 48 hour REI for pesticides belonging to toxicity category I for primary eye irritation.

Other Endpoints of Concern

The propachlor Toxicology Endpoint Selection (TES) document, dated May 7, 1997, indicates that there are toxicological endpoints of concern for propachlor. (See Dose-Response Section)

Epidemiological Information

The OPP Incident Data System, the Toxic Exposure Surveillance System (National Poison Control Centers), California Department of Food and Agriculture/Department of Pesticide Regulation Database, and the National Pesticide Telecommunications Network were searched for poisoning

incident data on the active ingredient propachlor. In these databases, no serious illnesses have been reported due to exposure to propachlor, although there are reports of dermatitis and skin sensitivity.

The World Health Organization (1993) reported a case concerning a 29 year old agricultural worker who had been in contact with propachlor for 8 days and experienced contact eczema on the palms, wrists, and forearms. The skin lesions disappeared after contact ceased. In another 1993 WHO report concerning a patch test of 17 farmers, there were seven cases that had a positive patch test reaction, and five cases that had an irritant reaction to propachlor. In a study of 79 workers manufacturing 65% propachlor, 19% of the workers showed contact dermatitis due to propachlor exposure.

Handler Exposure Assessment

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

(1) mixing/loading liquids for groundboom application;
(2) mixing/loading dry flowables for groundboom application;
(3) loading granulars for tractor-drawn spreader application;
(4) applying sprays with groundboom equipment; and
(5) applying granulars with a tractor-drawn spreader.

Dermal and inhalation exposures are presented in Table 14. No chemical-specific data were submitted; therefore, Table 14 was developed using the Pesticide Handlers Exposure Database (PHED), Version 1.1 surrogate data as estimated in the PHED Surrogate Exposure Guide, May, 1997. The PHED was developed by Health Canada, the American Crop Protection Association, and EPA. PHED was initially released for public use in 1992. PHED is a 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 exposure scenarios that are representative of the use of the chemical. The Agency, 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 calculates 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 Agency's 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, the level of concern is met or exceeded, then increasing levels of risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to recalculate the MOE's until exposure is sufficiently reduced to achieve an appropriate margin of exposure or cancer risk.

The formulas for all calculations are given in the foot-notes in the various Tables.

Table 14: Dermal and Inhalation Exposures to Propachlor

Exposure Scenario (Scenario.#)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Crop Applied[c]	Application Rate (lb ai/acre)[d]	Acres Treated (acres/day)[e]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]
Mixer/Loader Exposure							
Mixing/Loading Liquids for Groundboom Application (1)	2.9	1.2	corn	6	80	1,392	0.6
			grain sorghum, onions	5		1,160	0.5
Mixing/Loading Dry Flowables for Groundboom Application (2)	0.07	0.8	corn, grain sorghum	4.8	80	27	0.3
Loading Granulars for a Tractor-Drawn Spreader Application (3)	0.008	1.7	corn	6	80	3.8	0.8
			grain sorghum	5		3.2	0.7
Applicator Exposure							
Applying Sprays with a Groundboom Sprayer (4)	0.014	0.7	corn	6	80	6.7	0.3
			grain sorghum, onions	5		5.6	0.3
Applying Granulars with a Tractor-Drawn Spreader (5)	0.01	1.2	corn	6	80	4.8	0.6
			grain sorghum	5		4.0	0.5

[a] Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading for M/Ls, and open cab tractor for applicators. It should be noted that labels 524-328, -152, and -331 require use of gloves and protective eyewear for mixer/loaders, which is more protective than baseline.

[b] Baseline inhalation unit exposure represents no respirator.

[c] Corn crops include field corn, hybrid seed corn, and silage corn; the onion uses are limited to the states of Washington and Oregon (EPA Reg 524-331).

[d] Application rates are maximum values found in the propachlor labels, which is available as a flowable liquid (EPA Regs. 524-331 and 524-328), a dry flowable (EPA Reg. 524-423), and granular (EPA Reg. 524-152).

[e] Daily acres treated values are from HED estimates of acreage that could be treated in a single day for each exposure scenario of concern.

[f] Daily dermal exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/acre) * Acres treated (acres/day).

[g] Daily inhalation exposure (mg ai/day)= Exposure (µg/lb ai) x (1 mg/1000 µg) Conversion x Application Rate (lb ai/acre) x Acres treated (acres/day).

Table 15: Exposure Scenario Descriptions for the Use of Propachlor

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations (1)	PHED V1.1	80 acres for groundboom.	**Baseline:** Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 71 to 121 replicates; Inhalation = 85 replicates. High confidence in dermal and inhalation data. **PPE:** Hands and dermal acceptable grades. Hands = 59 replicates: Dermal = 71 to 121 replicates. High confidence in dermal and inhalation data. A 50% protection factor (PF) was applied on dermal, non-hand exposure to simulate coveralls - double layer clothing. **Engineering Controls:** Dermal = ABC, Hands and inhalation acceptable grades. Hands = 31 replicates; Dermal = 30 to 36 replicates; Inhalation = 27 replicates. High confidence in inhalation data. Medium confidence in dermal data. Gloves were worn during use of engineering controls.
Mixing/Loading Dry Flowable Formulations (2)	PHED V1.1	80 acres for groundboom.	**Baseline:** Hands, dermal, and inhalation acceptable grades. Hands = 7 replicates; Dermal = 16 to 26 replicates. Low Confidence in dermal data due to the small number of hand replicates. High confidence in inhalation data. **PPE:** Hands = ABC, Dermal and inhalation acceptable grades. Hands = 34 replicates; Dermal = 16 to 26 replicates. Medium Confidence in dermal data. High Confidence in inhalation data. A 50% protection factor (PF) was applied on dermal, non-hand exposure to simulate coveralls - double layer clothing. **Engineering Controls:** A 90% PF was applied on baseline dermal and inhalation exposure data to simulate a water soluble pack or closed mixing/loading system scenario.

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Loading Granular Formulations (3)	PHED V1.1	80 acres for row planters and tractor drawn spreaders.	**Baseline:** Hands all grades; dermal = ABC; Inhalation acceptable grades. Hands = 10 replicates; dermal = 33 to 78 replicates; inhalation = 58 replicates. Low confidence in dermal data due to the poor quality of the hand replicates and low replicate numbers. High confidence for inhalation data. **PPE:** Hands and inhalation acceptable grades; Dermal = ABC. Hands = 45 replicates; dermal 12 to 59 replicates; inhalation = 58 replicates. High confidence in inhalation data. Low confidence in dermal data due to low number of replicates. **Engineering Controls:** A 90% PF was applied on dermal and inhalation exposure to simulate a closed loading system scenario.
Applicator Descriptors			
Applying Sprays with a Groundboom Sprayer (4)	PHED V1.1	80 acres.	**Baseline:** Hands, dermal, and inhalation acceptable grades. Hands = 29 replicates; dermal = 23 to 42 replicates; inhalation = 22 replicates. High confidence in dermal and inhalation data. **PPE:** Hands = ABC grades; dermal and inhalation acceptable grades. Hands= 21 replicates; dermal = 23 to 42 replicates; inhalation = 22 replicates. Medium confidence in dermal data, and high confidence in inhalation data. A 50% protection factor (PF) was applied on dermal, non-hand exposure to simulate coveralls - double layer clothing. **Engineering Controls:** Hands and dermal= ABC grades; inhalation acceptable grades. Hands= 16 replicates; dermal = 20 to 31 replicates; inhalation = 16 replicates. Medium confidence in dermal data, and high confidence in inhalation data.

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Applying Granulars with a Tractor-Drawn Spreader (5)	PHED V1.1	80 acres.	**Baseline:** Hands, dermal, and inhalation = acceptable grades. Hands = 5 replicates; dermal = 1 to 5 replicates; inhalation = 5 replicates. Low confidence in dermal and inhalation replicates. **PPE:** Hands, dermal, and inhalation = acceptable grades. Hands = 5 replicates, dermal = 4 to 5 replicates, and inhalation = 5 replicates. Low confidence in hands, dermal, and inhalation. A 50% protection factor (PF) was applied on dermal, non-hand exposure to simulate coveralls - double layer clothing. A 90% PF was applied to hands to simulate gloves. **Engineering Controls:** Hands, dermal, and inhalation = acceptable grades. Hands = 24 replicates; dermal = 2 to 30 replicates; and inhalation = 37 replicates. High confidence in inhalation data. Low confidence in dermal and hands data.

[a] Standard Assumptions based on an 8-hour work day (i.e., how much a worker would handle in a single day).

[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. All handler exposure assessments in this document are based on the "Best Available" data as defined by HED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments.) Best available grades are assigned as follows: matrices with grades A and B data (which is defined as acceptable grade 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 (all grades) regardless of the quality and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection.

Data confidence as reported in the Table refers to both the quality and the quantity (number of replicates) of data for each PHED run. Each study in PHED has been graded from A to E. A high confidence run is grades A and B data and 15 or more replicates per body part. Any combination of A or B grade data are listed as AB grade data in the tables. A medium confidence run is grades A, B, and C data and 15 or more replicates per body part. Any combination of A, B, and C grade data are listed as ABC grade data in the tables. A low confidence run is all grades (any run that includes D or E grade data) or has less than 15 replicates per body part.

Occupational Risk Assessment

Handler Risk Assessment

All risks (MOEs and cancer estimates) are reported to 2 significant figures. The baseline daily exposures were divided by 70 kg to estimate the baseline dose. It was necessary to use PPE (personal protective equipment) to achieve a MOE greater than 100 for scenario 1, mixing/loading liquid formulations.

Table 16: Short-Term Risks to Propachlor

Exposure Scenario (Scenario #)	Baseline Dose (mg/kg/day)[a]	Baseline MOE[b]	Risk Mitigation Measures			
			Additional PPE			
			PPE Dermal Unit Exposure. (mg/lb ai)[c]	PPE Inhalation Unit Exposure (ug/lb ai)[c]	PPE Daily Dose (mg/kg/day)[a]	PPE MOE[b]
Mixer/Loader Risk						
Mixing/Loading Liquids for Groundboom Application (1)	20 (corn)	9	0.017	1.2	0.12	1,400
	17 (grain sorghum and onions)	10			0.10	1,700
Mixing/Loading Dry Flowables for Groundboom Application (2)	0.39 (corn and grain sorghum)	450	NA		NA	NA
Loading Granulars for Tractor-Drawn Spreader Application (3)	0.07 (corn)	2,750	NA		NA	NA
	0.06 (grain sorghum)	3,100				
Applicator Risk						
Applying Sprays with a Groundboom Sprayer (4)	0.1 (corn)	1,800	NA		NA	NA
	0.08 (grain sorghum and onions)	2,100				
Applying Granulars with a Tractor-Drawn Spreader (5)	0.08 (corn)	2,300	NA		NA	NA
	0.06 (grain sorghum)	2,800				

NA not applicable. MOE for the previous scenario is greater than 100; therefore, additional mitigation is not necessary.

[a] Total Dose (mg/kg/day) = Dermal exposure (mg/day) + Inhalation exposure (mg/day) / Body weight (70 kg). There is no dermal absorption factor; therefore, 100% dermal absorption is assumed; 100% inhalation absorption is assumed.

[b] MOE = (NOEL (175 mg/kg/day) / Daily Dose (mg/kg/day)).

[c] Additional PPE: Double layer of clothing and chemical resistant gloves; no respirator.

Propachlor is used as a preemergent on corn and sorghum. Therefore, the Agency believes that the intermediate-term scenario is the most typical and appropriate, since available information indicates that for pre-plant herbicide 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. This is supported by information that indicates that an early-season corn herbicide applied once per season would result in 20 days of exposure per year to commercial handlers. An early-season sorghum pesticide applied once per season would result in 14 days of exposure per year to commercial handlers.

Cancer risks were estimated beginning with the scenario for which intermediate term MOEs were greater than 100, since this level of mitigation would be required based on the risk assessment for the intermediate scenario. The Agency's default female body weight of 60 kg was used since the Q_1^* of 0.032 $(mg/kg/day)^{-1}$ was based on female rat ovarian tumors. No information on typical, actual use rates are available; therefore, maximum use (label) rates were used.

Table 17: Intermediate-Term Risks to Propachlor - Baseline and Personal Protective Equipment (PPE)

Exposure Scenario (Scenario #)	Baseline Dermal Dose (mg/kg/day)	Baseline Inhalation Dose (mg/kg/day)[a]	Baseline Total Dose (mg/kg/day)[b]	Baseline MOE[c]	Risk Mitigation Measures					
					Additional PPE[d]					
					PPE Dermal Unit Exp. (mg/lb ai)	PPE Inhalation Unit Exposure (µg/lb ai)	PPE Daily Dermal Dose (mg/kg/d)[e f]	PPE Daily Inhalation Dose (mg/kg/d)[e]	PPE Total Daily Dose (mg/kg/d)[b]	PPE MOE [c]
Mixer/Loader Risk										
Mixing/Loading Liquids for Groundboom Application (1)	20 (corn)	0.008	20	< 1	0.025	1.2	0.17	0.008	0.18	40
	17 (grain sorghum and onions)	0.007	17	< 1			0.14	0.006	0.15	47
Mixing/Loading Dry Flowables for Groundboom Application (2)	0.39 (corn and grain sorghum)	0.004	0.39	18	0.04	0.8	0.22	0.004	0.22	32
Loading Granulars for Tractor-Drawn Spreader Application (3)	0.05 (corn)	0.01	0.07	110	NA	NA	NA	NA	NA	NA
	0.05 (grain sorghum)	0.01	0.05	130			NA	NA	NA	NA
Applicator Risk										
Applying Sprays with a Groundboom Sprayer (4)	0.1 (corn)	0.004	0.1	71	0.01	0.7	0.069	0.005	0.074	96
	0.08 (grain sorghum and onions)	0.004	0.08	84			0.057	0.004	0.061	120
Applying Granulars with a Tractor-Drawn Spreader (5)	0.07 (corn)	0.009	0.08	92	0.004	1.2	0.027	0.008	0.035	200
	0.06 (grain sorghum)	0.007	0.06	110	NA	NA	NA	NA	NA	NA

NA not applicable. MOE for the previous scenario is greater than 100; therefore, additional mitigation is not necessary.

[a] Dose (mg/kg/day) = Exposure (mg/day) / Body weight (70 kg). There is no dermal absorption factor; therefore, 100% dermal absorption is assumed; 100% inhalation absorption is assumed. See Table 18 for baseline dermal and inhalation exposure estimates.

[b] Total Daily Dose = Dermal Daily Dose + Inhalation Daily Dose

[c] MOE = (NOEL (7.1 mg/kg/day) / Daily Total Dose (mg/kg/day)).

[d] Additional PPE for scenarios 1,2 and 4: Double layer of clothing and chemical resistant gloves; no respirator.

[e] PPE Daily Dose was estimated using application rate and acres treated per day from Table 18. See Table 18 footnotes for explanations and formulas.

Table 18: Intermediate-Term Risks to Propachlor (Engineering Controls)

Exposure Scenario (Scenario #)	Risk Mitigation Measures					
	Engineering Controls[d]					
	Eng. Controls Dermal Unit Exp. (mg/lb ai)	Eng. Controls Inhalation Unit Exposure (µg/lb ai)	Eng. Controls Daily Dermal Dose (mg/kg/d) [a]	Eng. Controls Daily Inhalation Dose (mg/kg/d) [a]	Eng. Controls Total Daily Dose (mg/kg/d)[b]	Eng. Controls MOE [c]
Mixer/Loader Risk						
Mixing/Loading Liquids for Groundboom Application (1)	0.009 (gloves)	0.08	0.062	0.0005	0.062	110
			0.051	0.00045	0.052	140
Mixing/Loading Dry Flowables for Groundboom Application (2)	0.007	0.08	0.038	0.00045	0.039	180
Loading Granulars for Tractor-drawn Spreader Application (3)	NA	NA	NA	NA	NA	NA
			NA	NA	NA	NA
Applicator Risk						
Applying Sprays with a Groundboom Sprayer (4)	0.005	0.04	0.034	0.000027	0.034	210
			NA	NA	NA	NA
Applying Granulars with a Tractor-Drawn Spreader (5)	NA	NA	NA	NA	NA	NA
			NA	NA	NA	NA

[a] Engineering Control Daily Dose was estimated using application rate and acres treated per day from Table 18. See Table 18 footnotes for explanations and formulas.
[b] Total Daily Dose = Dermal Daily Dose + Inhalation Daily Dose
[c] MOE = (NOEL (7.1 mg/kg/day) / Daily Total Dose (mg/kg/day)).
[d] Engineering Controls are closed mixing/loading system and gloves for scenario 1; closed mixing/loading system for scenario 2

Table 19: Combined Dermal and Inhalation Cancer Risk Assessment for Propachlor - Baseline and Personal Protective Equipment (PPE)

Exposure Scenario (Scenario #)	Baseline Dermal Dose (mg/kg/day)[a]	Baseline Inhalation Dose (mg/kg/day)[b]	Baseline Total Dose (mg/kg/day)[c]	Baseline LADD (mg/kg/day)[d]	Baseline Risk[e]	Risk Mitigation Measures						
						Additional PPE						
						PPE Dermal Unit Exp. (mg/lb ai)	PPE Inhalation Unit Exposure (µg/lb ai)	PPE Daily Dermal Dose (mg/kg/d)[f]	PPE Daily Inhalation Dose (mg/kg/d)[g]	PPE Total Daily Dose (mg/kg/d)[h]	PPE LADD (mg/kg/d)[i]	PPE Risk[j]
Mixer/Loader Risk												
Mixing/Loading Liquids for Groundboom Application (1)	(corn)	---	---	---	NA	---	---	---	---	---	---	NA
	(grain sorghum and onions)	---	---	---	NA			---	---	---	---	NA
Mixing/Loading Dry Flowables for Groundboom Application (2)	(corn and grain sorghum)	---	---	---	NA	---	---	---	---	---	---	NA
Loading Granulars for Tractor-Drawn Spreader Application (3)	0.05 (corn)	0.013	0.06	0.001	4.5E-05	0.0034	1.7	0.027	0.014	0.041	0.001	3.6E-05
	0.04 (grain sorghum)	0.011	0.05	0.0014	4.4E-05			0.022	0.011	0.033	0.0012	3.9E-05
Applicator Risk												
Applying Sprays with a Groundboom Sprayer (4)	(corn)	---	---	---	NA	0.01	0.7	0.08	0.0056	0.09	0.0025	8.0E-05
	(grain sorghum and onions)	---	---	---	NA			0.07	0.0047	0.075	0.0021	6.7E-05
Applying Granulars with a Tractor-Drawn Spreader (5)	0.07 (corn)	0.010	0.08	0.0022	7.0E-05	0.004	1.2	0.032	0.01	0.042	0.0012	3.8E-05
	0.06 (grain sorghum)	0.008	0.07	0.0019	6.1E-05			0.027	0.008	0.035	0.001	3.2E-05

---/NA The intermediate term MOE for this scenario with PPE or at baseline is less than 100. Note that cancer risks were estimated beginning with the scenario for which intermediate term MOEs were greater than 100, since this level of mitigation would be required based on the risk assessment for the intermediate scenario.

[a] Dermal Dose (mg/kg/d) = Dermal exposure (mg/day) / Body weight (60 kg). See Table 18 for dermal exposure.

[b] Inhalation Dose (mg/kg/d) = Inhalation exposure (mg/day) / Body weight (60 kg). See Table 18 for inhalation exposure. (100% inhalation exposure is assumed)

[c] Baseline Daily Total Dose (mg/kg/d) = Baseline Dermal Dose (mg/kg/day) + Baseline Inhalation Dose (mg/kg/day).

[d] Baseline LADD (mg/kg/d) = Total Daily Dermal Dose (mg/kg/d) * (20 days per year worked/365 days per year) * (35 years worked/70 years lifetime).

[e] Baseline Risk = Baseline LADD (mg/kg/d) * (Q_1^*). Where Q_1^*= 0.032 $(mg/kg/d)^{-1}$.

[f] PPE Dermal Dose (mg/kg/d)= (PPE Dermal Unit Exp (mg/lb ai) * Max.Application Rate (lb ai/acre) * Daily Acres Treated (acres/day)) / 60 kg body weight.

Note that Max Appl. Rate and Daily Acres Treated are provided in Table 18.

[g] PPE Inhalation Dose (mg/kg/d)= (PPE Inhalation Unit Exp (ug/lb ai) * Max. Appl. Rate (lb ai/acre) * Daily Acres Treated (acres/day) * CF (1,000 μg/mg)) / 60 kg body weight

[h] PPE Daily Total Dose (mg/kg/d)= PPE Dermal Dose (mg/kg/d) + PPE Inhalation Dose (mg/kg/d).

[I] PPE LADD (mg/kg/d) = PPE Dermal Dose (mg/kg/d) * (20 days per year worked/365 days per year) * (35 years worked/70 years lifetime).

[J] PPE Risk = PPE LADD (mg/kg/d) * (Q_1^*) Where Q_1^* = 0.032 $(mg/kg/d)^{-1}$.

Table 20: Combined Dermal and Inhalation Cancer Risk Assessment for Propachlor (Engineering Controls)

Exposure Scenario (Scenario #)	Risk Mitigation Measures						
	Engineering Controls						
	Eng. Controls Dermal Unit Exp. (mg/lb ai)	Eng. Controls Inhalation Unit Exposure (µg/lb ai)	Eng. Controls Daily Dermal Dose (mg/kg/d) [a]	Eng. Controls Daily Inhalation Dose (mg/kg/d) [b]	Eng. Controls Total Daily Dose (mg/kg/d) [c]	Eng. Controls LADD (mg/kg/d) [d]	Eng. Controls Risk [e]
Mixer/Loader Risk							
Mixing/Loading Liquids for Groundboom Application (1)	0.009	0.08	0.072	0.00064	0.073	0.002	6.4E-05
			0.06	0.00053	0.061	0.0017	5.4E-05
Mixing/Loading Dry Flowables for Groundboom Application (2)	0.007	0.08	0.0448	0.00051	0.045312	0.00124	4.0E-05
Loading Granulars for Tractor-drawn Spreader Application (3)	0.0008	0.17	0.0064	0.0014	0.00536	0.0001468	4.67E-06
			0.0033	0.0011	0.00443	0.0001213	3.8E-06
Applicator Risk							
Applying Sprays with a Groundboom Sprayer (4)	0.005	0.04	0.040	0.00032	0.040	0.0011	3.5E-05
			0.033	0.00027	0.033	0.00091	2.9E-05
Applying Granulars with a Tractor-Drawn Spreader (5)	0.0021	0.22	0.017	0.00176	0.019	0.00051	1.6E-05
			0.014	0.00147	0.016	0.00042	1.4E-05

[a] Eng. Controls Dermal Dose (mg/kg/d)= (Eng. Controls Dermal Unit Exp (mg/lb ai) * Max.Application Rate (lb ai/acre) * Daily Acres Treated (acres/day))/60 kg body weight. Note that Max Appl. Rate and Daily Acres Treated are provided in Table 18.

[b] Eng. Controls Inhalation Dose (mg/kg/d)= (Eng. Controls Inhalation Unit Exp (ug/lb ai) * Max. Appl. Rate (lb ai/acre) * Daily Acres Treated/ 60 kg body weight * CF (1000 μg/mg).

[c] Eng. Controls Daily Total Dose (mg/kg/d)= Eng. Controls Dermal Dose (mg/kg/d) + Eng. Controls Inhalation Dose (mg/kg/d).

[d] Eng. Controls LADD (mg/kg/d) = Eng. Controls Dermal Dose (mg/kg/d) * (20 days per year worked/365 days per year) * (35 years worked/70 years lifetime).

[e] Eng. Controls Risk = Eng. Controls LADD (mg/kg/d) * (Q_1^*) Where Q_1^*= 0.032 $(mg/kg/d)^{-1}$.

Post-Application Exposure Assessment

No residue dissipation data (e.g., DFR (dislodgeable foliar residue)) or exposure monitoring data were submitted for propachlor. However, the Agency believes that the potential for post-application worker exposure is low, provided the 48 hour Restricted Entry Interval (REI - based on propachlor's classification as toxicity category I for primary eye irritation) is observed. Therefore, there is low potential for exposure due to the timing of applications. Propachlor is applied to the soil and/or soil incorporated pre-emergent for corn and grain sorghum. This is well before the plants are mature, which likely mitigates the potential for post-application exposure due to contact with treated foliage. Additionally, most agricultural operations for corn and sorghum, particularly early in the season, are mechanical which minimizes the potential for contact. Significant exposure to propachlor during harvesting, or any other late season activities, is not likely since propachlor is applied 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 propachlor.

Occupational Summary of Risks

Note that the PHED data confidence for dermal exposure and the use of any protection factors (PF) is in parenthesis.

Short-Term Risk

The estimations of short-term dermal and inhalation risk indicate that the MOEs are more than 100 at **baseline** for the following scenarios:

- (2) mixing/loading dry flowables for groundboom application
  (Based on low confidence data and no PF);
- (3) loading granulars for tractor drawn spreader application
  (Based on low confidence data and no PF);
- (4) applying sprays with groundboom sprayer
  (Based on high confidence data and no PF);
- (5) applying granulars with a tractor-drawn spreader
  (Based on low confidence data and no PF);

The estimations of short-term dermal and inhalation risk indicate that the MOEs are more than 100 with **additional PPE** for the remaining scenario:

- (1) mixing/loading liquids for groundboom application
  (Based on high confidence data and a 50% PF).

Intermediate-Term Risk

The estimations of intermediate-term dermal and inhalation risk indicate that the MOEs are more than 100 at **baseline** for the following scenarios:

- (3) loading granulars for tractor-drawn spreaders (Based on low confidence data and no PF);
- (5) applying granulars to sorghum with a tractor-drawn spreader (Based on low confidence data and no PF).

The estimations of intermediate-term dermal and inhalation risk indicate that the MOEs are more than 100 with **additional PPE** for:

- (4) applying sprays to sorghum and onions with a groundboom sprayer (Based on medium confidence data and no PF).
- (5) applying granulars to corn with a tractor-drawn spreader (Based on low confidence data and no PF).

The estimations of intermediate-term dermal and inhalation risk indicate that the MOEs are more than 100 with **engineering controls** for:

- (1) mixing/loading liquids for groundboom application (Based on medium confidence data and no PF).
- (2) mixing/loading dry flowables for groundboom application. (Based on low confidence data and a 90% PF)
- (4) applying sprays to corn with a groundboom sprayer (Based on medium confidence data and no PF).

Cancer Risks

The estimations of cancer risks are within the 10^{-5} or 10^{-6} risk range for the following scenarios:

- (1) mixing/loading liquids for groundboom application **with engineering controls (**Based on medium confidence data and no PF**)**;
- (2) mixing/loading dry flowables for groundboom application **with engineering controls** (Based on low confidence data and a 90% PF)**;**
- (3) loading granulars for tractor-drawn spreader application at **baseline** (Based on low confidence data and no PF), **with additional PPE** (Based on low confidence data and no PF), and **with engineering controls** (Based on low confidence data and a 90% PF);
- (4) applying sprays with a groundboom sprayer with **additional PPE** (Based on medium confidence data and a 50% PF) and **with engineering controls** (Based on medium confidence data and no PF); and,

- (5) applying granulars with a tractor-drawn spreader at **baseline** (Based on low confidence data and no PF), **with additional PPE** (Based on low confidence data and two PFs - 90% and 50% PF), and **with engineering controls** (Based on low confidence data and no PF).

Although all risks are within the 10^{-5} risk range, going across Tables 22A and 22B, there is a steady reduction of the magnitude by an approximate factor of 2 with each progression from baseline to PPE to engineering controls.

Post-Application Risk

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

Occupational Risk Characterization

Several issues must be considered when interpreting the occupational exposure and the resultant risk assessment.

- No chemical-specific exposure data were submitted. As a result all risk estimates were performed using surrogate data in PHED.
- Several handler assessments were completed using "low quality " PHED data due to the lack of a more acceptable dataset.
- Several generic protection factors were used to calculate handler exposures. These protection factors are in general use, but have not been completely evaluated by the Agency.
- Acres treated per day for each application method are standard values used by the Agency, due to a lack of pertinent data. These values are based on the best professional judgement of the Agency staff and were arrived at after much internal discussion. The values are considered to represent typical values regardless of regional variability.
- A chemical-specific dermal absorption factor was not available. Therefore, 100% dermal absorption was assumed.
- A chemical-specific inhalation absorption factor was not available. Therefore, 100% inhalation absorption was assumed.
- Application rates are the maximum labeled rates for the sites and treatment scenarios used in the assessment. However, it is acknowledged that actual application rates can

vary. It is the Agency's policy that the maximum application rate be used for the short-term and intermediate-term scenarios, but that a typical application rate can be used for a carcinogenic assessment. The Agency has inadequate information on typical application rates for propachlor.

Further refinement to this risk assessment could occur if the registrant supplied any or all of the following information:

(1) a dermal absorption factor
(2) an acceptable 21-day dermal study
(3) additional information on number of days of exposure
(4) additional information on the systems/equipment typically used by M/L/As, especially the equipment used on large acreage farms
(5) additional information on typical use rates

There are two intermediate-risk scenarios for which MOEs of 92 and 96 were obtained. In all probability a dermal absorption factor or 21 day dermal study would allow the agency to use less than 100%, thus achieving MOEs greater than 100. Therefore, the Agency can go forward with this Reregistration Eligibility Decision at this time. Although the Agency is not requiring a 21-day dermal study, the registrant is currently providing an update to an unacceptable but upgradeable study for the further refinement of the risk assessment.

However, in the absence of such information, for mixer/loaders to mitigate for both the dermal intermediate-term scenario and the carcinogenic scenario, the following is required:

- (1) mixing/loading liquids for groundboom application requires a closed mixing/loading system, and chemical resistant gloves.
- (2) mixing/loading dry flowables for groundboom requires the use of engineering controls. However, the registrant has agreed to voluntarily cancel this formulation.
- (3) mixing/loading granulars for sorghum for tractor-drawn spreader application can be performed at baseline; mixing/loading granulars for corn for tractor drawn spreader application requires use of PPE. The Agency notes that the label currently requires the use of gloves; therefore, it seems prudent to require the use of PPE for both corn and sorghum.

For applicators to mitigate for both the intermediate-term scenario and the carcinogenic scenario, the following is required:

- (4) applying sprays with a groundboom requires the use of mitigation: PPE for sorghum and engineering controls for corn.
- (5) applying granulars with a tractor-drawn spreader can be performed at baseline for sorghum and with PPE for corn

5. FQPA Considerations

a. Cumulative Effects

Propachlor is a member of the acetanilide class of herbicides. It is structurally similar to acetochlor, butachlor, metolachlor, and alachlor.

Section 408(b)(2)(D)(v) of FQPA 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 policies and methodologies for conducting cumulative risk assessments. For most pesticides, 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.

However, at this time the Agency does not have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. The Agency has begun a pilot process to study this issue further through the examination of particular classes of pesticides. Hopefully, the results of this pilot process will enable the Agency to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments. Exceptions include pesticides that are toxicologically and structurally 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 the metabolite must be assessed as part of a common mechanism assessment).

In making individual tolerance decisions, the Agency will determine whether:

1) it has sufficient information to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances;

2) it is unable to conclude that a pesticide does not share a common mechanism of toxicity with other substances; or

3) it is able to conclude that a pesticide does share a common mechanism of activity with other substances.

Due to the structural similarities with acetochlor, metolachlor, butachlor, and alachlor, propachlor 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 propachlor only. The risk assessment has been performed for propachlor 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 propachlor shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for propachlor need to be modified or revoked.

b. Endocrine Disruptor Effects

The Agency 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, 1996) to implement this program. At that time, EPA may require testing of propachlor for endocrine disruptor effects.

c. Determination of Safety

FFDCA section 408(b)(2)(A)(I) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe”. FFDCA section 408(b)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and residential exposures, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...”

Determination of safety includes consideration of special sensitivity to children, potential cumulative effects with pesticides that have a common mode of toxicity and aggregate risks resulting from exposure to dietary residues, residues in drinking water, and residential sources.

The database for developmental and reproductive toxicity of propachlor is considered to be complete at this time. A developmental neurotoxicity study was not required. There is no unique or special sensitivity for pre- or post-natal exposure. Based on these three factors, the Agency has

concluded that the results of these data did not raise concerns regarding the use of 100 as the uncertainty factor. An uncertainty factor of 100 will adequately protect infants and children.

The Agency has determined that consideration of a common mode of toxicity with other chemicals such as acetochlor, butachlor, metolachlor, and alachlor is not appropriate at this time. Tolerance reassessments have occurred in the RED as a result of new data on the concentrations of propachlor residues present in food. As a result, the existing and unsupported tolerances will be revoked in conjunction with this RED.

There are no residential uses of propachlor. The aggregate risk assessment from exposure to propachlor in food and water, does not result in aggregate risk that exceeds the Agency's level of concern.

Thus, the agency concludes that there is a reasonable certainty of no harm to infants and children, and adults from consuming potential residues of propachlor. This conclusion encompasses residues from aggregate exposure (food and water).

Table 21: Residue Chemistry Science Assessments for Reregistration of Propachlor.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.211]	Must Additional Data Be Submitted?	References
860.1200: Directions for Use	N/A = Not Applicable	Yes [1]	
860.1300: Plant Metabolism	N/A	No	40068601, 42140301
860.1300: Animal Metabolism	N/A	No	40123101, 40129301
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No [2]	40584004, 43028601, 43028602, 43251801
- Animal commodities	N/A	No	40584004, 43028602, 43251801
860.1360: Multiresidue Methods	N/A	No	43028501 [3]
860.1380: Storage Stability Data	N/A	No	40081701, 40085301, 40584005, 42121302, 42121303, 42140302
860.1500: Crop Field Trials			
Root and Tuber Vegetables Group			
- Sugar beet, roots	Revoke	No [4]	
Leaves of Root and Tuber Vegetables Group			
- Sugar beet, tops	Revoke	No [5]	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.211]	Must Additional Data Be Submitted?	References
Legume Vegetables (Succulent or Dried) Group			
- Peas	Revoke	No [5]	
Foliage of Legume Vegetables Group			
- Peas vines and hay	Revoke	No [5]	
Cucurbit Vegetables Group			
- Pumpkins	Revoke	No [5]	
Cereal Grains Group			
- Corn, field, grain	0.1	No	40085301
- Corn, sweet (K+CWHR)	Revoke	No [5]	
- Sorghum, grain	0.25	No	40081701
Forage, Fodder, and Straw of Cereal Grains			
- Corn, field, forage and stover	1.5, forage	No	40085301
- Corn, sweet, forage and stover	1.5, forage	No [5]	
- Sorghum forage and stover	5.0, forage 5.0, fodder	No	40081701
Miscellaneous Commodities			
- Cotton, seed and gin byproducts	Revoke	No [5]	
- Flax seed	Revoke	No [5]	
- Crops grown solely for seed	None established	No [6]	
860.1520: Processed Food/Feed			
- Corn, field	None established	No	40085302, 42962501
- Cottonseed	None established	No [6]	
- Flax seed	None established	No [6]	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.211]	Must Additional Data Be Submitted?	References
- Sorghum	None established	No	40081702
- Sugar beet	None established	No [6]	
860.1480: Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.02	No	40584001, 40584003
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.02	No	40584002
860.1400: Water, Fish, and Irrigated Crops	None established	N/A	
860.1460: Food Handling	None established	N/A	
860.1850: Confined Rotational Crops	N/A	No	43064501
860.1900: Field Rotational Crops	None established	Yes [7]	

1. Product labels with uses on sorghum must be amended to remove the restriction against the grazing or feeding of sorghum forage or silage from treated fields to dairy animals, since the Agency no longer considers such restrictions to be practical.

   Until adequate field rotational crop data have been submitted, product labels with uses on rotatable crops should be amended to specify that only crops that are listed on the label may be rotated to fields treated with propachlor.

2. Provided that the comments made by ACB are incorporated into the method, CBRS concluded that the proposed enforcement method (Monsanto Report No. MSL-12679) is suitable for the enforcement of tolerances for plant and animal commodities.

3. These data were forwarded to FDA for review (memo from L. Edwards to H. Hundley dated 5/18/94).

4. There are currently no registered uses on this crop. The established tolerance(s) will be revoked.

5. There are no registered uses on this crop.

6. Propachlor was previously registered for use on barley, oats, soybeans, and wheat grown for seed. Because these uses have been removed from product labels, data are no longer required to support these uses.

7. The available confined rotational crop data indicate that limited field rotational crop studies must be conducted.

C. Environmental Assessment

1. Use Characterization

a. Application Rates and Methods

Propachlor is registered for pre-emergent weed control on corn (field, silage, and hybrid), grain sorghum, and onions grown for seed (in Washington and Oregon only). End use products include flowable concentrate, granular, and water-dispersible granule (dry flowable) formulations. The pesticide may be applied by ground broadcast (boom spray or spreader) or band treatment. The maximum application rate is 6 lb a.i./acre on corn and sorghum (Section II.B, pg. 2, and current labels). Only one application of propachlor is allowed per season.

b. Use in Corn 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.

c. 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 east 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.

2. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

Propachlor is moderately toxic to birds on an acute oral basis but practically nontoxic on a subacute dietary basis. The pesticide is considered practically nontoxic to mammals (based on tests on rats) and honey bees. Both the active ingredient and the formulated use product are considered moderately to highly toxic to freshwater fish and invertebrates on an acute basis. A comparison of acute LD_{50} data with the appropriate time-averaged PRZM/EXAMS EECs indicate that chronic toxicity or life-cycle studies for aquatic organisms is not required. Among nontarget terrestrial plants, lettuce and ryegrass exhibited the highest sensitivity in terms of seedling emergence and vegetative vigor. No data are available for any of the degradates of propachlor.

(1) Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of propachlor to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland game bird).

Table 22: Avian Acute Oral Toxicity

Species	% a.i.	LD_{50} (mg/kg)	Toxicity Category	MRID No. Author/Yr	Study Classification[1]
Bobwhite quail	96.6	88.0	Moderately toxic	00132907	Core

1 Core study (satisfies the guideline)

With an LD_{50} in the range of 50-100 mg/kg, propachlor is considered to be moderately toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 00132907).

Two subacute dietary studies using the TGAI are required to establish the toxicity of propachlor to birds. The preferred test species are mallard duck and bobwhite quail.

Table 23: Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC_{50} (ppm)[1]	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail (Colinus virginianus)	>96.5	>5620	practically non-toxic	00132908/ Wild. Int./ 1983	core
Bobwhite quail	90	>5000	practically non-toxic	00104335/ 1973	core
Mallard duck	90	>5000	practically non-toxic	00108087/ 1980	core
Mallard duck (Anas platyrhynchos)	>96.5	>5423	practically non-toxic	00134006/ Wild. Int./ 1983	core

[1] Test organisms observed an additional three days while on untreated feed.

With an LC_{50} greater than 5000 ppm and no observed effects, propachlor is considered practically non-toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRIDs 00132908, 00104335, 00108087, 00134006).

(2) Birds, Chronic

Propachlor is moderately toxic (LD_{50}, the lethal dose which affects 50% of the test population, was in the range of 50-100 mg/kg) to avian species on an acute oral basis and practically non-toxic (LC_{50}, the lethal concentration affecting 50% of the test population, is greater than 5000 ppm) to avian species on a subacute dietary basis. Both the acute oral (MRID 00132907) and subacute dietary (MRIDs 00132908, 00104335, 00108087, 00134006) guideline requirements are fulfilled. Chronic avian toxicity data are not required for propachlor because repeated or prolonged exposure to the chemical is not expected (the label calls for one application/year and the fate data suggest that propachlor is not highly persistent in most terrestrial environments).

(3) Mammals, acute and chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity study values were substituted for wild mammal testing.

Table 24: Mammalian Toxicity

Species/ Study Duration	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID No.
laboratory rat (Rattus rattus)	94.5	LD50	1800 mg/kg	mortality	00104350

Propachlor is practically non-toxic (LD_{50} of 1800 mg/kg) to mammalian species on an acute oral basis (MRID 00104350).

(4) Insects

A honey bee acute contact study using the TGAI is required for propachlor because its use (on corn and sorghum) will result in honey bee exposure.

Table 25: Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (μg/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee (Apis mellifera)	98	>25	practically non-toxic	431477-06 Hoxter et al./ 1993	Core

The results indicate that propachlor is practically non-toxic to bees on an acute contact basis. The guideline (141-1) is fulfilled. (MRID#431477-06).

A honey bee toxicity of residues on foliage study for the typical end-use product is required for propachlor if its use will result in honey bee exposure and the acute contact honey bee LD_{50} is less than 0.11 ug/bee. Because results of the acute contact test show an LD_{50} of greater than 25 ug/bee, the (141-2) guideline study is not required for propachlor. However, this study was completed and the results are shown in the following table:

Table 26: Nontarget Insect Subacute Dietary Toxicity Study

Species	% ai	LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee (Apis mellifera)	98	>1,000	practically non-toxic	431477-05 Hoxter et al./ 1993	Core

Propachlor is practically non-toxic (>25 ug/bee) to bees on an acute contact (MRID 431477-06) and subacute dietary basis (MRID 431477-05). The (141-1) guideline requirements have been fulfilled. Since the acute contact honey bee LD_{50} is greater than 0.11 *ug*/bee, the 141-2 guideline study for honey bee toxicity of residues on foliage is not required.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of propachlor to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish).

Table 27: Freshwater Fish Acute Toxicity

Species	% ai	96-hour LC50 (ppb)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout (Oncorhynchus mykiss)	96.6	170	highly toxic	Thompson,1980 00041335	Core
Bluegill sunfish (Lepomis macrochirus)	94.9	>1400	moderately toxic	Morrill,1973 00104337	Supplemental
Channel catfish (Ictalurus punctatus)	94.5	230	highly toxic	Mayer, Ellersiek, 1986 40098001	Core
Bluegill sunfish (Lepomis macrochirus)	42.9	420	highly toxic	Thompson,1980 00041337	Core
Rainbow Trout (Onchoryhncus mykiss)	42.9	1600*	moderately toxic	Thompson,1980 00041338	Supplemental
Channel catfish (Ictalurus punctatus)	47.9	280	highly toxic	Mayer, Ellersiek, 1986 40098001	Supplemental

* 72-hour LC50

With a 96-hour LC_{50} for the technical grade material (TGAI) within the range of 0.17 to >1.4 ppm, propachlor is moderately to highly toxic to freshwater fish on an acute basis. Since the 96-hour LC_{50} is between 0.28 to 1.6 ppm, the formulated products of propachlor are considered moderately to highly toxic to freshwater fish on an acute basis. The guideline (72-1) requirements are fulfilled for the TGAI (MRIDs 00041335, 00104337, GS01140003) and formulated product (00041338, 00041337, GS01140003). The TGAI was more toxic to rainbow trout than the formulated product; however, the formulated product was more toxic to the bluegill sunfish than the TGAI.

(2) Freshwater Fish, Chronic

No early life-stage studies with freshwater fish are available for propachlor. A comparison between the 56/60-day EEC generated by PRZM/EXAMS (7.6 ppb for sorghum at 6.0 lb ai/acre) and the most toxic LC50 for freshwater fish (170 ppb for rainbow trout) gives a RQ equivalent of 0.044. This does not trigger the need for any further chronic testing for freshwater fish.

(3) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI isutilized to establish the toxicity of propachlor to aquatic invertebrates. The preferred test species is *Daphnia magna.*

Table 28: Freshwater Invertebrate Acute Toxicity

Species/(Static or Flow-through)	% ai	48-hr LC50/ EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea (Daphnia magna)	>96.6	7.8 EC50	moderately toxic	00041336 Thompson,1980	core
Waterflea (Daphnia magna)	94.5	6.9 EC50	moderately toxic	40098001 Mayer & Ellersiek/1986	core
Chironomus (Chironomus plumosus)	94.5	0.79 EC50	highly toxic	40098001 Mayer & Ellersiek/1986	core
Waterflea (Daphnia magna)	42.9	13.4 LC50	slightly toxic	00041339 Thompson,1980	core
Waterflea (Daphnia magna)	47.9	6.9 LC50	moderately toxic	40098001 Mayer & Ellersiek/1986	core
Species/(Static or Flow-through)	% ai	48-hr LC50/ EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Chironomus (Chironomus plumosus)	47.9	0.79 LC50	highly toxic	40098001 Mayer & Ellersiek/1986	core

With the EC_{50} of the TGAI from 0.79 to 7.8 ppm, propachlor is considered moderately to highly toxic to aquatic invertebrates on an acute basis. Guideline requirement 72-2 is fulfilled (MRIDs 40098001, 00041336). Because the LC_{50} range is equal to or less than the maximum environmental concentration, which ranges from 4.4 ppm in 6 inches of water to 0.4 ppm in 6 feet of water, formulated product testing is utilized as the next tier of data evaluation.

The EC_{50} values for formulated products range from 0.79 to 13.4 ppm. The formulated product is thus considered slightly to highly toxic to aquatic invertebrates. The guideline for the technical end product (TEP) is fulfilled (MRIDs 40098001, 00041339).

(4) Freshwater Invertebrate, Chronic

No chronic aquatic invertebrate toxicity data are available for propachlor. A comparison between the 21-day EEC generated by PRZM/EXAMS (19.1 ppb for sorghum at 6.0 lb ai/acre) and the most toxic EC50 for aquatic invertebrates (790 ppb for *Chironomus*) gives a RQ equivalent of 0.024. This does not trigger the need for any further chronic testing for aquatic invertebrates.

(5) Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for propachlor because the end-use product is expected to reach this environment because of its use in coastal counties. Because propachlor is registered for use on sorghum and corn, two crops associated with estuarine and marine environments, the 72-3a guideline is required. Since no studies were submitted, the 72-3a guideline requirement is not fulfilled.

(6) Estuarine and Marine Fish, Chronic

Although propachlor may be expected to reach estuarine or marine environments due to its use on corn and sorghum, the need for an estuarine/marine fish early life-stage study is deferred until the results of an acute study, 72-3a, are submitted.

(7) Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for propachlor because the end-use product is expected to reach this environment because of its use in coastal counties. The preferred test species are mysid shrimp and eastern oyster. Because propachlor is registered for use on sorghum and corn, two crops associated with estuarine and marine environments) the 72-3b and 72-3c guideline is required. Since no studies were submitted, the 72-3b and 72-3c guideline requirements are not fulfilled.

(8) Estuarine and Marine Invertebrates, Chronic

Although propachlor may be expected to reach estuarine and marine environments due to its use on corn and sorghum, the need for an estuarine/marine invertebrate life cycle study is deferred until the results of an acute study are submitted. No data have been submitted for these studies and the guideline requirements are not fulfilled.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial non-residential outdoor use patterns and that may move off the application site through volatilization (vapor pressure $>1.0 \times 10^{-5}$ mm Hg at 25°C) or drift (aerial or irrigation) and/or that may have endangered or threatened plant species associated with the application site.

For seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (Glycine max) and the second is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (Zea mays).

Terrestrial Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs ai/A or less) and any pesticide showing a negative response equal to or greater than 25% in Tier I tests. These studies are intended to measure the response of plants, relative to a control, and five or more test concentrations. In the case of propachlor, only Tier II studies were submitted and reviewed. Results from these toxicity tests on the technical/TEP material are tabulated below.

Table 29: Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II)

Species	% ai	EC25 (lbs.a.i./A)	Affected Endpoints	MRID No. Author/Year	Study Classification
Monocot- Corn	97.1	>6.0	ND[1]	424857-05 Chetram(1992)	Core
Monocot-oats	97.1	0.08	Dry weight	"	Core
Monocot- ryegrass	97.1	0.021	Dry weight	"	Core
Monocot- onion	97.1	1.8	Dry weight	"	Core
Dicot-lettuce	97.1	0.07	Plant height	"	Core
Dicot- Soybean	97.1	6.2	Plant height	"	Core
Dicot- radish	97.1	6.1	Dry weight	"	Core
Dicot-tomato	97.1	0.7	Dry weight	"	Core
Dicot- cucumber	97.1	0.13	Dry weight	"	Core
Dicot- cabbage	97.1	1.1	Dry weight	"	Core

1) Not determined

For Tier II seedling emergence, lettuce is the most sensitive dicot (EC25 = 0.07 lbs ai/A) and ryerass is the most sensitive monocot (EC25 = 0.021 lbs ai/A). The guideline (123-1) is fulfilled (MRID 424857-05).

Table 30: Nontarget Terrestrial Plant Vegetative Vigor Toxicity (Tier II)

Species	% ai	EC25 (lbs. a.i/A)	Affected Endpoints	MRID No. Author/Year	Study Classification
Monocot- Corn	97.1	6.0	ND[1]	424857-06 Chetram (1992)	Core
Monocot-Onion	97.1	>6.0	ND	"	Core
Dicot- Cabbage	97.1	>6.0	ND	"	Core
Monocot-Oat	97.1	2.0	ND	"	Core
Dicot-Radish	97.1	>6.0	Plant height	"	Core
Dicot- Soybean	97.1	>6.0	ND	"	Core
Monocot- Ryegrass	97.1	0.059	Dry weight	"	Core

Table 30: Nontarget Terrestrial Plant Vegetative Vigor Toxicity (Tier II)

Species	% ai	EC25 (lbs. a.i/A)	Affected Endpoints	MRID No. Author/Year	Study Classification
Dicot-lettuce	97.1	0.59	Dry weight	"	Core
Dicot- tomato	97.1	0.49	Dry weight	"	Core
Dicot- cucumber	97.1	>6.0	ND	"	Core

1) Not determined

For Tier II vegetative vigor, tomato appears to be the most sensitive dicot (EC_{25} = 0.49 lbs ai/A) and ryegrass is the most sensitive monocot (EC_{25} = 0.059 lbs ai/A). The guideline (123-1) is fulfilled (MRID #424857-06).

(2) Aquatic Plants

Aquatic plant studies (tier II) are required for propachlor because its outdoor terrestrial uses may result in runoff to aquatic areas. The following species should be tested at Tier II: Kirchneria subcapitata (Selenastrum capricornutum), Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom.

Table 31: Nontarget Aquatic Plant Toxicity (Tier II)

Species	% ai	EC50/ EC05 (ppb)	MRID No. Author/Year	Study Classification
Green algae Kircheria subcapitata	97.9	13.5 (EC05)	425847-03 Hughes (1992)	Core

The Tier II results indicate that the EC_{50} of propachlor to green algae (Kircheria subcapitata), non-vascular aquatic plant is 13.5 ppb. However, testing on the other four species of aquatic plants has not been submitted. Therefore, the guideline requirement (123-2) is partially fulfilled (MRID #425847-03).

Aquatic plant data on technical propachlor are outstanding for four additional species: Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom.

For Tier II seedling emergence on nontarget terrestrial plants, lettuce is the most sensitive dicot (EC_{25} = 0.07 lb ai/acre) and ryegrass is the most sensitive monocot (EC_{25} = 0.021 lb ai/acre). For Tier II vegetative vigor, tomato appears to be the most sensitive dicot (EC_{25} = 0.49 lb ai/acre) and ryegrass is the most sensitive monocot (EC_{25} = 0.059 lb ai/acre). The guideline (123-1) for Tier II seedling emergence and vegetative vigor is fulfilled (MRIDs 424857-05 and -06). The Tier II results for aquatic plants indicate that the EC_{50} of propachlor to Kircheria subcapitata, a non-vascular aquatic plant, is 13.5 ppb. The guideline (123-2) is partially fulfilled (MRID #425847-03). Testing on four other species of aquatic plants has not been fulfilled.

3. Environmental Fate Characteristics

Exposure Characterization

While highly mobile, propachlor is not expected to persist substantially on the soil surface under most conditions (aerobic soil metabolism half-life of <3 days; 50% field dissipation rates of 1 to 6 days). The major dissipation routes are aerobic soil metabolism and, in the absence of an active microbial population, leaching. Propachlor may be more persistent under low moisture conditions, in soils with low microbial activity, or under anaerobic conditions. Mobility will be influenced by climate (especially rainfall) and crop management factors that influence leaching and runoff. Because of its high solubility and low affinity for adsorption, propachlor is likely to dissipate rapidly from plant and soil surfaces.

Propachlor has three major degradates -- propachlor oxanilic acid, propachlor sulfinylacetic acid, and propachlor sulfonic acid (the analog of this degradate for alachlor and acetochlor is referred to as ESA) -- that appear to be persistent and very mobile. These three degradates have carboxylic or sulfonic acid functional groups, which render a negative (anionic) character to the molecules under normal environmental conditions. These degradates have a high mobility in soils and, based on laboratory aerobic soil metabolism and terrestrial field dissipation studies, appear to persist much longer than the parent compound. All three degradates were detected through the lowest soil depth interval sampled in the field dissipation studies.

Propachlor is expected to be highly mobile because of its low affinity to adsorb to soil. Microbial degradation under most conditions substantially reduces the potential for propachlor to reach ground water or surface water. However, detections of propachlor and/or its degradates have been reported (0.02-3.5 ppb) in some wells, suggesting that the chemical or its degradates may reach ground water under some conditions. Propachlor is most likely to reach ground water in soils which have little microbiological activity, high permeability, and a shallow water table. If leaching rainfalls occur shortly after application, propachlor may move to subsurface soil layers where microbial populations are lower, resulting in an increase in persistence. Propachlor is likely to be more persistent under anaerobic conditions common to ground water. While the potential propachlor use area would encompass highly vunerable ground-water areas of the Delmarva penisula, eastern coastal plain, and Florida, current use is minimal in these areas. Small, localized areas vunerable to ground-water contamination still may occur within the major propachlor use area.

Propachlor would most likely contaminate surface water if runoff-producing rain events occur within the first few days to weeks after application. Propachlor's low soil/water partitioning and high solubility suggest it will primarily be dissolved in runoff water and in the water body. Areas with the highest vulnerability to runoff, and thus the highest potential for propachlor contamination in surface waters, 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. Except for the Missouri River Valley, propachlor

is not currently used extensively in these highly vunerable areas. However, localized areas of highly vunerable soils and watersheds may occur in major propachlor use areas.

Once it reaches surface water, the fate of propachlor is uncertain. Soil metabolism studies suggest a susceptibility to biodegradation; the persistence of propachlor in surface waters with high microbiological activities may therefore be limited. However, the extent of metabolic degradation in water is uncertain because of an absence of aerobic aquatic metabolism data. For this reason, model predictions of estimated environmental concentrations (EECs) in aquatic environments assumed that propachlor was more stable than the observed half-life from the aerobic soil metabolism study.

The three major acid degradates appear to be very mobile and persistent. Based upon limited fate data, these degradates appear to be available for runoff longer than the parent propachlor, moving primarily by dissolution in runoff water. Furthermore, these degradates have characteristics of chemicals that are known to leach to ground water. The reported detections of propachlor in surface and ground waters may be all or in part due to the presence of these persistent degradates.

Data Gaps and Uncertainties in the Exposure Assessment:

The persistence characterization of propachlor is based largely on the results of one aerobic soil metabolism study, which showed a non-first order dissipation pattern. The model from which the $t_{1/2}$ was derived overestimates initial dissipation but underestimates long-term dissipation. A single study is not adequate to determine whether a biphasic dissipation pattern is typical for propachlor. EFED is requesting additional aerobic soil metabolism data to better characterize the dissipation pattern and rate for propachlor in aerobic soils.

While soil studies indicate that metabolism is a major mode of dissipation, such data is not available for aerobic aquatic conditions. Since propachlor may reach surface waters under certain conditions, an aerobic aquatic metabolism study is required to better characterize the fate of propachlor in such environments.

The additional studies are needed to reduce the degree of uncertainty in the environmental fate characterization of propachlor. A decision on pursuing further water monitoring studies would be deferred pending the results of these metabolism studies.

a. Degradation

Propachlor is a soluble molecule (613 ppm in water at 25°C), with an octanol/water partition coefficient of 201, and a vapor pressure of 7.9×10^{-5} mm Hg. Propachlor was stable in aqueous buffered solutions at pH's 5, 7, and 9 in the dark. It did not photodegrade significantly in water when exposed to natural sunlight for 30 days. Photolysis in soil does not appear to be an important degradation pathway. In a supplemental soil photolysis study, propachlor degraded faster in the dark

control than in the irradiated samples. The differences may have been due to differences in moisture between the irradiated and the dark samples.

161-1 Hydrolysis (MRID#42485701)

This study is acceptable and can be used to satisfy the Hydrolysis data requirement. No additional data are required.

[^{14}C]-Propachlor, at 9.4-10.0 ppm, did not hydrolyze in sterile aqueous pH 5, 7, and 9 buffer solutions that were incubated at 20.0-25.5°C in the dark for 30 days.

161-2 Photolysis in Water (MRID# 42527401)

This study is acceptable and can be used to satisfy the Photolysis in Water data requirement. No additional data are required.

[^{14}C]-Propachlor, at 10.93 ppm, did not photodegrade significantly in sterile aqueous pH 7 buffered solution that was irradiated with natural sunlight for 30 days at 22.1-28.3°C. At 30 days posttreatment, propachlor comprised 89.0-92.1% in the irradiated sample and 91.5-92.2% in the dark control.

161-3 Photolysis on Soil (MRID# 42527402)

This study provides supplemental information about the photodegradation of propachlor on soil. The study does not fulfill the data requirement because the degradation of propachlor in the dark control was faster than in the irradiated samples. In addition, the results of the dark control do not agree with the aerobic soil metabolism study. Since the absorption spectrum of propachlor shows no significant peaks above 290 nm and the aqueous photolysis study shows little or no photolysis during the 30 days irradiation, the Agency believes that photolysis on soil does not constitute an important route of degradation for propachlor. No additional data are required at this time.

[^{14}C]-Propachlor, at 6.51 lb a.i./A, degraded slowly, with an estimated half-life of 57 days on sandy loam soil incubated in natural sunlight at 18.7-31.7°C for 30 days. In contrast, [^{14}C]-propachlor degraded with a calculated half-life of 19.2 days in a dark control. The degradate, 2-hydroxy-N-(1-methylethyl)-N-phenylacetamide (hydroxypropachlor), was observed in both the irradiated and dark control samples at 4.3% of the applied during the course of the study.

b. Metabolism

Aerobic soil metabolism is the most important degradation route for propachlor. In a sandy loam soil, propachlor degraded with a fitted half-life ($t_{1/2}$) of approximately 2.7 days, calculated using the Gustafson and Holden (1990) model to fit the data. The data show a biphasic degradation pattern that is not well-represented by a first-order degradation model. The fitted model appears to

overestimate the rate of degradation in the initial days, but underestimates long-term degradation. The observed 50% dissipation time (DT_{50}) was 5 days. A single study is not adequate to characterize the aerobic soil metabolism of propachlor. Additional studies would show whether the biphasic pattern is typical for propachlor or is an exception. In addition, the slow degradation noted in the soil photolysis study may suggest that propachlor is more persistent under certain conditions.

Two major degradates were observed. Propachlor oxanilic acid was a maximum average of 33% of the applied at 1 month and remained at 29% after 12 months. Propachlor sulfonic acid was a maximum average of 19% of the applied at 1 month and remained at 14% after 12 months. Other metabolites were identified but comprised <10% of the applied at all test intervals.

Under anaerobic conditions, propachlor degraded slowly from a clay loam sediment; lake water system. The calculated half life under the testing conditions was 4.9 months (146 days). Hydroxypropachlor was the major degradate observed, which increased steadily to a maximum average of 37% of the applied 9 months after treatment.

162-1 Aerobic Soil Metabolism (MRID# 42962502)

This study is acceptable and can be used to satisfy the Aerobic Soil Metabolism data requirement.

[^{14}C]-Propachlor, at 6.0 ppm, degraded with a calculated non-linear regression $t_{1/2}$ of 2.7 days, in a sandy loam soil incubated in the dark at 24.0-26.0°C. The observed DT_{50} was 5 days. Propachlor was 94.6-99.6% of the applied immediately posttreatment, 50.1-55.1% of the applied at day 5 posttreatment, and 1.3% of the applied after 365 days incubation. Two major degradates were observed:

[(1-methylethyl)phenylamino]oxoacetic acid (propachlor oxanilic acid), which increased to a maximum average of 33.3% of the applied at 1 month posttreatment, and stayed approximately at that level throughout the rest of the study (it averaged 29.0% of the applied at 12 months).

2-[(1-methylethyl)phenylamino]-2-oxoethanesulfonic acid (propachlor sulfonic acid), which increased to a maximum average of 19.1% of the applied at 1 month; it averaged 12.1% of the applied at all the remaining test interval; at 12 months posttreatment it averaged 14.2% of the applied.

Various minor degradates were observed:

(([(1-methylethyl)phenylamino]acetyl)sulfinyl)acetic acid (propachlor sulfinylacetic acid), which was observed at low levels all throughout the study, with a maximum average of 6.7% of the applied at 1 month after treatment.

2-hydroxy-N-(1-methylethyl)-N-phenylacetamide (hydroxypropachlor), which was observed at low levels all throughout the study, with a maximum average of 6.0% of the applied on day 5 after treatment.

N-(1-methylethyl)-2-(methylsulfonyl)-N-phenylacetamide (propachlor methyl sulfone), which was observed at low levels all throughout the study, with a maximum average of 3.2% of the applied at 4 months after treatment.

N-(1-methylethyl)-N-phenylacetamide (norchloropropachlor), which was observed at low levels all throughout the study (average 1.2% of the applied).

After 12 months of incubation 9.5-10.6% of the applied radioactivity was recovered in the NaOH traps (corresponding to $^{14}CO_2$). <21.4% of the applied was unextractable radioactivity.

162-2 Anaerobic Soil Metabolism (MRID# 42962503)

This study is acceptable and can be used to satisfy the Anaerobic Soil Metabolism data requirement. No additional data are required.

[^{14}C]Propachlor, at 5.9 ppm, degraded slowly, with a registrant-calculated half-life of 146 days (4.9 months) for a lake water-sediment system incubated under anaerobic conditions in the dark at 24-26°C for 12 months. [^{14}C]Propachlor averaged 98.1% of the applied on day 0, it averaged 60.6% of the applied 4 months after treatment, and it averaged 20.2% of the applied 12 months after treatment. The major degradate observed was:

2-hydroxy-N-(1-methylethyl)-N-phenylacetamide (propachlor alcohol), which increased steadily to a maximum average of 37.3% of the applied 9 months after treatment.

Several minor degradates were detected sporadically and quantified.

c. Mobility/Leachability

Propachlor and its oxanilic acid and sulfonic acid degradates are very mobile. While the parent degraded relatively quickly under aerobic soil metabolism, the degradates appear to be more persistent and may leach substantially under normal conditions.

163-1 Mobility - Column Leaching (MRID# 00087854)

This study had been previously reviewed and the portion related to parent propachlor was found to be acceptable. This study provides useful information about the mobility of parent propachlor.

Based on column leaching studies, [^{14}C]-propachlor, at approximately 6 lb a.i./A, was determined to be very mobile (>40% of the applied in leachate) in 30-cm columns of loamy sand, sandy loam, and

silt loam soils, and mobile (approximately 5% in leachate) in columns of silty clay loam soil that were leached with 20 inches of water. Increasing mobility appeared to be correlated with decreasing soil organic matter.

163-1 Mobility - Batch Equilibrium for Parent Propachlor (MRID# 42485702)

This study is acceptable and can be used to partially satisfy the Mobility data requirement. The study provides information about the mobility of parent propachlor. No additional information about the mobility of parent propachlor are required.

Based on batch equilibrium studies, [^{14}C]-Propachlor was determined to be very mobile in loamy sand, sandy loam, loam, and silty clay loam soil:solution slurries (1:3) equilibrated in the dark for 24 hours at 25°C. Freundlich K_{ads} and K_{des} values, and respective K_{OC} values are summarized in the table below:

Table 32: Adsorption-desorption values for Propachlor.

Soil type	%OC	K_{ads}	K_{OC} for adsorption	K_{des}	K_{OC} for desorption
loamy sand	0.40	0.45	113	4.36	1090
sandy loam	1.79	1.30	73	4.12	230
loam	1.11	1.39	125	5.49	495
Soil type	%OC	K_{ads}	K_{OC} for adsorption	K_{des}	K_{OC} for desorption
silty clay loam	0.61	0.84	138	3.06	502
average	N/A	1.00	112	426	679

163-1 Mobility - Batch Equilibrium for Propachlor Oxanilic Acid (MRID# 42485703)

This study is acceptable and can be used to partially satisfy the Mobility data requirement. The study provides information about the mobility of one major degradate of propachlor, propachlor oxanilic acid. No additional information about the mobility of propachlor oxanilic acid is required.

Based on batch equilibrium studies, [^{14}C]-propachlor oxanilic acid was determined to be very mobile in loamy sand, sandy loam, loam and silty clay loam soil:solution slurries equilibrated in the dark for 24 hours at 25°C. Freundlich K_{ads} and K_{des} values, and respective K_{OC} values are summarized in the table below.

Table 33: Adsorption-desorption values for Propachlor Oxanilic Acid.

Soil type	%OC	K_{ads}	K_{OC} for adsorption	K_{des}	K_{OC} for desorption
loamy sand	0.40	0.03	8	4.48	1120
sandy loam	3.40	0.04	2	15.86	886
loam	2.11	0.08	7	4.34	391
silty clay loam	1.16	0.06	10	20.91	3428
average	N/A	0.05	7	11.40	1456

163-1 Mobility - Batch Equilibrium for Propachlor Sulfonic Acid (MRID# 42485704)

This study is acceptable and can be used to partially satisfy the Mobility data requirement. The study provides information about the mobility of one major degradate of propachlor, propachlor sulfonic acid. No additional information about the mobility of propachlor sulfonic acid are required.

Based on batch equilibrium studies, [^{14}C]-propachlor sulfonic acid was determined to be very mobile in sand, sandy loam, loam, and silty clay loam soil:solution slurries equilibrated in the dark for 24 hours at 25°C. Freundlich K_{ads} and K_{des}, and respective K_{OC} values are summarized in the table below.

Table 34: Adsorption-desorption values for Propachlor Sulfonic Acid.

Soil type	%OC	K_{ads}	K_{OC} for adsorption	K_{des}	K_{OC} for desorption
sand	0.42	0.03	7	1.33	317
sandy loam	1.00	0.06	6	6.24	624
loam	1.11	0.05	5	1.73	156
silty clay loam	2.59	0.07	3	1.23	47
average	N/A	0.05	5	2.63	286

d. Fate of Propachlor and its Degradates in the Field

The registrant submitted three Terrestrial Field Dissipation studies, conducted in Janesville, Iowa; York, Nebraska; and Uvalde, Texas. At each of the three locations two plots were treated with Ramrod® 4L and Ramrod® 20G. The studies were conducted on clayey to sandy loam surface soils (full soil classification was not provided). The dissipation half-lives (DT_{50}) observed for propachlor

in the field were of the same order of magnitude as the half-life observed in the aerobic soil metabolism study:

aerobic soil metabolism	DT_{50}=~5 days; $t_{1/2}$ = 2.7 days
Janesville, Iowa	DT_{50}=1.0-1.7 days
York, Nebraska	DT_{50}=5.0-5.8 days
Uvalde, Texas	DT_{50}=2.3-2.8 days

The range in values in the three field dissipation studies represent differences in the granular and flowable formulations of propachlor. Differences in DT_{50} values between sites were greater than differences between formulations on the same site, suggesting that the site conditions have a greater effect on dissipation than the formulation. Detections of propachlor were largely in the upper 0-6 inch soil layer in all the three sites. Some minor detections in lower soil depths were reported.

The degradates observed in the field at high concentrations were propachlor oxanilic acid, propachlor sulfinylacetic acid, propachlor sulfonic acid, and hydroxypropachlor. Of these degradates, the first three are acids that under normal environmental conditions are negatively charged and have high mobility (as also evidenced in the mobility studies). These degradates leached substantially, especially in the Janesville, Iowa, and Uvalde, Texas sites; the degradates were observed as deep as 36-42 inch soil depth, which is the lowest soil depth interval tested. In the York, Nebraska site, the level of leaching was not as extensive as in the other two sites. All the acid metabolites appeared to persist much more than the parent propachlor.

The degradate hydroxypropachlor, a minor degradate in the aerobic soil metabolism study but the major degradate in the anaerobic soil metabolism study, was present at relatively high concentrations in all three study sites; however, it did not persist long, with all detections observed generally on or before day 30 after application. Hydroxypropachlor remained in the upper 0-6 inch soil depth.

Two minor degradates, norchloropropachlor and propachlor methylsulfone, were also detected. Only norchloropropachlor reached relatively high levels (average 0.101-0.104 ppm) in the Uvalde, Texas plot only. Norchloropropachlor was largely confined to the upper 0-6 inch soil depth. Propachlor methylsulfone, although present at low levels, appeared to be more persistent and somewhat mobile, with detections through 552 days in Janesville, Iowa; 120 days in York, Nebraska; and 365 days in Uvalde, Texas.

<u>164-1 Terrestrial Field Dissipation (MRID# 43525101)</u>

This study is acceptable and can be used to satisfy the Terrestrial Field Dissipation data requirement for propachlor. The study provides information about the dissipation of propachlor in three sites (Iowa, Nebraska, Texas). It also provides information about the formation and decline of three acid metabolites (propachlor oxanilic acid, propachlor sulfinylacetic acid, and propachlor sulfonic acid) and three neutral metabolites (hydroxypropachlor, norchloropropachlor, and propachlor methylsulfone) of propachlor. No additional information is required.

Janesville, Iowa

Propachlor (Ramrod® 4L and Ramrod® 20G), applied once at 6 lb a.i./A, dissipated with a registrant-calculated DT_{50} of 1.0-1.7 days and DT_{90} of 6.8-8.8 days from a bareground plot of loamy sand soil in Janesville, Iowa. In the 0-6 inch soil depth of the plot treated with Ramrod® 4L, propachlor averaged a maximum of 2.402 ppm on day 3 after application,, 1.729 ppm on day 7, and 0.359 on day 14 after application. In the 0-6 inch soil depth of the plot treated with Ramrod® 20G, propachlor averaged a maximum of 2.031 ppm on day 0, 1.246 ppm on day 3, and 0.135 ppm on day 14 after application. Propachlor remained in the upper 0-6 inch soil layer.

The degradates monitored in the field were as follows:

Propachlor oxanilic acid, which was a maximum of 0.525 and 0.308 ppm at 14 days after application in the plot treated with Ramrod® 4L and Ramrod® 20G, respectively. This degradate was observed as deep as 36-42 inch soil depth (the lowest depth interval tested, on day 61 after application) for the plot treated with Ramrod® 4L, and 30-36 inch soil depth (day 61 and 125 after application) for the plot treated with Ramrod® 20G. Detections were reported through day 180 after application.

Propachlor sulfinylacetic acid, which was a maximum of 0.169 and 0.130 ppm at 14 days after application in the plots treated with Ramrod® 4L, and Ramrod®20G, respectively. This degradate leached as deep as 36-42 inch soil depth, with a detection averaging 0.012 ppm on day 180 after application in the plot treated with Ramrod® 20G. The majority of the detections occurred prior to or on day 61 after application.

Propachlor sulfonic acid averaged a maximum of 0.230 and 0.150 ppm on day 14 after application in the plot treated with Ramrod® 4L and Ramrod® 20G, respectively. It appears that substantial leaching occurred between the day 14 and 21 after application in both plots. On day 21 after application, this degradate averaged 0.153 and 0.141 ppm in the 6-12 inch soil depth in the plots treated with Ramrod® 4L and Ramrod® 20G, respectively. Detections of propachlor sulfonic acid were reported as deep as 36-42 inch soil depth (the lowest depth interval tested) on day 61 after application in both plots, treated with Ramrod® 4L and Ramrod® 20G. Detections appear to be consistent through day 61 after application for the plot treated with Ramrod® 4L and through day 125 for the plot treated with Ramrod® 20G,

The neutral degradate observed at high concentrations was hydroxypropachlor, which was a maximum of 0.351 and 0.201 ppm on day 3 after application in the plots treated with Ramrod® 4L and Ramrod® 20G, respectively. Hydroxy-propachlor remained in the 0-6 inch soil depth. The last detection of this degradate occurred on day 30 and 180 days after application for both plots treated with Ramrod® 4L and Ramrod® 20G, respectively.

Norchloropropachlor and propachlor methylsulfone reached relatively low values through the study (0.053 ppm). Norchloropropachlor remained in the upper 0-6 inch soil depth. Detections of

methylsulfone were reported in the 12-18 inch soil depth on days 180, 364, and 552 after application, averaging 0.010-0.011 ppm.

York, Nebraska

Propachlor (Ramrod® 4L and Ramrod® 20G), applied once at 6 lb a.i./A, dissipated with a registrant-calculated DT_{50} of 5.0-5.8 days and DT_{90} of 16.5-19.1 days from a bareground plot of a loam soil in York, Nebraska. In the 0-6 inch soil depth of the plot treated with Ramrod® 4L, propachlor averaged a maximum of 2.078 ppm on day 3 after application, 1.134 ppm on day 7 after application, and 0.145 ppm on day 14 after application. In the 0-6 inch soil depth of the plot treated with Ramrod® 20G, propachlor averaged a maximum of 2.314 ppm on day 3 after application, 1.744 ppm on day 7 after application, and 0.145 ppm after application.

Propachlor remained largely in the upper 0-6 inch soil layer. One detection was reported in the 6-12 inch soil layer in the plot treated with Ramrod® 4L (average 0.048 ppm, day 1 after application). In the plot treated with Ramrod® 20G, detections were reported in the 6-12 inch soil depth from day 0 to day 14 after treatment (0.010-0.046 ppm), and one detection in the 12-18 inch soil depth on day 14 after application (average 0.021 ppm).

The following degradates were monitored in the soil:

Propachlor oxanilic acid was the degradate present at highest concentrations in the soil. It was a maximum of 0.295 and 0.472 ppm on day 21 after application in the fields treated with Ramrod® 4L and Ramrod®20G, respectively. The degradate remained largely in the 0-6 inch soil depth for both plots. Detections were observed through day 120 after application in both plots.

Propachlor sulfinylacetic acid reached a maximum average of 0.130 ppm on day 14 after application in the plot treated with Ramrod® 4L and 0.188 ppm on day 21 after application in the plot treated with Ramrod® 20G. The degradate remained largely in the 0-6 inch soil depth for both plots. Detections were observed through day 60 after application.

Propachlor sulfonic acid reached a maximum average of 0.178 ppm on day 30 after application in the plot treated with Ramrod® 4L and 0.302 ppm on day 21 after application in the plot treated with Ramrod® 20G. In the plot treated with Ramrod® 4L, the sulfonate remained largely in the 0-6 inch soil depth; detections were reported through 365 days after application. In the plot treated with Ramrod® 20G, there were various observations of the sulfonate in the 6-12 inch soil depth through 365 days after application and there was one observation in the 12-18 soil depth (average 0.015 ppm on day 21 after application).

Hydroxypropachlor was a maximum average of 0.160 ppm on day 3 after application in the plot treated with Ramrod® 4L; it was a maximum average of 0.177 ppm on day 7 after application in the plot treated with Ramrod® 20G. In both plots, it appears that the degradate was not very persistent,

with detections reported through 30 days after application. In all cases, hydroxypropachlor stayed in the upper 0-6 inch soil layer.

Norchloropropachlor and propachlor methylsulfone were present at relatively low levels (average 0.078 ppm) through the study in both plots. Norchloropropachlor was detected through day 30 after application and methylsulfone was detected through day 120 after application. All detections occurred in the upper 0-6 inch soil depth.

Uvalde, Texas

Propachlor (Ramrod® 4L and Ramrod® 20G), applied once at 6 lb a.i./A, dissipated with registrant calculated DT_{50} of 2.3-2.8 days and DT_{90} of 7.6-9.1 days from a bareground plot of clay soil in Uvalde, Texas. In both plots, treated with Ramrod® 4L and Ramrod® 20G, propachlor was a maximum on day 0 after application (averages of 2.130 and 3.038 ppm, respectively). By day 8 after application, the level of propachlor had decreased substantially (0.062 and 0.417 ppm). Propachlor remained in the upper 0-6 inch soil layer in both plots, treated with Ramrod® 4L and Ramrod® 20G.

The following degradates were monitored in the soil:

Propachlor oxanilic acid reached a maximum average of 0.452 and 0.668 ppm on day 8 after application in the plots treated with Ramrod® 4L and Ramrod® 20G, respectively. Most detections occurred prior to or on day 62 after application. Detections were observed to a depth of 24-30 inch (with a reported average of 0.013 ppm on day 16 after application in the plot treated with Ramrod® 20G).

Propachlor sulfinylacetic acid was a maximum average of 0.148 and 0.201 ppm on day 8 after application, in the plot treated with Ramrod® 4L and Ramrod® 20G, respectively. Detections of this degradate were observed through 62 days after application in both plots. Various detections were reported in the 6-12 inch soil layers, and one minor detection averaging 0.012 ppm was observed in the 12-18 inch soil depth on day 16 after application in the plot treated with Ramrod® 20G.

Propachlor sulfonic acid was a maximum average of 0.326 and 0.416 ppm on day 8 after application for the plots treated with Ramrod® 4L and Ramrod® 20G, respectively. Various detections were reported in the 6-12, 12-18, and 18-24 inch soil layers. In the plot treated with Ramrod® 20G, detections in the 24-30 inch were reported on days 16 and 62 days after application. Additionally on day 62 after application, a minor detection averaging 0.014 ppm was reported in the 30-36 inch soil depth in the plot treated with Ramrod® 20G. The majority of the detections were observed prior to or on day 62 after application.

Hydroxypropachlor was a maximum average of 0.206 ppm on day 0 after application in the plot treated with Ramrod® 4L; it was a maximum average of 0.180 ppm on day 3 after application in the plot treated with Ramrod® 20G. All the detections of hydroxypropachlor were confined to the upper

0-6 inch soil layer in both plots. All detections on day 16 after application and thereafter were 0.023 ppm.

Norchloropropachlor was a maximum on day 8 after application for both plots , treated with Ramrod® 4L and Ramrod® 20G, with averages of 0.104 and 0.101 ppm, respectively. Norchloropropachlor was largely confined to the upper 0-6 inch; however, detections averaging 0.019 ppm were reported on days 16 and 31 in the 6-12 inch layer of the plot treated with Ramrod® 4L, and on day 8 (12-18 inch soil layer) and 16 (6-12 inch soil layer) of the plot treated with Ramrod® 20G.

Propachlor methylsulfone was 0.046 ppm at all test intervals and was observed in the 0-6 and 6-12 inch soil layer through day 365 after application.

e. Bioaccumulation

The octanol/water partition coefficient of 201 for propachlor predicts a slight potential for bioaccumulation. The laboratory results indicate a low bioaccumulation potential. Maximum bioconcentration factors for propachlor residues in bluegill sunfish were 13X for edible tissues, 71X for nonedible tissues, and 37X for whole fish. Depuration was fast (84% of the accumulated residues were released into water by day 3). The ^{14}C residues contained the cysteine and mercapturic acid conjugates of propachlor.

<u>165-4 Bioaccumulation in Fish (MRID# 42711801)</u>

This study is acceptable and can be used to satisfy the Bioaccumulation in Fish data requirement. No additional data are required.

Propachlor residues accumulated in bluegill sunfish that were continuously exposed to [^{14}C]-propachlor, at 14 μg/L. The maximum bioconcentration factors observed were 13X for edible tissues, 71X for nonedible tissues, and 37X for the whole fish. By day 3 of the depuration period, 84% of the accumulated residues had been eliminated from the whole fish. Two major propachlor degradates were identified in the edible and nonedible tissues:

Cysteine conjugate was 47.7-64.9% of the [^{14}C] residues in the edible tissue, and 24.9-29.6% of the recovered in the nonedible tissues.

Mercapturic acid conjugate was 6.2-7.2% of the [^{14}C] residues in the edible tissue, and 59.5-62.3% of the [^{14}C] residues recovered in the nonedible fish tissues.

f. Spray Drift

The labels indicate that propachlor may be applied by ground spray boom equipment but not aerially. No propachlor-specific ground spray drift studies were reviewed. The Spray Drift Task

Force (SDTF), a consortium of pesticide registrants, has completed and submitted to the Agency a series of studies which are intended to characterize spray drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. EPA is 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 propachlor to nontarget organisms is warranted.

4. Water Resource Assessment

a. Surface Water Assessment

Propachlor can contaminate surface water via runoff if runoff-producing rain events occur within the first few days to weeks post application. A very low soil/water partitioning of propachlor (K_{ads}=0.45-1.39), and its solubility in water (613 ppm) suggest that propachlor will primarily move via dissolution in runoff water (as opposed to adsorption to eroding soil). It appears that the persistence of propachlor in surface waters with high microbiological activities may be limited by its susceptibility to biodegradation. In waters with short hydrological residence times, its persistence is limited by flow out of the system. However, its resistance to abiotic hydrolysis and photolysis, coupled with its low volatilization potential (vapor pressure 7.9×10^{-5} mm Hg, calculated Henry's law constant 3.59×10^{-8} atm m^3/mol) should make it more persistent in waters with low microbiological activities and long hydrological residence times (e.g., lakes and reservoirs).

Surface water monitoring data collected and reported to the STORET system on the occurrence of propachlor between 1978 and 1997 indicates its presence in surface water in association with known use areas. Concentrations above the LOQ were reported for approximately 295 samples; the maximum being 10 ppb. More than 16,000 samples were reported as either below the LOQ (ca. 95 percent of samples) or below the LOD (ca. 5 percent of samples). The LOQs ranged from 0.001 to 1.3 ppb and LODs ranged from 0.002 to 0.5 ppb. Sample locations were dominated by streams, lakes, and reservoirs. No association with drinking water intakes could be confirmed for the sample sets.

The data collected on the occurrence of propachlor in surface water may represent both the parent and its degradates. The analytical procedures used in several of the studies, where the authors could be contacted, indicated that it wasn't possible to distinguish between the parent and several of the more mobile and structurally similar degradates or the results were reported as both the parent and known degradates. Therefore, it is possible that concentrations reported to STORET include both the parent and/or several of the related degradates.

The major acid degradates of propachlor in the aerobic soil metabolism study were propachlor oxanilic acid, propachlor sulfonic acid, and propachlor sulfinylacetic acid. Even though complete data are not available to fully assess the fate of such degradates, based on the low adsorption coefficient for propachlor oxanilic acid and propachlor sulfonic acid (K_{ads} 0.08), it appears that such degradates are only weakly adsorbed to soil surfaces. Based on the results of the aerobic soil metabolism and

the terrestrial field dissipation studies, it appears that these major degradates may be available for runoff longer than parent propachlor and will probably runoff primarily by dissolution in runoff water. Available metabolism studies suggest that these degradates may also persist longer in surface waters as well.

b. Ground Water Assessment

Based on the laboratory and field studies conducted, it appears that the parent propachlor does not pose a significant threat to ground-water quality under most conditions. The chemical has a high mobility (K_{ads}=0.45-1.39) but is susceptible to aerobic soil metabolism ($t_{1/2}$ <3 days; DT_{50} ~5 days). The terrestrial field dissipation studies also suggest that propachlor does not persist long enough to exhibit substantial leaching (DT_{50} 1-7 days). However, the three acidic degradates have a high potential to leach to and persist in ground water.

Ground-water monitoring data collected and reported to the STORET system on the occurrence of propachlor between 1980 and 1997 indicates its presence in ground water in association with known use areas. Concentrations above the level of quantification were reported for 10 samples; the maximum being 0.17 ppb. More than 7500 samples were collected and reported to STORET as either below the level of quantification (LOQ) which ranged from 0.004-0.4 ug/L (ca. 75 percent of 7500 samples) or below the level of detection (LOD) which ranged from 0.004-0.012 ug/L (ca. 25 percent of 7500 samples). A substantial number of the samples could not be correlated with time of application and, in some instances, it could not be confirmed that sampling occurred in known use areas.

The data collected on the occurrence of propachlor in ground water may represent both the parent and its degradates. The analytical procedures used in several of the studies, where the authors could be contacted, indicated that it wasn't possible to distinguish between the parent and several of the more mobile and structurally similar degradates or the results were reported as both the parent and known degradates. Therefore, it is possible that concentrations reported to STORET include both the parent and/or several of the closely related degradates.

Interpretation of STORET ground water monitoring data and perhaps the Pesticide in Ground Water Database data may be complicated by the presence of closely related parent metabolites. Degradates such as hydroxypropachlor, propachlor oxanilic acid, and propachlor sulfonic acid may have been detected and reported as propachlor due to the limitations of the analytical methods or, in the case of STORET data, a lack of an appropriate input parameter value for data storage. Additionally, metabolites of propachlor tend to be more persistent and mobile which may explain the presence of propachlor in ground water if the method or lack of parameter values results in the metabolite being reported as the parent.

Ground-water monitoring data from the EPA's *Pesticides in Ground Water Database* reported samples collected over 6 years in 11 states representing 2718 samples. Concentrations above the LOD were reported in 33 of the wells in 5 states as 0.02 to 3.5 ppb. Positive results were obtained in

several of the major corn and sorghum growing regions. As indicated above, the uncertainty of the reported values as parent, parent and degradate, or degradate applies to these data as well.

Three acidic degradates of propachlor (propachlor oxanilic acid, propachlor sulfonic acid and propachlor sulfinyl acetic acid) were observed both in the aerobic soil metabolism and the terrestrial field dissipation studies. In the laboratory, under aerobic soil metabolism conditions, it appeared that propachlor oxanilic acid and propachlor sulfonic acid were persistent. In the field, the three degradates appeared to persist and leach substantially (to a 36-42 inch soil depth).

c. Aquatic Exposure Assessment

Preliminary aquatic EECs are estimated using GENEEC, 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). When risk quotients (RQs) for aquatic organisms are exceeded, refined aquatic EECs are calculated using PRZM/EXAMS.

Table 35: Environmental fate parameters used to predict propachlor EECs.

Parameter	Value
water solubility (ppm):	613 ppm
Koc:	112
aerobic soil metabolism, t1/2:	8.1 days[1]
hydrolysis t1/2, pH 7:	Stable
aerobic aquatic metabolism, t1/2	Not available
aqueous photolysis t1/2:	Stable

[1]The calculated aerobic soil metabolism half-life was 2.7 days. The value was multiplied by a factor of 3 to account for variability with such studies and the absence of more than one study.

The Pesticide Root Zone Model (PRZM2.3) simulates pesticides in field runoff on daily time steps, incorporating runoff, infiltration, erosion, and evapotranspiration. The model calculates foliar dissipation and runoff, pesticide uptake by plants, microbial transformation, volatilization, and soil dispersion and retardation. The Exposure Analysis Modeling System (EXAMS II) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep).

Table 36: Estimated Environmental Concentrations (EECs) For Aquatic Exposure from Aerial Application on Selected Uses Using GENEEC and PRZM/EXAMS.

Site	Application Rate x No/ Interval (da)	----- Estimated Environmental Concentrations (EECs), ug/l -----					
		Peak	4-day	21-day	56/60-day	90-day	long-term avg
Tier 1: GENEEC							
Corn / Sorghum	3.0 x 1	101	100	99	97	--	--
	6.0 x 1	202	201	199	193	--	--
Tier 2: PRZM2.3/EXAM II 1 in 10 year EECs							
Corn	6.0 x 1	44.0	35.6	16.3	6.4	4.3	0.5
Sorghum	6.0 x 1	64.0	46.7	19.1	7.6	5.1	0.6

5. Estimated Water Concentrations For Drinking Water

The estimated concentrations for drinking water provided below. They are for the parent propachlor only.

a. Ground Water Sources

A preliminary ground water assessment was made using SCI-GROW to estimate the "maximum" ground-water concentration from the application of a pesticide to crops. SCI-GROW is based on the fate properties of the pesticide, the application rate, and the existing body of data from small-scale ground-water monitoring studies. The model assumes that the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimates. As such, the estimated "maximum" concentration derived using SCI-GROW should be considered a high-end to bounding estimate of "acute" exposure. The concentration for parent propachlor estimated using SCI-GROW is approximately 0.03 ppb. The results of this model should be compared to available monitoring data when determining the potential for human exposure.

b. Surface Water Sources

Tier II surface water drinking water EECs were calculated using PRZM 2.3 to simulate the agricultural field and Exams II for fate and transport in surface water. Spray drift was simulated using the assumption that 1% of applied propachlor reached surface water at the time of application and 95% of the chemical deposited on the target site. The remaining 4% either remained airborne or deposited on the ground beyond the drainage basin for the pond.

The scenarios chosen for propachlor were a corn field in Pottawattamie County, Iowa and a sorghum field in Neosho County, Kansas. Scenarios were chosen to represent sites that were

expected to produce runoff greater than 90% of the sites where the appropriate crop is grown. Model simulations were made with the maximum application rate. Tier II one-in-ten year (upper tenth percentile) EECs are presented in Table 36. The EECs have been calculated so that in any given year, there is a 10% probability that the maximum average concentration of that duration in that year will equal or exceed the EEC at the site.

The overall upper 90% confidence bound on the mean concentrations of propachlor were 0.5 ug/l from the application to corn, and 0.6 ug/l from the application to grain sorghum. These upper 90% confidence bounds are the best value to use in cancer risk assessments as they are the best estimate of lifetime mean concentrations. The maximum 1 in 10 year concentrations are 44 ug/L from the application to corn and 64 ug/L from the application to grain sorghum. These values are the suggested value for use in acute risk assessments.

c. Use of Screening Estimates for Drinking Water Assessments

EFED recommends that the EECs generated from SCI-GROW (for ground water sources) and from PRZM/EXAMS (for surface water sources) be used for drinking water risk assessments for the parent propachlor. The monitoring data reported here are not considered reliable for use in drinking water assessments because they were not well-correlated with the use patterns for propachlor or to drinking water intakes. The model predictions provide a screen to eliminate those chemicals that are not likely to cause drinking water problems. Exceedances in drinking water risk assessments using the screening model estimates do not necessarily mean a problem actually exists but point to the need for better data (such as monitoring studies specifically designed to relate water concentrations to usage) on which to make a decision. It is possible that the additional data will show no problem; it is also possible that the data will show that in some instances a problem may still exist. If degradates are to be included in the tolerance expression, the monitoring data may have to be re-evaluated for usefulness and/or the modeling data will have to be re-calculated to include the appropriate degradates.

6. Comparative Assessment With Other Acetanilides

Propachlor appears to be similar in mobility but less persistent than the acetanilides alachlor, acetochlor, and metolachlor. However, the available half-life and DT_{50} values for the four chemicals are within the same order of magnitude.

A table summarizing the environmental fate characteristics of the four acetanilides follows this discussion. An inspection of the physico-chemical characteristics of these chemicals reveals that propachlor has a smaller molecular weight because there are no substitutions in the phenyl ring. Propachlor has the highest solubility in water. All the compounds have relatively low octanol/water partition coefficients, low vapor pressures, low calculated Henry's Law constants, and relatively small 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 67 days for metolachlor. The available studies indicate that anaerobic soil metabolism is not an important route of degradation for the acetanilides. All four compounds have high mobility.

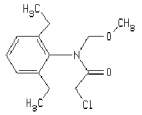
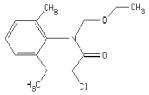
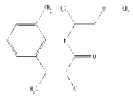
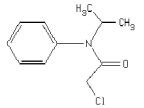
The half-lives observed in the field are of the same order of magnitude of the half-lives of aerobic soil metabolism studies in all cases. Results of the field studies confirm aerobic soil metabolism as an important route of dissipation for the four compounds.

The following tables provide a comparison of environmental fate and ecological toxicity data for the acetanilides alachlor, acetochlor, metolachlor, and propachlor.

The environmental fate data for the four acetanilides come from a combination of data reported in the EFED Environmental Fate One-Liner Database and from recently-completed environmental fate assessments.

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 those studies classified as Core data were used in the analysis. Study identification numbers are shown as either an MRID#, Accession No., or an EPA ID# (Fiche No.). Category terminology was taken directly from Brooks, et al. (1973).

Table 37: Comparison of the Environmental Fate Characteristics of Alachlor, Acetochlor 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
Anaerobic Soil Metabolism	Not available	230 days in sandy loam soil	81 days	146 days in a clay-loam sediment/lake water system

Characteristic	Alachlor	Acetochlor	Metolachlor	Propachlor
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, and propachlor are not only structurally related, but they also exhibit similar fate properties.

Table 38: Comparison of avian acute oral LD_{50} data (mg/kg) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	Avian LD50 (mg/kg)	Category	MRID/Acc#/ EPA ID#	Classification
Propachlor	88	Moderately toxic	00132907	Core
Alachlor	1499	Slightly toxic	0079523	Core
	>2000	Slightly toxic	00160000	Core
	>2610	Slightly toxic	00107908	Core
Acetochlor	49	Highly toxic	41963303	Core
	1567	Slightly toxic	0079598	Core
	1788	Slightly toxic	41565129	Core
Metolachlor	4640	Slightly toxic	00015547	Core

* Technical Grade Material

Table 39: Comparison of avian subacute dietary LC_{50} data (ppm) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	Avian LC50	Category	ID #	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

Table 40: Comparison of freshwater fish 96-hr LC_{50} data (ppm) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	96-hr LC50*	Category	ID #	Classification
Propachlor	0.23	Highly toxic	40098001	Core
	0.17	Highly toxic	00041335	Core
Alachlor	1.0	Highly toxic	234628	Core
	5.6	Moderately toxic	234628	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

Chemical	96-hr LC50*	Category	ID #	Classification
	4.9	Moderately toxic	0015534	Core
	8.0	Moderately toxic	40098001	Core
	10.0	Moderately toxic	00018723	Core

Table 41: Comparison of aquatic invertebrate 48-hour LC_{50} data (ppm) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	48-hr LC50*	Category	ID #	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 42: Comparison of estuarine fish 48-hour LC_{50} data (ppm) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	48-hr LC50*	Category	ID #	Classification
Alachlor	3.9	Moderately toxic	44524301	Core
Propachlor	No Data			
Acetochlor	2.1	Moderately toxic	42713102	Core
	3.9	Moderately toxic	41565137	Core
Metolachlor	9.8	Moderately toxic	43487101	Core

Table 43: Comparison of estuarine invertebrate 96-hour LC_{50} /EC_{50} data (ppm) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	48-hr LC50*	Category	ID #	Classification
Alachlor	2.4	Moderately toxic	44524302	Core
Alachlor	1.6	Moderately toxic	44524303	Core
Propachlor	No Data			
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 44: Comparison of mammalian acute oral LD_{50} data (mg/kg) for propachlor, acetochlor, alachlor and metolachlor.

Chemical	96-hr LD50*	Category	ID #	Classification
Propachlor	1800		00104350	Core
Alachlor	No Data			
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

a. 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.

b. Mammalian Species

Available toxicity data suggest that propachlor is practically nontoxic while acetochlor and metolachlor are moderately toxic to mammalian species. No mammalian toxicity data are available for alachlor.

c. Fish Species

The freshwater fish 96-hour LC_{50} data suggest that propachlor is the most toxic of the four herbicides. 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. No estuarine fish toxicity data are available for propachlor. However, the toxicity data for acetochlor, alachlor, and metolachlor suggest that propachlor is only moderately toxic to estuarine fish species.

d. 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. There are no estuarine invertebrate toxicity data for propachlor. However, the available toxicity data for acetochlor, alachlor, and metolachlor indicate that propachlor is only moderately toxic to estuarine invertebrate species.

7. Environmental Risk Assessment

Propachlor is moderately toxic to birds on an acute oral basis but practically nontoxic on a subacute dietary basis. The pesticide is considered practically nontoxic to mammals (based on tests on rats) and honey bees. Both the active ingredient and the formulated use product are considered moderately to highly toxic to freshwater fish and invertebrates on an acute basis. A comparison of acute LD_{50} data with the appropriate time-averaged PRZM/EXAMS EECs (table 36) indicate that chronic toxicity or life-cycle studies for aquatic organisms is not required. Among nontarget terrestrial plants, lettuce and ryegrass exhibited the highest sensitivity in terms of seedling emergence and vegetative vigor. No data are available for any of the degradates of propachlor.

To evaluate the potential risk to nontarget organisms from the use of propachlor products, risk quotients (RQs) are calculated from the ratio of estimated environmental concentrations (EECs) to ecotoxicity values. RQs are then compared to levels of concern (LOCs) used by the Agency to indicate potential risk to nontarget organisms and the need to consider regulatory action.

a. Risk Quotients and Levels of Concern

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. Risk quotients (RQs) are calculated by dividing estimated exposure concentrations (EECs) by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

Rqs are then compared to levels of concern (LOCs). These LOCs are used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs address the following risk presumption categories:

(1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification,

(2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification,

(3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and

(4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted.

The Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammals or birds.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are:

(1) LC_{50}, the lethal concentration for 50% of the test population (fish and birds),

(2) LD_{50}, the lethal dose for 50% of the test population (birds and mammals),

(3) EC_{50}, the concentration resulting in an adverse effect for 50% of the test population (aquatic plants and aquatic invertebrates), and

(4) EC_{25}, the concentration resulting in an adverse effect for 50% of the test population (terrestrial plants).

Examples of toxicity test effect levels derived from long-term laboratory studies that assess chronic effects are:

(1) LOEC, lowest observed effect concentration (birds, fish, and aquatic invertebrates),

(2) NOEC, no observed effect concentration (birds, fish and aquatic invertebrates), and

(3) MATC, geometric mean of the NOEC and LOEC (fish and aquatic invertebrates).

For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement end point is production of offspring or survival.

The table below gives the corresponding RQs and LCs for each of the risk presumption categories.

Table 45: Risk Presumptions for Non-Target Organisms

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50	0.2
Acute Endangered Species	mg/kg)	0.1
Chronic Risk	EEC/LC50 or LD50/sqft or LD50/day	1
	EEC/NOEC	
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50	0.2
Acute Endangered Species	mg/kg)	0.1
Chronic Risk	EEC/LC50 or LD50/sqft or LD50/day	1
	EEC/NOEC	
Aquatic Animals		
Acute High Risk	EEC[3]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[4]/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
Aquatic Plants		
Acute High Risk	EEC[5]/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{\text{mg/ft}^2}{\text{LD50 * wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{\text{LD50 * wt. of bird}}$

[3] EEC = (ppm or ppb) in water

[4] EEC = lbs ai/A

[5] *EEC = (ppb/ppm) in water*

b. Exposure and Risk to Nontarget Terrestrial Animals

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 (6.0 lb ai/acre).

Table 46: Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 and 6 lb ai/A*

Food Items	EEC (ppm) Max. Residue for 1 and 6 lb ai/acre		EEC (ppm) Mean Residue for 1 and 6 lb ai/acre	
Short grass	240	1,440	85	510
Tall grass	110	660	36	216
Broadleaf plants and small insects	135	810	45	270
Fruits, pods, seeds, and large insects	15	75	7	42

*(Hoerger and Kenaga, 1972, as modified by Fletcher et al, 1994)

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. The maximum EEC for a broadcast granular formulation is 62.5 mg/ft^2 at the maximum 6.0 lb ai/acre application rate. 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)

Propachlor is not concentrated in the bands. The banded application reduces the area treated while the EECs remain the same within the treated band width.

LOC exceedances for nontarget terrestrial animals are summarized below.

Table 47: Summary of Acute Level of Concern (LOC) Exceedances For Non-Target Terrestrial Animals From the Use of Products Containing Propachlor.

Site/App. Meth./ Formul./ Rate	Non-Target Organism	Food Items	Acute RQ	Trigger(s) Exceeded
Corn, sorghum / Broadcast / Granular				
6.0 lb ai/acre	Songbird (20 g body wt)	granules on the surface	34.44	acute restricted use & high risk, endangered species
	Upland game bird (180 g)	granules on the surface	3.94	acute restricted use & high risk, endangered species
	Mammal (15-35g wt), based on rat study	granules on the surface	2.31-0.99	acute restricted use & high risk, endangered species
3.0 lb ai/acre	Songbird (20 g)	granules on the surface	17.22	acute restricted use & high risk, endangered species
	Upland game bird (180 g)	granules on the surface	1.97	acute restricted use & high risk, endangered species
	Mammal (15-35 g)	granules on the surface	1.16-0.50	acute restricted use & high risk, endangered species
Corn, sorghum / Ground spray / Non-granular				
6.0 lb ai/acre	Mammal (15-35g wt), based on rat study	Short grass	0.76-0.53	acute restricted use & high risk, endangered species
		Forage/ small insects	0.43-0.30	acute restricted use, endangered species
3.0 lb ai/acre	Mammal (15-35 g)	Short grass	0.38-0.27	acute restricted use, endangered species
		Forage/ small insects	0.21-0.15	acute restricted use, endangered species

(1) Birds

Non-granular Risk: Actual risk quotients for applications of the nongranular formulation of propachlor were not calculated since all reported LC_{50} values were greater than 5,000 ppm. However, terrestrial EECs (1,440 ppm for short grasses) are well below the avian LC_{50} values so it is unlikely that dietary risk to avian species will occur. In addition, the Agency has no reported incidents involving propachlor and any avian species.

Granular Risk: Birds may be exposed to granular pesticides by ingesting granules when foraging for food or by other routes, such as by walking on exposed granules or drinking water contaminated

by granules. The number of lethal doses (LD_{50}s) available within one square foot immediately after application ($LD_{50}s/ft^{2)}$ is used as the risk quotient for granular products. Risk quotients are calculated for three separate weight classes: 1000 g (e.g., waterfowl), 180 g (e.g., upland game bird) and 20 g (e.g., songbird).

Banded applications of granular formulations will result in a reduction of the area treated with no concentration of herbicide within the bands (the label prescribes reducing the application rate in lbs ai/acre by the fraction of the treated area). As a result, the EEC and subsequent RQ will be the same in the treated areas as with the broadcast applications. However, the area available for exposure is reduced roughly by the fraction of the area treated. Furrow applications which incorporate a portion of the applied pesticide reduce the overall fraction of propachlor exposed at the surface, reducing the EEC and RQ.

For broadcast applications of granular formulations of propachlor, avian acute high risk LOC are exceeded for songbird and upland game bird species at application rates equal to or greater than 3 lb a.i./acre, while the application of propachlor at 6 lb a.i./acre results in exceedences of the acute high risk LOC for all avian species. Banded applications of granular formulations reduce the area treated without concentrating the herbicide within the bands. As a result, the EEC and RQ in the treated areas will be the same as with the broadcast applications. Furrow applications which incorporate a portion of the applied pesticide would reduce the overall fraction of propachlor exposed at the surface, reducing the EEC and RQ.

(2) Mammals

Non-granular Risk: Estimating the potential for adverse effects to wild mammals is based upon the Agency's draft 1995 SOP of mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). The concentration of propachlor in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (usually a rat LD_{50}) by the decimal fraction of body weight consumed. A risk quotient is calculated by dividing the EEC by the derived LC_{50} value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds).

Broadcast applications of nongranular formulations of propachlor at rates of 3 lb. a.i./acre or more exceed the endangered species and acute restricted use LOCs for herbivores and insectivores. The maximum rate of 6 lb. a.i./acre exceeds the endangered species, acute restricted use and acute high risk LOC for herbivores and insectivores but does not exceed any LOC for granivores.

Granular Risk: Mammalian species may be exposed to granular pesticides by ingesting granules or other routes, such as by walking on exposed granules or drinking water contaminated by granules. The number of lethal doses (LD_{50}s) available within one square foot immediately after application can be used as a risk quotient for exposure to granular pesticides. Risk quotients are calculated for three separate weight classes of mammals: 15 g, 35 g and 1000 g.

For granular products, mammalian acute high risk, acute restricted use and endangered species LOCs are exceeded for small mammals (35 grams or less) at application rates equal to or greater than 3 lbs. a.i./acre.

(3) Beneficial Insects

Currently, the Agency does not assess risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions.

c. Exposure and Risk to Nontarget Aquatic Animals

Table 48: Summary of Acute Level of Concern (LOC) Exceedances For Non-Target Aquatic Animals From the Use of Products Containing Propachlor.

Crop/App. Meth./ Rate (lb ai/Ac)	Non-Target Organism	Acute RQ	Trigger(s) Exceeded
Corn / ground/ (a) 6.0	Freshwater fish (rainbow trout)	(a) 0.26	acute restricted use, endangered species
(b) 3.0		(b) 0.13	acute restricted use, endangered species
Sorghum/ground (a) 6.0	Freshwater fish (rainbow trout)	(a) 0.38	acute restricted use, endangered species
(b) 3.0		(b) 0.19	acute restricted use, endangered species
Corn/ ground/ 6.0	Freshwater invertebrate (daphnia)	0.06	endangered species
Sorghum/ ground/ 6.0	Freshwater invertebrate (daphnia)	0.08	endangered species

(1) Freshwater Fish

Using refined EECs (generated with PRZM/EXAMS), acute RQs exceeded the endangered species and acute restricted use LOCs for freshwater fish at a maximum application rate equal to or greater than 3 lbs. a.i./acre. No chronic RQs were calculated since life-cycle or early life stage tests for freshwater fish are not required.

(2) Freshwater Invertebrates

With refined EECs, acute RQs exceeded the endangered species, and acute restricted use LOCs for freshwater invertebrates at a maximum application rate equal to or greater than 6 lbs. a.i./acre. No chronic RQs were calculated since life-cycle tests for freshwater invertebrates are not required.

(3) Estuarine and Marine Animals

Because of a lack of toxicity data for estuarine and marine fish and invertebrates, potential LOC exceedences for estuarine and marine animals could not be determined.

(4) Data Gaps for Degradate Exposure and Risk to Non-target Aquatic Animals

Acute LC_{50} tests conducted with the analogous sulfonic acid and oxanilic acid degradates of alachlor indicate these degradates were practically nontoxic to rainbow trout (MRIDs 437747-04 and 437747-06). If the same toxicity trend between the parent and degradate holds true for propachlor and its degradates, further studies regarding the toxicity of propachlor degradates are not required.

To evaluate toxicity data gaps for the degradates, the Agency performed a Quantitative Structure Activity Relationship (QSAR) analysis for parent propachlor and its six identified degradates. The QSAR analysis estimated toxicity data for rainbow trout and Daphnia magna. QSAR assessments are generally more reliable for neutral organics than for acetanilide pesticides and their degradates primarily due to the multiple subclasses within this group of chemicals. Because of the uncertainty, QSAR was coupled with available data and a comparative assessment with the other acetanilides only as a screen to determine whether additional testing for the degradates was required. It was not intended to take the place of actual toxicity tests.

Table 49: Comparison of Aquatic Toxicity Values Estimated From QSAR Analyses and Actual Toxicity Studies for Propachlor.

Toxicity Study	Parent/Degradate	QSAR Estimate	Actual Studies
Fish 96-hour LC50	Propachlor Propachlor oxanilate Propachlor sulfonate Propachlor sulfinyl acetate Hydroxy propachlor Propachlor methyl sulfone Norchloropropachlor	0.70 ppm >1000 ppm >1000 ppm >1000 ppm 650 ppm >100 ppm 310 ppm	0.17 ppm
Aquatic Invert. 48-hr EC50	Propachlor Propachlor oxanilate Propachlor sulfonate Propachlor sulfinyl acetate Hydroxy propachlor Propachlor methyl sulfone Norchloropropachlor	0.34 ppm >1000 ppm >1000 ppm >1000 ppm 670 ppm >100 ppm 330 ppm	0.79 ppm

The QSAR analysis estimated acute toxicity values for propachlor that were in the same order of magnitude as actual measured acute toxicity values. The estimates for acute toxicity from the QSAR

analysis suggests that the degradates were more than two orders of magnitude less toxic than the estimated toxicity for the parent.

d. Exposure and Risk to Nontarget Plants

(1) EECs for terrestrial plants inhabiting areas adjacent to treatment sites

Unincorporated ground application:
Runoff = maximum application rate (lbs ai/A) x runoff value
Drift = maximum application rate x 0.01
Total Loading = runoff (lbs ai/acre) + drift (lbs ai/A)

Incorporated ground application:
Runoff = [maximum application rate (lbs ai/A) ÷
minimum incorporation depth (in.)] x runoff value
Drift = maximum application rate x 0.01
(Note: drift is not calculated if the product is incorporated at the time of application.)
Total Loading = runoff (lbs ai/A) + drift (lbs ai/A)

Aerial, airblast, forced-air, and chemigation applications:
Runoff = maximum application rate (lbs ai/A) x 0.6
(60% application efficiency assumed) x runoff value
Drift = maximum application rate (lbs ai/A) x 0.05

Total Loading = runoff (lbs ai/A) + drift (lbs ai/A)
Calculating EECs for semi-aquatic plants inhabiting wet, low-lying areas

(2) EECs for semi-aquatic plants inhabiting adjacent wet, low-lying areas

Unincorporated ground application:
Runoff = maximum application rate (lbs ai/A) x runoff value x 10 acres
Drift = maximum application rate x 0.01
Total Loading = runoff (lbs ai/A) + drift (lbs ai/A)

Incorporated ground application:
Runoff = [maximum application rate (lbs ai/A)/minimum incorporation depth (in.)]
x runoff value x 10 acres
Drift = maximum application rate x 0.01
(Note: drift is not calculated if the product is incorporated at the time of application.)
Total Loading = runoff (lbs ai/A) + drift (lbs ai/A)

Aerial, airblast, and forced-air applications:
Runoff = maximum application rate (lbs ai/acre) x 0.6

(60% application efficiency assumed) x runoff value x 10 acres
Drift = maximum application rate (lbs ai/A) x 0.05
Total Loading = runoff (lbs ai/A) + drift (lbs ai/A)

(3) Terrestrial and Semi-Aquatic Plants

Terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, spray drift or volatilization. Semi-aquatic plants are those that inhabit low-lying wet areas that may be dry at certain times of the year. The Agency's runoff scenario is: (1) based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one inch; (2) characterized as "sheet runoff" (one treated acre to an adjacent acre) for terrestrial plants; (3) characterized as "channelized runoff" (10 treated acres to a distant low-lying acre) for semi-aquatic plants; and (4) based on % runoff values of 0.01, 0.02, and 0.05 for water solubility of <10 ppm, 10-100 ppm, and >100 ppm, respectively.

Current labels for propachlor only allow for the unincorporated ground application of propachlor as a preemergent herbicide for corn and grain sorghum. Spray drift exposure from ground application is assumed to be 1% of the application rate. Spray drift from aerial, airblast, forced-air, and chemigation applications is assumed to be 5% of the application rate.

The EC_{25} value of the most sensitive species in the seedling emergence and vegetative vigor study is compared to runoff plus drift exposure to determine the risk quotient (ECC/toxicity). Analysis of propachlor plant data show that after a single application, plant acute high risk and endangered species levels of concern are exceeded for terrestrial plants in dry and semi-aquatic areas at a registered single application rate equal to or greater than 3.0 lbs ai/A.

EECs are calculated for the following application methods: (1) unincorporated ground applications, (2) incorporated ground application, and (3) aerial, airblast, forced-air, and chemigation applications. Estimated environmental concentrations for dry and semi-aquatic areas are tabulated below.

Table 50: EECs (lbs ai/A) For Dry and Semi-Aquatic Areas for a Single Application

Site/ Application Method/ Rate of Application in lbs ai/A	Minimum Incorp. Depth (cm)	Runoff Value	Sheet Run-off (lbs ai/A)	Channelized Runoff (lbs ai/A)	Drift (lbs ai/A)	Ttl Loading to Adjacent Area (Sheet Runoff+Drift)	Ttl Loading to Semi-aquatic Area (Channel Run-off+ Drift)
Corn / Unincorp. Ground / 6.0	0	0.05	0.30	3.00	0.06	0.36	3.06
Corn / Unincorp. Ground / 3.0	0	0.05	0.15	1.50	0.03	0.18	1.53

Table 51: Acute High Risk Quotients from a Single Application for Terrestrial Plants in Dry and Semi-Aquatic Areas*

Site, Method, Appl. Rate (lbs ai/A)	Seedling Emerg-ence EC25 (lbs ai/A)	Vegetative Vigor EC25 (lbs ai/A)	Drift (lbs ai/A)	Ttl Loading to Adjacent Area (Sheet Runoff+Drift)	Ttl Loading to Semi-aquatic Area (Channeliz-ed Runoff+ Drift)	Emer-gence RQ[1] Dry Area	Emer-gence RQ[1] Semi-Aquatic Area	Vegetative Vigor RQ[1] Both Areas
Corn / Unincorp. Ground / 6.0	0.021	0.059	0.06	0.36	3.06	17.14*	145.71*	1.02*
Corn / Unincorp. Ground / 3.0	0.021	0.059	0.03	0.18	1.53	8.57*	72.86*	0.51

* exceeds acute high risk LOC (1)

1 Based On a (Rygrass) Emergence EC25 of 0.021 lbs ai/A and a (Rygrass) Vegetative Vigor EC25 of 0.059 lbs ai/A.

The NOEC or EC_{05} (if NOEC is unavailable) value of the most sensitive species in the seedling emergence study is compared to runoff and drift exposure to determine the endangered species risk quotient. The NOEC or EC_{05} value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the endangered species risk quotient.

EECs and acute (endangered species) risk quotients for terrestrial plants based on a single application are tabulated below.

Table 52: Acute Endangered Species Risk Quotients from a Single Application for Terrestrial Plants in Dry and Semi-Aquatic Areas*

Site, Method Appl. Rate (lbs ai/A)	Seedling Emergence NOEC or EC05 (lbs ai/A)	Vegetative Vigor NOEC or EC05 (lbs ai/A)	Drift (lbs ai/A)	Ttl Loading to Adjacent Area (Sheet Runoff+ Drift)	Ttl Loading Semi-aquatic Area (Chan-nelized Runoff+ Drift)	Emer-gence RQ[1] Dry Area	Emer-gence RQ[1] Semi-Aquatic Area	Vegeta-tive Vigor RQ[1] Both Areas
Corn / Unincorp. Ground / 6.0	0.019	0.037	0.05	0.36	3.06	18.95*	161.05*	1.35*
Corn / Unincorp. Ground / 3.0	0.019	0.037	0.05	0.18	1.53	9.47*	80.53*	1.35*

* exceeds endangered species (1).
1 Based On a (Rygrass) Emergence NOEC of 0.019 lbs ai/A and a (Rygrass) Vegetative Vigor NOEC of 0.037 lbs ai A.

An analysis of the results indicate that for a single application, plant acute high risk and endangered species levels of concern are exceeded for terrestrial plants in dry and semi-aquatic areas at a registered maximum single application rate equal to or greater than 3.0 lbs ai/A. Currently, the Agency does not perform chronic risk assessments for terrestrial plants.

(3) Aquatic Plants

Aquatic plant testing (tier II) is required for propachlor because of its outdoor nonresidential uses that may result in the compound moving off-site by runoff and by spray drift. The following species should be tested at Tier II: Kirchneria subcapitata, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom. Results of the Tier II toxicity testing on technical propachlor are tabulated below.

Table 53: Acute Risk Quotients for Aquatic Plants

Site/ Application Method/ Rate of Application (lbs ai/A)	Species	EC_{50} (ppm)	EEC[1] (ppm)	NOEC (ppm)	Endangered Species RQ[2] (EEC/NOEC)	Non-target plant RQ (EEC/EC_{50})
Corn (unincorporated, ground) 6.0 lbs ai/A	K. subcapitata	0.0135	0.044	0.0035	3.85*	3.25*
Corn (unincorporated, ground) 3.0 lbs ai/A	K. subcapitata	0.0135	0.022	0.0035	6.29*	1.63*

1 PRZM/EXAMS Model
* exceeds endangered species and acute high risk (1)
2 Based upon a nonvascular plant (Kircheria subcapitata) EC_{50} of 0.0135 ppm ai. For endangered species, the NOEC =0.0035 ppm ai.

The outdoor use of propachlor may result in exposure to nontarget aquatic plants through runoff or spray drift from adjacent sites. As a result, tier II plant testing is required on aquatic vascular plants (duckweed, *Lemna gibba)* and aquatic non-vascular species (three algae species *Kirchneria subcapitata, Skeletonema costatum,* and *Anabaena flos-aquae,* and a diatom). Runoff and drift exposure are computed using the PRZM/EXAMS model. Although only one study (aquatic algae) was submitted, the data suggest that plant acute high risk and endangered species levels of concern are exceeded at the registered maximum rates equal to or greater than 3 lbs ai/A.

e. Exposure and Risk to Endangered Species

The use of propachlor on corn and sorghum exceeds the endangered species level of concern for birds, mammals, freshwater fish and invertebrates, and plants. The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of propachlor will be required to protect endangered and threatened species, but these limitations have not been defined

and may be formulation specific. EPA anticipates that a future consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of that consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

8. Environmental Risk Characterization

The risk assessment for propachlor is based on a single seasonal application to corn or soybeans by ground broadcast or band treatment at a maximum rate of 6.0 lb. a.i./acre. The end products include flowable concentrate, granular, and water-dispersible granule formulations.

Information provided by the registrant (Suba, L.A. 1998. Monsanto's Response to the HED, EFED and Occupational Exposure Assessment Chapters for the Propachlor RED dated March 9, 1998. DP Barcode D246291) shows that the current major propachlor uses are in the Midwest -- Nebraska, Kansas, Minnesota, Missouri, and Iowa. Little or no propachlor use is reported in the eastern coastal plain; minor use is reported in Delaware and New Jersey. Based on current use information, the extent of propachlor use is smaller than the potential area covered by the labeled uses.

Even though some LOC triggers were exceeded, the overall toxicological spectrum for propachlor suggests that it is slightly to moderately toxic to most nontarget organisms. The Agency has no reported incidences of adverse impacts on nontarget organisms from the use of propachlor. The granular formulations posed the greatest risk to nontarget organisms. The granular assessment was based on an unincorporated broadcast application at a maximum rate of 6 lb a.i/acre. This scenario would likely result in a greater potential exposure to most avian and mammalian species than would the banded application. While the banded application would result in similar EECs and RQs within the treated area, banding would reduce the treated area per acre. A comparison with the acetanilides alachlor, acetochlor, and metolachlor suggests that propachlor is slightly more toxic to fish and aquatic invertebrates on an acute basis than are the other herbicides.

The potential chronic (long-term) exposure of nontarget organisms to propachlor is reduced because it is not persistent under most conditions and because the pesticide is only applied once in a growing season. This evaluation does not preclude the possibility that chronic effects may occur from a one-time exposure to propachlor. However, based on the weight of toxicological evidence for propachlor, the Agency believes such effects are unlikely.

The degradates of propachlor, particularly the oxanilic acid, sulfonic acid, and sulfinylacetic acid degradates, are more persistent than the parent. However, based on the QSAR analysis, they also appear to be less toxic (by at least two orders of magnitude).

11. Recommended Risk Reduction Measures and Labeling

The existing precautionary statements for propachlor, as modified for consistency in label language, should be maintained. Specific labeling requirements are detailed in section five of this document.

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 generic (i.e., active ingredient specific) data to support reregistration of products containing propachlor active ingredients. 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 propachlor. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propachlor, 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 propachlor and to determine that propachlor can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing propachlor as the active ingredient are eligible for reregistration provided that terms and conditions as set forth in this RED document are met. The reregistration of specific products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base 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 propachlor are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing propachlor, 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

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient propachlor, the Agency has sufficient information on the health effects of propachlor and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that propachlor products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency

concludes that products containing propachlor for all liquid and granular formulations are eligible for reregistration.

The Agency had concerns for the occupational risk posed to mixers/loaders of the dry flowables. The registrant has agreed to voluntarily cancel their formulation of the dry flowable product. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propachlor, and lists the submitted studies that the Agency found acceptable.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of propachlor are eligible for reregistration with the exception of the dry flowable formulation which the registrant has agreed to voluntarily cancel.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for propachlor. To lessen the risks posed by propachlor, EPA is requiring the following mitigation measures for propachlor-containing products. These measures are the new conditions of registration.

To Protect Non-Target Species:

-The label must now include warning statements referencing hazards to birds, wildlife, aquatic invertebrates, and other organisms. Label language is specified in section V.

To Control Ground and Surface Water Contamination:

-Labels must contain advisory language intended to minimize contamination of drinking water sources and aquatic habitats, including implementation of spray drift best management practices.

To Protect Workers:

-The Agency is requiring, in certain scenarios, the increased use of personal protective equipment and engineering controls to reduce exposure.

To Protect Food Quality:

-Until the required rotational crop data are received and reviewed, rotation to crops not specified on the label is prohibited.

-Tolerances have been reassessed and obsolete tolerances for which the registrant no longer supports will be proposed for revocation.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for propachlor, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) 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 acute and chronic) from non-occupational sources, food and drinking water.

Because there are no propachlor products registered for home use, or for use in or around schools, parks or other public areas, a residential exposure assessment was not conducted. Nor is there a residential exposure assessment to aggregate with the total dietary assessment.

Propachlor, alachlor, acetochlor, butachlor and metolachlor are structurally similar and therefore may share a common mechanism of toxicity. However, at this time the Agency has not yet made a final decision concerning a possible commom 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 upon the best available and useful information of propachlor only. The propachlor risk assessment has been performed assuming that no common mechanism of toxicity exists.

Thus, for the purpose of the tolerance reassessments in this RED, EPA has assumed that propachlor does not have a common mechanism of toxicity with other substances. Therefore, the risk assessments in this RED consider only the toxic effects of propachlor. However, these decisions will be reexamined after the Agency (1) completes the process for determining that a common mechanism for toxicity does exist for these chemicals, (2) determines the appropriate methodology for combining exposures, and (3) after reviewing the use information/patterns, determines for which of the exposures/scenarios for which of the five chemicals that cummulative exposure does exist. Once the methodologies and procedures for integrating information concerning common mechanism of toxicity into the risk assessment are developed, then 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 propachlor, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C), 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 propachlor residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from propachlor residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on the current data requirements, propachlor has a complete database for developmental and reproductive toxicity. Reliable studies cited earlier in this document indicate no special sensitivity of young organisms to propachlor (see Section IIIb.). The Agency has determined that the additional ten-fold margin of safety for the protection of infants and children is not necessary in this case. Therefore, the Agency has concluded that an overall uncertainty factor of 100 is adequate for assessing the risks of propachlor.

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

Tolerances are currently established in or on corn and sorghum for residues of the herbicide propachlor and its metabolite, 2-chloro-N-isopropylacetanilide, from 40 CFR §180.211.

Tolerance Reassessment Summary

Tolerances for propachlor residues (40 CFR §180.211) are presently expressed in terms of residues of propachlor and its metabolites, calculated as propachlor. Based on new metabolism data,

the Agency has determined that the propachlor residues to be regulated in plant and livestock commodities are those which contain the NIPA moiety. The Agency has determined that the residues of concern (i.e. those to be regulated in the tolerance expression) in plant and animal commodities are propachlor and all metabolites containing the N-isopropylaniline (NIPA) moiety. Therefore, the tolerances should be expressed in terms of the combined residues of propachlor and its metabolites containing the N-isopropylaniline moiety, calculated as propachlor.

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). Due to these changes, some commodity definitions must be corrected. In addition, tolerances for commodities for which there are currently no registered uses of propachlor need to be revoked, and the "N" notation next to some tolerance levels designating negligible residues should be deleted. A summary of reassessed tolerances is presented below.

Table 54: Tolerance Reassessment Summary for Propachlor.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.211			
Beets, sugar, roots	0.2	Revoke	There are currently no registered uses of propachlor on this commodity.
Beets, sugar, tops	1.0		
Cattle, fat	0.02 (N)	0.05	The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden
Cattle, mbyp	0.02 (N)	0.05	*[Cattle, mbyp (except kidney)]* The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.
Cattle, meat	0.02 (N)	0.02	
Corn, grain	0.1 (N)	0.2	*[Corn, field, grain]* Highest residue detected in corn grain in a 1X field trial is 0.19 ppm.
Corn, sweet (K + CWHR)	0.1 (N)	Revoke	There are currently no registered uses of propachlor on this commodity.
Cotton seed	0.1 (N)	Revoke	There are currently no registered uses of propachlor on this commodity.
Flax, seed	3.0	Revoke	There are currently no registered uses of propachlor on this commodity.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.211			
Flax, straw	10.0	Revoke	There are currently no registered uses of propachlor on this commodity.
Goats, fat	0.02 (N)	0.05	The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.
41Goats, mbyp	0.02 (N)	0.05	*[Goats, mbyp (except kidney)]* The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.
Goats, meat	0.02 (N)	0.02	
Hogs, fat	0.02 (N)	0.02	
Hogs, mbyp	0.02 (N)	0.02	*[Hogs, mbyp (except kidney)]*
Hogs, meat	0.02 (N)	0.02	
Horses, fat	0.02 (N)	0.05	The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.
Horses, meat	0.02 (N)	0.02	
Milk	0.02 (N)	0.02	
Peas (with pods)	0.2	Revoke	There are currently no registered uses of propachlor on this commodity.
Peas, forage	1.5	Revoke	There are currently no registered uses of propachlor on this commodity.
Pumpkins	0.1	Revoke	There are currently no registered uses of propachlor on this commodity.
Sheep, fat	0.02 (N)	0.05	The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.
Sheep, mbyp	0.02 (N)	0.05	*[Sheep, mbyp (except kidney)]* The tolerance increase is based on residues detected in a dairy cattle feeding study and an estimation of maximum ruminant dietary burden.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.211			
Sheep, meat	0.02 (N)	0.02	
Sorghum, fodder	5.0	12.0	*[Sorghum, stover]* Highest residue detected in sorghum fodder in a .8X or 1.2X field trial is 10.59 ppm.
Sorghum, forage	5.0	8.0	Highest residue detected in sorghum forage in a .8X or 1.2X field trial is 7.67 ppm.
Sorghum, grain	0.25	0.25	
Eggs	0.02 (N)	Revoke	Based on the available data, residues in poultry commodities can be classified under Category 3 of 40 CFR §180.6(a); therefore, tolerances for residues in poultry commodities are not required.
Poultry, fat	0.02 (N)		
Poultry, mbyp	0.02 (N)		
Poultry, meat	0.02 (N)		
Cattle, kidney	0.02 (N)	0.2	Feeding study data indicate that separate tolerances for residues in kidney are required.
Goats, kidney	0.02 (N)	0.2	
Hogs, kidney	0.02 (N)	0.02	
Horses, kidney	0.02 (N)	0.2	
Sheep, kidney	0.02 (N)	0.2	
Corn, field, stover	--	1.0	

a. Codex Harmonization

There are no Codex MRLs established for propachlor; therefore, issues of compatibility with U.S. tolerances do not exist.

D. Summary of Risk Management Decisions

1. Human Health

(1) Dietary

Acute Dietary

An acute dietary risk assessment was performed to estimate the risk of consuming a large amount of propachor residues in the food consumed on a single day. The assessment, a tiered approach, uses a single high-end residue estimate, usually the tolerance, combined with a distribution of individual food consumption values.

Using a Margin of Exposure approach and a NOEL of 175mg/kg/day, the MOE's for adult females was 53,000, 62,000 for adult males and 17,000 for children between the ages of one and six. Since all population sub-groups greatly exceed 100, the Agency has no concerns for acute dietary exposure.

Chronic Dietary (non-carcinogenic)

A chronic dietary assessment was performed to estimate the lifetime risk of consuming an average amount of propachlor residues. Using the DRES (Dietary Risk Evaluation System) modeling and percent crop-treated estimates derived from Federal and private market survey data, chronic dietary risk is calculated for the U.S. population and 22 sub-groups.

The chronic (non-carcinogenic dietary risk) %RfD for all of the following sub-groups: U.S. population, children (1-6years), 0.20%, adult females (20+ years), 0.05%, and adult males (20+ years), 0.05%, totaled less than 1% which is much less than EPA's level of concern of 100%.

Chronic Dietary (carcinogenic)

The chronic dietary assessment was performed to estimate the additional lifetime carcinogenic risk of consuming an average amount of propachlor residues. The exposure (mg/kg/day) is the same as that estimated by DRES for the chronic dietary assessment. Carcinogenic dietary risk is calculated for the U.S. population (for both males and females) by using the Q_1* approach.

The Q_1* of 0.032 $(mg/kg/day)^{-1}$ which was used to quantify the total dietry carcinogenic risk, when calculated for both adult males ($9.0x10^{-7}$) and females ($9.3x10^{-7}$) , the dietary risk is below the Agency's $1x10^{-6}$ level of concern.

2. Worker (Mixer/Loader/Applicator)

Acute (Short-Term) and Intermediate Term

An occupational exposure assessment was conducted for propachlor based upon the toxicological criteria which were triggered by the determination that propachlor is a "likely" human carcinogen. The potential for exposure does exist.

In the short-term risk assessment, the end-point selection is usually made using toxicity generated by the same route as the likely exposure - in this case dermal. However, no dermal study was available for selecting the NOEL therefore, a dermal absorption factor of 100% was used in estimating the risk. The MOE's for the short-term dermal and inhalation risk assessment were all greater than 100 with the exception of one scenario, the mixing/loading of liquids for groundboom application which required additional PPE.

As in the short-term assessment, the intermediate-term dermal and inhalation risk assessment assumed a 100% dermal absorption factor in estimating the risk. The risk assessment indicates that the MOE's are greater than 100 at baseline for the loading of granulars for tractor-drawn spreaders and the application of granulars to sorghum with tractor-drawn spreaders. Additional PPE is required to reduce exposure and to raise the MOE's above 100 for both the application of sprays to sorghum with a groundboom sprayer and the application of granulars to corn with tractor-drawn spreaders. Enginering controls are required to raise the MOE's above 100 for the last three scenarios: the mixing/loading of liquids for groundboom application, the mixing/loading of dry flowables for groundboom application, and the application of sprays to corn with groundboom sprayers.

Post-Application

EPA believes that, based on the current uses of propachlor, post-application exposure will be negligible. Therefore, the Agency is not requiring post-application studies.

3. Environmental

(1) Avian

Acute and Chronic

Propachlor is considered to be moderately toxic to avian species on an acute oral basis and is considered to be practically nontoxic to avian species on a subacute dietary basis. Application of granular formulations of propachlor exceed acute risk levels of concern for small birds (20g weights, representative of songbirds) and medium-sized birds (180g weights, representative of upland game birds). However, even though some LOC triggers were exceeded, the overall toxicological spectrum for propachlor suggests that it is slightly to moderately toxic to most nontarget organisms. The Agency has no reported incidences of adverse impacts on nontarget organisms from the use of propachlor.

The potential chronic (long-term) exposure of nontarget organisms to propachlor is reduced because it is not persistent under most conditions and because the pesticide is only applied once in a growing season. However, based on the weight of toxicological evidence for propachlor, the Agency believes such effects are unlikely.

Chronic avian toxicity data are not required for propachlor because repeated or prolonged exposure to the chemical is not expected. The label calls for one application per year and the fate data suggest that propachlor is not highly persistent in most terrestrial environments.

(2) Mammals

Acute and Chronic

Propachlor is practically non-toxic to mammalian species on an acute oral or chronic basis.

(3) Insects

Results indicate that propachlor is practically non-toxic to honey bees on an acute contact basis and a subacute dietary basis.

(4) Freshwater Fish

Acute and Chronic

Propachlor is considered moderately to highly toxic to freshwater fish on an acute basis. While the technical grade material (TGAI) is more toxic to rainbow trout than the formulated product, the formulated product is more toxic to bluegill sunfish than the technical grade material.

No early life-stage studies with freshwater fish are available for propachlor. Yet, a comparative analysis generated by PRZM / EXAMS yields an RQ value which does not trigger the need for any further chronic testing for freshwater fish.

(5) Aquatic invertebrates

Propachlor is considered moderately to highly toxic to aquatic invertebrates on an acute basis. No chronic aquatic invertebrate toxicity data are available for propachlor. Yet, a comparative analysis generated by PRZM / EXAMS yields an RQ value which does not trigger the need for any further chronic testing for aquatic invertebrates.

(6) Estuarine and Marine Organisms

Estuarine and Marine Fish,Acute

The toxicity testing with marine / estuarine fish is required for propachlor because the end-use product is expected to reach this environment because of its use in coastal counties. No studies have been submitted, therefore guideline 72-3a is not fulfilled.

Estuarine and Marine Fish, Chronic

Propachlor may be expected to reach estuarine or marine environments due to its use on corn and sorghum, the need for an estuarine / marine fish early-life stage study is deferred until the results of an acute study, 72-3a, is submitted.

Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine / marine invertebrates is required for propachlor due to similar end-product use patterns as stated above. Since no studies were submitted, guidelines 72-3b and 72-3c are not fulfilled.

Estuarine and Marine Invertebrates, Chronic

Because propachlor is registered on crops associated with marine environemnts, studies are required to assess the toxicity to estuarine / marine fish and invertebrates. No data have been submitted, therefore guideline 72-3 is not fulfilled.

(7) Nontarget Plants (Terrestrial, Semi-Aquatic, and Aquatic)

Terrestrial, semi-aquatic, and aquatic plants may be exposed to propachlor from runoff, spray drift or volatilization. An analysis of the results indicate that for a single application, plant acute high risk and endangered species levels of concern are exceeded at a registered single application rate equal to or greater than 3.0 lbs ai/A. However, even though some LOC triggers were exceeded, the overall toxicological spectrum for propachlor suggests that it is slightly to moderately toxic to most nontarget organisms. The Agency has no reported incidences of adverse impacts on nontarget organisms from the use of propachlor.

The potential chronic (long-term) exposure of nontarget organisms to propachlor is reduced because it is not persistent under most conditions and because the pesticide is only applied once in a growing season. However, based on the weight of toxicological evidence for propachlor, the Agency believes such effects are unlikely.

(8) Surface Water

Under certain conditions, propachlor and/or its metabolites may have a potential for runoff into surface water for several days to weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface 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 overlaying tile drainage systems that drain to surface water.

(9) Ground Water

Propachlor and /or its metabolites are known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

E. Occupational and Residential Labeling Rationale/Risk Mitigation

1. Restricted Use Classification

There are no residential uses of propachlor.

2. Reference Dose Exceedance

Current propachlor usage does not exceed the reference dose limits established by available data and current tolerances. All %RfD's are less than 1% which is much less than the Agency's level of concern of 100%.

3. Occupational Labeling Rationale

Occupational and Residential Labeling Rationale/Risk Mitigation

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.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

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 (chemical resistant apron, chemical resistant gloves and chemical resistant footwear) 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

For the mixing and loading of liquids for groundboom application, the Agency is requiring workers to use a closed mixing/loading system and to wear chemical resistant gloves. This requirement is based upon a combination of both the carcinogenic and the intermediate-term risk assessment for propachlor which requires the use of a closed system and the use of chemical resistant gloves to achieve an acceptable Margin of Exposure.

For the application of liquids, the Agency has determined that acceptable MOE's can not be achieved for applicators without requiring the use of a closed cab system. These mitigation measures are based upon both the carcinogenic and the intermediate term exposure scenarios for the application of liquids. The Agency does not differentiate between crops for mitigation purposes. Therefore, the most protective personal protective equipment and engineering controls are chosen for both the mixing/loading and the application to all commodities.

For the loading of granulars for tractor-drawn spreader application, based upon both the carcinogenic and intermediate term exposure assessment, a double layer of clothing and chemical resistant gloves are required to achieve an acceptable Margin of Exposure. Instead of requiring mixers and loaders to wear a coverall garment over their long sleeved shirt and long pants, EPA requires mixer/loaders to wear 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.

For the application of granulars with a tractor-drawn spreader, applicators must wear additional personal protective equipment consisting of a double layer of clothing, and chemical resistant gloves. EPA has found the Margins of Exposure to be above an acceptable limit when these PPE are used.

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 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. Accordingly, EPA determined that the restricted-entry interval for all occupational-use products that contain propachlor are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 48 hours. The basis for this decision is that propachlor is categorized as toxicity category I (severe) for eye irritation potential and also is classified as a strong dermal sensitizer.

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.

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.

3. Since propachlor is classified as category I (severe irritant) for eye irritation potential, protective eyewear is required.

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. EPA has determined that double notification is not required for propachlor end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of propachlor (classified as toxicity category I for eye irritation potential and is a strong skin sensitizer), EPA is establishing entry restrictions for all nonWPS occupational uses of propachlor end-use products. Entry will be restricted until sprays have dried and dusts have settled. For specific requirements, refer to Section V of this document.

4. Endangered Species Statement

Currently, the Agency is developing a program ("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.

5. Other Labeling Requirements

Label amendments are required to support uses of propachlor on sorghum and crops which can be rotated. Grazing and feeding restrictions are no longer considered to be practical by the Agency, and must be removed from any labels allowing application to sorghum. Registered labels must be amended to include a statement restricting crop rotation to either corn or sorghum, the only food

crops for which there are registered uses of propachlor, pending submission of limited field rotational crop studies.

6. 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.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of propachlor for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required to be conducted on the generic active ingredient:

- 72-3 (a) Acute toxicity to estuarine and marine fish
- 72-3 (b) Acute toxicity to estuarine and marine mollusks
- 72-3 (c) Acute toxicity to esturarine and marine shrimp
- 123-2 Aquatic Plant Growth on four of the five required species is still outstanding: *Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and freshwater diatom.*
- 162-1 Aerobic Soil Metabolism. An additional study is needed to better characterize the rate of dissipation of propachlor.
- 162-4 Aerobic Aquatic Metabolism
- 165-1 Limited Field rotational Crop

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 55 at the end of this section. Any use instructions on current labels that conflict with those listed below should be removed.

All products distributed or sold by **registrants and distributors (supplemental registrants)** should bear labeling that is consistent with this notice within **26 months from receipt date** of this RED and all products distributed or sold by **persons other than registrants or supplemental registrants** after **50 months** should bear correct labeling.

3. End-Use Products

For **sole-active-ingredient** end-use products that contain propachlor:

- Revise the product labeling to adopt the handler personal protective equipment/engineering control requirements set forth in this section.
- Revise the product labeling to adopt the entry restrictions set forth in this section.

For **multiple-active-ingredient** end-use products that contain propachlor:

- Compare the handler personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.
- 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 this section to the entry restrictions on the current labeling.
- 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".)

a. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA requires the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria 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.

b. 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 easily be read and understood by the average person likely to use or 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 necessary

information to answer four major questions regarding the use of the pesticide. These four questions are:

(1) Why is the pesticide being used? For what pest(s) or problems?
(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 graphic symbols whenever possible, to clarify the written label.

National Pesticide Telecommunications Network (NPTN) Hotline Number

All propachlor labels must refer consumers to the NPTN number for additional information. This reference must bear the labeling contained in the table at the end of this section.

First Aid (Statement of Practical Traetment)

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.

4. Required Labeling Changes Summary Table

Table 55 summarizes the labeling requirements being imposed by this RED for propachlor products. Any use instructions on current labels that conflict with the following table should be removed.

Table 55:	Summary Table of Labeling Changes for Propachlor Products	
Description	**Required Labeling**	**Placement**
	Manufacturing Use	Directions for Use.
One of these statements may be added to a label to allow reformation 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 uses: corn (field, silage and/or hybrid), sorghum and onions."	
	"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 Statement	"This product is toxic to fish, aquatic invertebrates and birds. 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	
	All End Use Products Intended for Occupational Use (Not marketed for use by homeowners)	
Information regarding product	"For more information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticides Communications Network at 1-800-858-7378."	Hazards to Humans and Domestic animals

Description	Required Labeling	Placement
Sensitizer Precautionary Statements	"This product may cause skin sensitization reactions in some people."	Precautionary Statements under Hazards to Humans and Domestic animals
Mixing/Loading PPE for all Liquid formulation products	"Personal Protective Equipment (PPE) Mixers and Loaders must wear: -Chemical resistant gloves"	Precautionary Statements Hazards to Humans and Domestic Animals
Mixing and Loading PPE for all Granular products.	"Personal Protective Equipment (PPE) Mixers and Loaders must wear: -Long-sleeved shirt, long pants -Chemical-resistant apron -Chemical-resistant footwear -Chemical resistant gloves"	
Applicator PPE for all granular products	"Applicators applying this product must wear: -Coveralls or a double layer of clothing -Chemical resistant gloves"	Precautionary Statements Hazards to Humans and Domestic Animals (Directly below mixing and loading PPE)
Engineering Controls for application of all liquid formulation products	"Engineering Controls The Application of this product requires use of a closed cab system."	Precautionary Statements Hazards To Humans and Domestic Animals (Directly following PPE)

Description	Required Labeling	Placement
Engineering Controls for mixing/loading of all liquid formulation products	"Engineering Controls Mixing and loading of this product requires use of a closed system."	Precautionary Statements Hazards To Humans and Domestic Animals (Directly following PPE)
User Safety Requirements	"User Safety Requirements" "Follow the 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." Discard clothing or other materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements Hazards To Humans and Domestic Animals (Directly following PPE)
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 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 (Directly following Engineering Controls) (Must be placed in a box)
Environmental Hazards	"This product is toxic to fish, aquatic invertebrates, and wildlife." "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 "Do not contaminate water when disposing of equipment washwater or rinsate."	Precautionary Statements under Environmental Hazards

Description	Required Labeling	Placement
Environmental Hazards for Granular Products	In addition to the above statements, add: “Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas.”	Precautionary Statements under Environmental Hazards
Ground Water Advisory Statement	“This chemical and/or its metabolites are known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.”	Precautionary Statements under Environmental Hazards
Surface Water Advisory Statement	“Under some conditions, this chemical and/or its metabolites may have a potential for runoff into surface water for several days to weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, areas with in-field canals or ditches that drain into surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain to surface waters.”	Precautionary Statements under Environmental Hazards
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.”	Direction for Use.
Restricted-Entry Interval (Required by Supplement Three of PR Notice 93-7)	A 48-hour Restricted-Entry Interval is required for the uses within the scope of the WPS on all propachlor products.	Directions For Use (Agricultural Use Requirements Box)
Personal Protective Equipment Required for Early Entry	“The PPE required for early entry is: -protective eyewear"	
Rotational Crop Restriction	“Rotation to crops not specified on this label is prohibited.” “Only for crops for which there are registered propachlor uses may be rotated to treated fields.”	Directions For Use

Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93--11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (4 0 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices. The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

Effluent Discharge Labeling Statements

Refer to table 55 for labeling requirements for effluent discharge.

5. Spray Drift Labeling

The current labels indicate that propachlor may be applied by ground boom spray equipment but not aerially. No propachlor-specific ground spray drift studies were reviewed. The Spray Drift Task Force (SDTF), a consortium of pesticide registrants, has completed and submitted to the Agency a series of studies which are intended to characterize spray drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. EPA is 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 propachlor to nontarget organisms is warranted.

B. Tolerance Revocation and Import Tolerances

It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. As a result, any parties interested in supporting the tolerance/regulation for import purposes in the absence of a registered U.S. use should notify EPA as soon as possible.

In responding, EPA will provide detailed information on the outstanding data requirements for these tolerances and/or regulations. The Agency will consider commitments made to generate data to support such tolerances/regulations and the timeliness of data submissions in its assessment of whether the tolerances/regulations should be retained. Persons interested in establishing a new tolerance for import purposes only, or retaining a current tolerance for import purposes following cancellation of the related use, must submit a petition along with the appropriate fees and supporting data.

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 propachlor 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.

VI. APPENDICES

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. Dose /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED													
FOOD/FEED USES													
CORN			Use Group: TERRESTRIAL FEED CROP										
Soil band treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h			C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h			C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS			C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)
	G	NA	2.8 lb A	*	NS	NS	NS	NS	NS	48 h			C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil broadcast treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h			C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h			C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS			C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED											
FOOD/FEED USES 2(con't)											
CORN (con't)			Use Group: TERRESTRIAL FEED CROP (con't)								
Soil broadcast treatment, Preemergence, Spreader	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil incorporated treatment by irrigation, Preemergence, Soil incorporation equipment	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C94, CAC, CAL, CAT, CAU, CWE, CWH
CORN (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP								
Soil band treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h	C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS	C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)
	G	NA	2.8 lb A	*	NS	NS	NS	NS	NS	48 h	C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil broadcast treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h	C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED											
FOOD/FEED USES (con't)											
CORN (UNSPECIFIED) (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS	C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)
Soil broadcast treatment, Preemergence, Spreader	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil incorporated treatment by irrigation, Preemergence, Soil incorporation equipment	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C94, CAC, CAL, CAT, CAU, CWE, CWH
CORN, FIELD			Use Group: TERRESTRIAL FOOD+FEED CROP								
Soil band treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h	C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS	48 h	C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS	C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED											
FOOD/FEED USES (con't)											
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	G	NA	2.8 lb A	*	NS	NS	NS	NS	NS 48 h		C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil broadcast treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS 48 h		C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	6 lb A 5.5 lb A 5 lb A	F M C	NS	NS	NS	NS	NS 48 h		C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS NS		C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21)
Soil broadcast treatment, Preemergence, Spreader	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS 48 h		C94, CAC, CAL, CAT, CAU, CWE, CWH
Soil incorporated treatment by irrigation, Preemergence, Soil incorporation equipment	G	NA	6 lb A 5.4 lb A 5 lb A	F M C	NS	NS	NS	NS	NS 48 h		C94, CAC, CAL, CAT, CAU, CWE, CWH
ONION			Use Group: TERRESTRIAL FOOD CROP								
Spray, At planting, Ground	FlC	NA	UC	*	NS	NS	NS	NS	NS 48 h OR		C14, CAU, GE6, GF3, GI9
	FlC	NA	UC	*	NS	NS	NS	NS	NS 48 h WA		C14, CAU, GE6, GF3, GI9
Spray, Preemergence, Ground	FlC	NA	UC	*	NS	NS	NS	NS	NS 48 h OR		C14, CAU, GE6, GF3, GI9

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED											
FOOD/FEED USES (con't)											
ONION (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)								
	FlC	NA	UC	*	NS	NS	NS	NS	NS	48 h	WA	C14, CAU, GE6, GF3, GI9
SORGHUM			Use Group: TERRESTRIAL FOOD+FEED CROP								
Soil band treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h		C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	5 lb A	*	NS	NS	NS	NS	NS	48 h		C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS		C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
	G	NA	2.34 lb A	*	NS	NS	NS	NS	NS	48 h		C94, CAC, CAL, CAT, CAU, CWE, CWH, GI8
Soil broadcast treatment, Preemergence, Ground	DF	NA	4.1366 lb A 3.367 lb A 3.006 lb A	F M C	NS	NS	NS	NS	NS	48 h		C13, C46, C94, CAG, CAL, CAT, CAU, CSA(15), CWE, G01(21), G08(21), GI8
	FlC	NA	5 lb A	*	NS	NS	NS	NS	NS	48 h		C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES CONSIDERED FOR THE RED													
FOOD/FEED USES (con't)													
SORGHUM (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	FlC	NA	4.125 lb A 3.375 lb A 3 lb A	F M C	NS	NS	NS	NS	NS	NS			C13, C46, CAG, CAL, CAT, CAU, CSA(15), CWE, CWG, CWH, G01(21), G08(21), GI8
Soil broadcast treatment, Preemergence, Spreader	G	NA	5 lb A	*	NS	NS	NS	NS	NS	48 h			C94, CAC, CAL, CAT, CAU, CWE, CWH, GI8

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Re-Entry Intv. : Reentry Intervals
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

DF : WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
FlC : FLOWABLE CONCENTRATE
G : GRANULAR

ABBREVIATIONS

AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 0177 [Propachlor] Chemical 019101 [Propachlor]

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APPLICATION RATE (CONT.)
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C13 : Groundwater restriction.
C14 : Grown for seed only.
C46 : Do not apply through any type of irrigation system.
C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.
CAC : Keep out of lakes, streams, and ponds.
CAG : Do not apply where runoff is likely to occur.
CAL : Do not contaminate water, food or feed.
CAT : Do not place in locations accessible to children, pets or domestic animals.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
CSA : Do not apply when wind velocity is _____ mph or greater.
CWE : This product is highly toxic to birds, fish, and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed.
CWG : Drift and runoff may be hazardous to aquatic organisms in neighboring areas.
CWH : Do not contaminate water by cleaning of equipment or diposal of equipment wash waters.
G01 : __ day(s) pregrazing interval.
G08 : __ day(s) prefeeding interval of threshings or stubble to livestock.
GE6 : Do not feed treated screenings or hay to livestock.
GF3 : Do not feed treated grasses, seed or seed screenings to livestock.
GI8 : Do not graze or feed forage, silage or fodder (stubble) from treated fields to dairy animals.
GI9 : Do not graze or feed fodder and forage to livestock.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
OR : Oregon
WA : Washington

REENTRY INTERVAL ABBREVIATIONS
h : hour(s)

SELECTED PRODUCTS
000524-00152 000524-00310 000524-00328 000524-00331 000524-00423 019713-00163 OR95002200
WA95003100

UNIT DESCRIPTIONS
A : acre
lb : pound

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case propachlor covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to propachlor 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.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Propachlor

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	all	00104354
61-2A	**Start. Mat. & Mnfg. Process**	all	00104354,00152340
61-2B	**Formation of Impurities**	all	00104354,00152340
62-1	**Preliminary Analysis**	all	00152340
62-2	**Certification of limits**	all	00152340
62-3	**Analytical Method**	all	00104310,00104354,00152340
63-2	**Color**	all	00104354,00152340
63-3	**Physical State**	all	00104354,00152340
63-4	**Odor**	all	00152340
63-5	**Melting Point**	all	00104354,00152340
63-6	**Boiling Point**	all	NOT REQUIRED
63-7	**Density**	all	00104354,00152340
63-8	**Solubility**	all	00104354,00152340
63-9	**Vapor Pressure**	all	00104354,00152340
63-10	**Dissociation Constant**	all	00104354
63-11	**Octanol/Water Partition**	all	00152340
63-12	**pH**	all	00152340
63-13	**Stability**	all	00104354,00152340
63-14	**Oxidizing/Reducing Action**	all	00152340

Data Supporting Guideline Requirements for the Reregistration of Propachlor

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	all	00152340
63-16	**Explodability**	all	00152340
63-17	**Storage stability**	all	00152340
63-20	**Corrosion characteristics**	all	00152340,42828101
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	all	00132907
71-2A	**Avian Dietary - Quail**	all	00132908,00104335
71-2B	**Avian Dietary - Duck**	all	00134006, 00108087
71-3	**Wild Mammal Toxicity**	all	00104350
72-1A	**Fish Toxicity Bluegill**	all	00104337
72-1B	**Fish Toxicity Bluegill - TEP**	all	00041337
72-1C	**Fish Toxicity Rainbow Trout**	all	00041335
72-1D	**Fish Toxicity Rainbow Trout- TEP**	all	00041338
72-2A	**Invertebrate Toxicity**	all	40098001,00041336
72-2B	**Invertebrate Toxicity - TEP**	all	40098001, 00041339
72-3B	**Estuarine/Marine Toxicity - Mollusk**	all	DATA GAP
72-3C	**Estuarine/Marine Toxicity - Shrimp**	all	DATA GAP
123-1A	**Seed Germination/Seedling Emergence**	all	42485705

Data Supporting Guideline Requirements for the Reregistration of Propachlor

REQUIREMENT		USE PATTERN	CITATION(S)
123-1B	**Vegetative Vigor**	all	42485705, 42485706
123-2	**Aquatic Plant Growth**	all	42584703, DATA GAP
141-1	**Honey Bee Acute Contact**	all	43147706
141-2	**Honey Bee Residue on Foliage**	all	43147705
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	all	00104350
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	all	00104351
81-3	**Acute Inhalation Toxicity - Rat**	all	41986001
81-4	**Primary Eye Irritation - Rabbit**	all	00151787
81-5	**Primary Dermal Irritation - Rabbit**	all	00104353
81-6	**Dermal Sensitization - Guinea Pig**	all	00151789
81-8	**Acute Neurotoxicity - Rat**	all	42584702
82-1A	**90-Day Feeding - Rodent**	all	00152151, 00152865
82-1B	**90-Day Feeding - Non-rodent**	all	00157852
82-2	**21-Day Dermal - Rabbit/Rat**	all	44590801
82-5A	**90-Day Neurotoxicity - Rat**	all	43575701
83-1A	**Chronic Feeding Toxicity - Rodent**	all	44168301
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	all	40081601
83-2B	**Oncogenicity - Mouse**	all	40162501, 40248701, 44069801, 44158001
83-3A	**Developmental Toxicity - Rat**	all	00115136

Data Supporting Guideline Requirements for the Reregistration of Propachlor

REQUIREMENT		USE PATTERN	CITATION(S)
83-3B	**Developmental Toxicity - Rabbit**	all	00150936,40113801 40398301,42348002 42584701
83-4	**2-Generation Reproduction - Rat**	all	00157168,43226701 43862901
83-5	**Chronic Toxicity/ Carcinogenicity - Rat**	all	40473101, 44168301
84-2A	**Gene Mutation (Ames Test)**	all	00153939
84-2B	**Structural Chromosomal Aberration**	all	00153940, 40312701
84-4	**Other Genotoxic Effects**	all	00144512,40068401 43221801
85-1	**General Metabolism**	all	00157496, 00157497, 00157498 00157499, 00157500, 00157501 00157502, 00157503, 00157504 00157505, 00157506, 00157507
86-1	**Domestic Animal Safety**	all	WAIVED
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	all	42485701
161-2	**Photodegradation - Water**	all	42527401
161-3	**Photodegradation - Soil**	all	42527401
162-1	**Aerobic Soil Metabolism**	all	42962502, DATA GAP
162-2	**Anaerobic Soil Metabolism**	all	42962503
164-4	**Aerobic Aquatic Metabolism**	all	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Propachlor

REQUIREMENT		USE PATTERN	CITATION(S)
163-1	**Leaching/Adsorption/Desorption**	all	00087854, 42485702, 42485703, 42485704
164-1	**Terrestrial Field Dissipation**	all	43525101
165-1	**Confined Rotational Crop**	all	DATA GAP
165-4	**Bioaccumulation in Fish**	all	42711801
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	all	43028601
171-4B	**Nature of Residue - Livestock**	all	40123101
171-4C	**Residue Analytical Method - Plants**	all	43251801, 43028601, 43028602
171-4D	**Residue Analytical Method - Animal**	all	43251801, 43028602
171-4E	**Storage Stability**	all	42121302, 4211303
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	all	40584001
171-4K	**Crop Field Trials**	all	40085301, 40081701, 40081702

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.

BIBLIOGRAPHY

MRID	CITATION

00041335 Thompson, C.M.; Forbis, A.D.; Oleson, F.B.; et al. (1980) Acute Toxicity of Propachlor (AB-79-080) to Rainbow Trout (,~Salmo ,~gairdneri~,): Static Acute Bioassay Report # 24019. (Unpublished study including letter dated Nov 13, 1979 from F.B. Oleson to W.D. Carpenter, received Sep 19, 1980 under 524-310; prepared in cooperation with Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:099654-B)

00041336 Thompson, C.M.; Forbis, A.D.; Fuhremann, T.W. (1980) Acute Toxicity of Propachlor (AB-79-250) to~Daphnia magna~,: Static Acute Bioassay Report 24708. (Unpublished study including letter dated Jan 8, 1980 from T.W. Fuhremann to W.D. Carpenter, received Sep 19, 1980 under 524-310; prepared in cooperation with Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:099654-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 with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Citation Forms

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: Attachment 3 (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

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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. 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, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms 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 and the Requirements Status and Registrant's Response Forms (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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), 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.

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 (Attachment 3), 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. You must also complete a Data Call-In Response Form 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, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. 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 and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form 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. 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, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form 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 and Requirements Status and Registrant's Response Form (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, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. 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 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. 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. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form 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.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form 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 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 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 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 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 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 EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 6. 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 and a Requirements Status and Registrant's Response Form 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:

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.

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.

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.

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.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form 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 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 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.

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 and the Requirements Status and Registrant's Response Form, 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. 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, 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.

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. 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:

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 and a Requirements Status and Registrant’s Response Form.

   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.

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, 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 (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), 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 need be submitted.

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
6 - Confidential Statement of Formula, Cost Share and Data Citation Forms

PROPACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing propachlor.

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 propachlor. 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 Response Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this propachlor Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for propachlor are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on propachlor 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 propachlor 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 Mark Perry at (703) 305-9548.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Mark Perry
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: **propachlor**

PROPACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing propachlor.

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 propachlor. 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 Response Form (Attachment 3), (4) a list of registrants receiving this DCI (Attachment 5), and (5) the Cost Share and Data Compensation Forms in replying to this propachlor Generic Data Call In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for propachlor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on propachlor are needed. These data are needed to fully complete the reregistration of all eligible propachlor 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 Anne Mitchell at (703) 308-8068.

All responses to this Notice for the generic data requirements should be submitted to:

Anne Mitchell, Chemical Review Manager
Reregistration Branch 3
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **propachlor**

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" 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." 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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
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.

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.

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
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 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.

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.**

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 initialled 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.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" 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.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

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.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

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
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.

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.

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" for generic data.

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" 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 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

EPA'S BATCHING OF PROPACHLOR PRODUCTS FOR MEETING ACUTE 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 propachlor 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.

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.

Six active products were found which contain propachlor as the active ingredient. Two products have been placed in batch 1 while the other four products were placed in the "no batch" category based on the active/inert ingredients and formulation type. The following bridging schemes may also be employed:

- EPA Reg. No. 524-152 may be supported by any category III/IV acute mammalian toxicity data performed with technical propachlor.

- EPA Reg. No. 524-331 may be supported by category III/IV acute oral, acute dermal and acute inhalation toxicity data performed with technical propachlor.

At a minimum, the acute data cited or submitted to support these products should meet the acceptance criteria included in this document. In addition, the acute toxicity values for propachlor [also included in this document] are for informational purposes only, and the data supporting these values may or may not meet the acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient	Formulation Type
	524-310	96.5	Solid
	19713-163	93.0	Solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	524-152	20.0	Solid
	524-328	31.5	Liquid
	524-331	42.0	Liquid
	524-423	48.1	Solid

Attachment 5 List of All Registrants Sent This Data Call-In (insert) Notice

THIS PAGE MUST BE REMOVED PRIOR TO PRINTING AND REPLACED WITH THE REGISTRANT LISTING PRODUCED FROM THE DCI MODULE.

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

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, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	**Company Number**

Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	**Date of Offer**

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	**Date**

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date			EPA Reg No./File Symbol		Page of
Applicant's/Registrant's Name & Address			Product		
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
Signature			Name and Title		Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	EPA Reg No./File Symbol	Page of
Applicant's/Registrant's Name & Address	Product	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

Signature	Name and Title	Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

The following is a list of available documents for propachlor that my 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 Anne Mitchell at (703)-308-8068.

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 propachlor.

The following documents are part of the Administrative Record for propachlor 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