



Reregistration Eligibility Decision (RED)

Triclopyr



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 triclopyr which includes the active ingredients triclopyr acid, triclopyr triethylamine salt and triclopyr butoxyethyl ester. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1997, contains the Agency's evaluation of the data base of these chemicals, its conclusions regarding 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 triclopyr 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 the 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 C.P. Moran at (703) 308-8590. Address any questions on required generic data to the Special Review and Reregistration Division representative Dean Monos at (703) 308-8074.

Sincerely yours,

Lois A. Rossi, 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).

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

TRICLOPYR

LIST B

CASE 2710

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD ₁₀	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

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

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

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 Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

Triclopyr is a systemic herbicide used on rice, rangeland and pasture, rights-of-way, forestry and turf, including home lawns, for control of broadleaf weeds and woody plants. There are currently 12 registered products containing triclopyr butoxyethyl ester (BEE) and 24 products containing triclopyr triethylamine salt (TEA).

The Agency has reassessed triclopyr food and feed tolerances under the standards of FQPA and determined that, based on available information, there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to triclopyr residues under the use conditions and limitations specified in this RED. EPA evaluated only dietary and drinking water exposure in the aggregate assessment, since other non-occupational exposures to triclopyr are expected to be minimal. Calculations using existing triclopyr tolerances result in a TMRC which represents <1% of the RfD for the general population and < 3% of the RfD for children less than one year old, considering food only.

Chronic aggregate dietary risk, including both food and an upper bound estimate of triclopyr residues in drinking water, accounted for 16% of the RfD for females (13+ years) and 49% of the RfD for children ages 1 to 6.

The acute dietary (food only) MOE for the most sensitive subgroup, females of child bearing age, is 2500. The acute aggregate dietary MOE for the sub-population of greatest concern (pregnant females 13+) including food and drinking water is 1250.

Both triclopyr and the insecticide chlorpyrifos produce the metabolite 3,5,6-trichloro-2-pyridinol (TCP). EPA conducted an assessment of the aggregate contributions of TCP from known dietary sources using upper bound exposure estimates. The assessment indicates that, even using exaggerated exposure assumptions, neither the acute nor the chronic aggregate dietary risk from the metabolite TCP is of concern for the general population or any sub group.

In reaching the determination of safety for infants and children, the Agency found that the toxicity data base for triclopyr is complete, based on current requirements, and that the effects observed in pre- and post-natal studies do not indicate any increased sensitivity of infants or children to triclopyr. Therefore, the Agency has determined that an uncertainty factor of 100 (10 for interspecies differences in response, and 10 for intraspecies differences) is adequately protective of infants and children. Thus, for risk assessment purposes the chronic dietary (RfD) calculations include a factor of 100, and the acute dietary risk assessments assume that a margin of exposure (MOE) of 100 or greater is acceptable.

The Agency has determined that certain administrative revisions to the tolerance expression and the tolerance level for "grass, hay" are required. Label amendments are required to clarify grazing restrictions and limit maximum application rates on pasture and rangeland and other sites where cattle can be grazed.

To reduce risks to wildlife and water resources, EPA is requiring reductions in application rates, a ground water advisory statement, and implementation of spray drift management practices. To protect handlers, the Agency is establishing restricted entry intervals, and specifying personal protective equipment.

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

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 the 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 ingredients 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 use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. In addition, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of triclopyr 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 triclopyr, 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 triclopyr. Section V discusses the reregistration requirements for triclopyr. 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(s) are covered by this Reregistration Eligibility Decision:

- ! **Common Name:** Triclopyr
- ! **Chemical Name:** Triclopyr[[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid]
- ! **Chemical Family:** Pyridinyloxyacetic acids
- ! **CAS Registry Number:** 55335-06-3
- ! **OPP Chemical Code:** 116001
- ! **Empirical Formula:** $C_7H_4Cl_3NO_3$
- ! **Basic Manufacturer:** DowElanco

-
- ! **Common Name:** Triclopyr triethylamine salt (TEA)
 - ! **CAS Registry Number:** 57213-69-1
 - ! **OPP Chemical Code:** 116002
 - ! **Empirical Formula:** $C_{13}H_{19}Cl_3N_2O_3$
 - ! **Basic Manufacturer:** DowElanco

-
- ! **Common Name:** Triclopyr butoxyethyl ester (BEE)
 - ! **CAS Registry Number:** 64700-56-7
 - ! **OPP Chemical Code:** 116004
 - ! **Empirical Formula:** $C_{13}H_{16}Cl_3NO_4$
 - ! **Basic Manufacturer:** DowElanco

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of **active ingredients 116002 and 116004** is in Appendix A. Currently, there are no registered uses for triclopyr acid (active ingredient 116001).

For 116002 and 116004:

Type of Pesticide: broad leaf herbicide

Use Sites: rice, pasture and rangeland, rights-of-way, forestry, and turf, including home lawns and gardens.

Target Pests: broad leaf weeds & brush

Formulation Types Registered:

1. Triclopyr triethylamine salt (TEA)
soluble concentrate, emulsifiable concentrate, liquid (pressurized and ready to use), granular, formulation intermediate, wettable powder, pelleted
2. Triclopyr butoxyethyl ester (BEE)
formulation intermediate, emulsifiable concentrate, ready-to-use liquid

Method and Rates of Application:

Methods

Broadcast

Ground (GB)

Aerial (AA)

High Volume Foliar (HVF)

Low Volume Foliar (LVF)

Individual Plant Treatment (IPT)

Equipment -airplane, helicopter, ground spreader, backpack sprayers

Rates -Please refer to Appendix A for rates of application.

Timing - Not specified

C. Estimated Usage of Pesticide

The table below summarizes the best estimates available for the pesticide uses of triclopyr TEA and BEE products. (Note: Data were unavailable to differentiate between usage for BEE and TEA for the sites listed below). 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.

Table 1: Average Annual Triclopyr Usage by Site 1987-1995

Site	Acres grown X 1000	Acres treated X 1000	Percentage Treated	Pounds of AI Applied X 1000
Pasture	120,387	327	0.5%	292
Woodland	62,825	126	0.2%	100
Rights of way	3,200	75	2.3%	85
Rice	2,921	165	5.6%	77
Railroad	1,060	90	8.5%	45
Commercial/ residential use	32,700	75	0.2%	40
Other (lots and farmsteads)	24,815	66	0.3%	34
Totals				673

Source: US EPA proprietary sources, USDA, CA EPA, and National Center for Food and Agriculture Policy.

D. Data Requirements

The Agency required the registrants to submit studies as specified in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. See Appendix B for a complete list of data that support the reregistration of triclopyr.

E. Regulatory History

Triclopyr TEA was first registered on May 8, 1979 as a herbicide on non-crop areas and in forestry use for the control of broadleaf weeds and woody plants. Triclopyr BEE was subsequently registered on June 11, 1980 for use on the same sites. Both formulations were

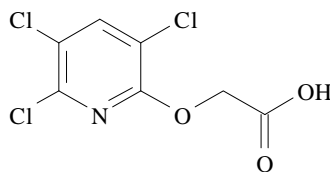
registered for use on turf sites in 1984. On April 16, 1985, triclopyr BEE was registered for use on rangeland and permanent grass pastures. Most recently (January 11, 1995), triclopyr TEA was registered for use on rice to control many hard to control broadleaf weed species. An application for registration on aquatic use sites is pending. A Data Call-In Notice (DCI) was issued in August 1991 requiring the submission of product chemistry, residue chemistry, ecological and environmental fate data for both TEA and BEE and toxicological data for TEA.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

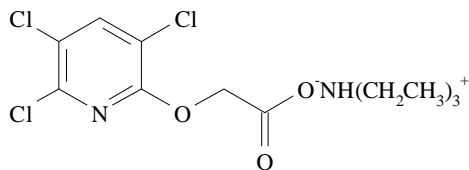
Triclopyr Acid (no active products)

Empirical Formula: $C_7H_4Cl_3NO_3$
 Molecular Weight: 256.5
 CAS Registry No.: 55335-06-3
 Shaughnessy No.: 116001



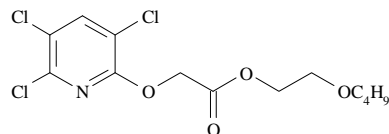
Triclopyr Triethylamine salt (TEA)

Empirical Formula: $C_{13}H_{19}Cl_3N_2O_3$
 Molecular Weight: 371.7
 CAS Registry No.: 57213-69-1
 Shaughnessy No.: 116002



Triclopyr Butoxyethyl Ester (BEE)

Empirical Formula: $C_{13}H_{16}Cl_3NO_4$
 Molecular Weight: 356.6
 CAS Registry No.: 64700-56-7
 Shaughnessy No.: 116004



Triclopyr is a fluffy colorless solid with a melting point of ~148-150 C. Triclopyr TEA is a grayish white granular solid with a melting point of 111-117 C. Triclopyr TEA is slightly soluble in toluene (2.7 g/100 mL) and ethyl acetate (2.1 g/100 mL), and practically insoluble in hexane (<0.02 g/100 mL). Triclopyr BEE is an oil-soluble liquid which is soluble in acetonitrile, methanol, and n-hexane at ≥70% by weight. Triclopyr TEA is slightly soluble in toluene (~2.7 g/100 mL) and ethyl acetate (~2.1 g/100 mL), and practically insoluble in hexane (<0.02 g/100 mL). Triclopyr BEE is an oil-soluble liquid which is soluble in acetonitrile, methanol, and n-hexane at ≥70% by weight.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on triclopyr is adequate and will support reregistration eligibility.

a. Acute Toxicity

Acceptable studies for acute inhalation, primary eye irritation, primary dermal irritation, and dermal sensitization were not available for the technical grade of triclopyr free acid. However, based on the bioequivalency of the three forms of triclopyr, acute studies with the TEA or BEE form of triclopyr are acceptable in place of the free acid. The acceptable acute toxicity studies conducted with triclopyr indicate low toxicity with the exception of eye irritation, which was conducted with triclopyr TEA.

The Acute Oral LD₅₀ in male rats with the free acid form of triclopyr was 729 mg/kg and 630 mg/kg in female rats, with a Toxicity Category of III (MRID # 00031940). The same toxicity categories were obtained from testing of the TEA and BEE forms of triclopyr (except eye irritation). The Acute Dermal LD₅₀ in rabbits using either the free acid, TEA, or BEE form of triclopyr was > 2000 mg/kg (Toxicity Category III; MRID #'s 00056009 [free acid], 41443302 [TEA], and 40557005 [BEE]). The Acute Inhalation LC₅₀ in male and female rats was > 2.6 mg/L using the TEA form, and >4.8 mg/L using the BEE form with a Toxicity Category of IV (MRID #'s 41443303 [TEA] and 40557006 [BEE]).

In a primary eye irritation study in rabbits (MRID # 41443304) triclopyr TEA was found to be corrosive, with corneal involvement present through day 21 post-dose. Using the BEE form, only minimal eye irritation was observed (MRID # 40557007). Both triclopyr TEA and triclopyr BEE were found to be non-irritating to the skin of white rabbits (MRID #'s 41443305 [TEA] and 40557008 [BEE]). In dermal sensitization studies in guinea pigs (MRID #'s 41443306 [TEA] and 40557009 [BEE]), sensitization was observed with both forms of triclopyr. It is noted that acute toxicity studies conducted with triclopyr BEE (MRID #'s 40557004 through 40557009) showed the same results as those for triclopyr TEA, with the exception of the primary eye irritation, in which only minimal eye irritation was observed with triclopyr BEE.

Table 2: Acute Toxicity Categories-Triclopyr Acid (Technical Grade)

Guideline No.	Study Type	Test Material	Results	Toxicity Category
81-1	Acute Oral	Triclopyr tech.	LD ₅₀ = 729 mg/kg (M); 630 mg/kg (F)	III
81-2	Acute Dermal	Triclopyr tech.	LD ₅₀ >2000 mg/kg	III
81-3	Acute Inhalation	Triclopyr acid TGAI study not available		
81-4	Primary Eye Irritation	Triclopyr acid TGAI study not available		
81-5	Primary Dermal Irritation	Triclopyr acid TGAI study not available		
81-6	Dermal Sensitization	Triclopyr acid TGAI study not available		

Table 3: Acute Toxicity Categories Triclopyr TEA (44.4% a.i.)

Guideline No.	Study Type	Results	Toxicity Category
81-1	Acute Oral	LD ₅₀ = 1847 mg/kg (M+F)	III
81-2	Acute Dermal	LD ₅₀ >2000 mg/kg	III
81-3	Acute Inhalation	LC ₅₀ >2.6 mg/L	IV
81-4	Primary Eye Irritation	Corrosive	I
81-5	Primary Dermal Irritation	Not irritating	IV
81-6	Dermal Sensitization	sensitizer	N/A

Table 4: Acute Toxicity Categories-Triclopyr BEE (97.1% a.i.)

Guideline No.	Study Type	Results	Toxicity Category
81-1	Acute Oral	LD ₅₀ = 803 mg/kg (M+F)	III
81-2	Acute Dermal	LD ₅₀ >2000 mg/kg	III
81-3	Acute Inhalation	LC ₅₀ >4.8 mg/L	IV
81-4	Primary Eye Irritation	Minimally irritating	III
81-5	Primary Dermal Irritation	Not irritating	IV
81-6	Dermal Sensitization	sensitizer	N/A

Bioequivalency

It is noted that toxicology studies conducted with triclopyr have been performed using either the free acid, triethylamine salt (TEA), or the butoxyethyl ester (BEE) form of triclopyr. The issue of bioequivalency for the purpose of testing the three chemical forms of triclopyr (acid, triethylamine salt, and butoxyethyl ester) was addressed by the registrant conducting special studies with the triethylamine and butoxyethyl ester forms of triclopyr. These studies, which included data on comparative disposition, plasma half-life, tissue distribution, hydrolytic cleavage under physiological and environmental conditions for triclopyr triethylamine salt and triclopyr butoxyethyl ester (MRID #'s 43394101, 42444701, and 42437901) were found to adequately address the issue of bioequivalency. In addition, subchronic toxicity studies conducted with each form supported the pharmacokinetic data in demonstrating bioequivalence. Therefore, with the exception of the acute toxicity database (where differences in Toxicity Categories have been noted above), studies conducted with any one form of triclopyr have been used to support the toxicology database as a whole.

b. Subchronic Toxicity

In a subchronic oral toxicity study (MRID # 00150378), male and female Fischer 344 rats received dietary concentrations of triclopyr technical (98% a.i.) at doses of 0, 5, 20, 50, or 250 mg/kg/day for 13 weeks. Degeneration of the proximal tubules of the kidneys of male and female rats was observed in increased incidence at 20 mg/kg/day and above for both sexes. Absolute and relative kidney weight was significantly increased in male rats at the 50 mg/kg/day dose, while relative kidney weight was increased in male and female rats at 250 mg/kg/day. **The systemic NOEL was 5 mg/kg/day, and the systemic LOEL was 20 mg/kg/day, based on histopathological changes in the kidneys of male and female rats.** This study is **acceptable** and satisfies the guideline requirement [OPPTS 870.3100; OPP §82-1(a)] for a subchronic toxicity study in rodents.

In a 183-day toxicity study in dogs (MRID # 00071794), male and female beagle dogs received dietary doses of triclopyr technical at 0, 0.1, 0.5, or 2.5 mg/kg/day for 183 days (males) or 184 days (females). There were no significant treatment related effects on body weight, food consumption, hematology, or clinical chemistry in male or female dogs. A decreased rate of phenolsulfonhalein (PSP) excretion was observed in dogs receiving 2.5 mg/kg/day triclopyr. This effect was later determined to be a result of competition between triclopyr and PSP for renal excretion, and was not considered toxicologically relevant (HED document # 008593). **The Systemic NOEL was determined to be ≥ 2.5 mg/kg/day, and the Systemic LOEL was determined to be > 2.5 mg/kg/day in both sexes.** This study is **supplementary** and does not satisfy the guideline requirement for a subchronic toxicity study [OPPTS 870.3151; OPP §82-1(b)] in non-rodents.

c. Chronic Toxicity

In a 228-day toxicity study in dogs (MRID # 00071793), male and female beagle dogs 14 months of age were administered Triclopyr technical in the diet at doses of 0, 5, 10, or 20 mg/kg/day for 228 days. At the 20 mg/kg/day dose level, body weight gain in male dogs for weeks 0-13 (days 0-95) was decreased 4% below control, and weight gain for the entire study period was decreased 5% below control. For female dogs, body weight gain for weeks 0-13 (days 0-95) was decreased 27% vs control, and was decreased 20% vs control for the entire study period. The decrease in body weight gain for female dogs was matched by a similar decrease in food consumption for both the 0-95 day time period and the 0-228 day time period (21% decrease). Food consumption in male dogs was decreased by 12% for the 0-95 day time period and by 2% for the entire study period. In male and female dogs, hematological parameters at 172 days showed decreased packed cell volume (21% in both sexes), decreased hemoglobin (24% in males, 26% in females), and decreased red cell count (16% in males, 20% in females). These decreases were still observed in both sexes at day 225 of the study. Elevations in alkaline phosphatase (approximately 2-fold in males and females), SGPT (approximately 2-fold in males, 2-6-fold in females), and SGOT (approximately 2-fold) were observed in male and female dogs at the 20 mg/kg/day dose on days 167, 176, and study termination. Absolute and relative liver weight in male dogs was increased 18% and 26% respectively at the 20 mg/kg/day dose, while relative kidney weight was increased 12% in females at the 20 mg/kg/day dose. Increased incidence of microscopic liver pathology was noted at 20 mg/kg/day in both male and female dogs (focal aggregates of reticuloendothelial cells containing brown pigment surrounded by degenerate appearing hepatocytes; focal areas of eosinophilic granulomatous inflammation).

Based on the decreased body weight gain in male dogs, decreased hematological parameters in male dogs, changes in clinical chemistry in male and female dogs, and liver histopathology in male and female dogs, the **LOEL is 20 mg/kg/day for male and female dogs. The NOEL is 10 mg/kg/day.** This study is classified as **acceptable** and, in conjunction with MRID 41200301 (1-year toxicity study in dogs), satisfies the guideline requirement for a chronic oral toxicity study in dogs [OPPTS 870.4100; OPP §83-1b].

In a one year dietary toxicity study (MRID # 41200301), Triclopyr technical (98.9% a.i.) was administered to male and female beagle dogs (4/sex/dose) at doses of 0, 0.5, 2.5, or 5.0 mg/kg/day. There were no significant effects of treatment on mortality, clinical signs, body weight, or food consumption in male and female dogs at any dose level tested. Increases in urea nitrogen and creatinine were observed at all dose levels tested. At 12 months, urea nitrogen was increased by 12, 37, and 68% in male dogs and by 11, 17, and 35% in female dogs. Creatinine was increased by 30 and 40% in male dogs at the 2.5 and 5.0 mg/kg/day dose levels, and increased by 55 and 44% in female dogs at 12 months. The changes in clinical chemistry at 2.5 and 5.0 mg/kg/day, while statistically significant, do not represent a toxic response to the test chemical, but a physiologic response of the dog, based on the limited ability of the dog to excrete organic acids at higher plasma concentrations. The lack of histopathologic alterations in the kidneys of both sexes is supportive of this conclusion.

The Systemic NOEL is \geq 5.0 mg/kg/day for both sexes; the Systemic LOEL is $>$ 5.0 mg/kg/day.

This study is classified as supplementary and does not satisfy the guideline requirement for a chronic toxicity study in non-rodents. However, in conjunction with MRID # 00071793, these two studies fulfill the guideline requirement (OPPTS 870.4100; OPP §83-1) for a chronic toxicity study in non-rodents. Therefore, the guideline requirement is satisfied.

d. Chronic Toxicity/Carcinogenicity

In a chronic toxicity/carcinogenicity study, triclopyr technical (98.0% a.i.) was administered in the diet to groups of male and female ICR mice at dose levels of 0, 50 ppm (**5.55 mg/kg/day** in males, **5.09 mg/kg/day** in females), 250 ppm (**28.6 mg/kg/day** in males, **26.5 mg/kg/day** in females) or 1250 ppm (**143 mg/kg/day** in males, **135 mg/kg/day** in females). Main test groups of 60 mice/sex/dose received diets for 95 weeks, while satellite groups of 40 mice/sex/dose were used for sacrifice of 10 mice/sex/dose at 26 and 52 weeks of treatment at the same dose levels (MRID # 40356601).

At 143 mg/kg/day in males and 135 mg/kg/day in females, body weight gain in male mice was decreased 10.1% vs control for the 22-month study period, while body weight gain in female mice was decreased 10.6% for the 22-month study period. An increase in the incidence of thymic enlargement was observed in high dose male and female mice, but there were no data on thymus weight.

At 26 weeks of treatment, plasma BUN in male mice at 143 mg/kg/day was increased 25% vs control, while water consumption was increased an average of 25% at this dose beginning at week 13 of the study. In female mice, kidney weight was increased 10-16% at the 135 mg/kg/day dose, while urinary protein at the 135 mg/kg/day dose was also increased at week 52. However, there were no pathology data to support a true toxic effect on the kidney of males or females. Liver weight in male mice was increased by 17% at the 143 mg/kg/day dose level at week 26 only.

For the chronic toxicity portion of this study, the LOEL was tentatively considered to be 143 mg/kg/day in male mice and 135 mg/kg/day in female mice, based on the decreased body weight gain. The NOEL is considered to be 28.6 mg/kg/day in male mice, and 26.5 mg/kg/day in female mice.

There were no compound-related tumors observed in male mice. Female mice had a significant increasing trend in mammary gland adenocarcinomas at $p < 0.05$. There were no significant differences in the pair-wise comparisons of the dosed groups with the controls.

Support for the selection of the high dose in the chronic toxicity/ carcinogenicity study in mice is taken from a 28-day range-finding study in which male and female mice were exposed to

triclopyr technical in the diet at dose levels of 0, 200, 400, 800, 1600, or 3200 ppm (nominal doses of 30, 60, 120, 240, and 480 mg/kg/day). At the 480 mg/kg/day dose, male mice were observed with single cell necrosis of the liver, significant increases in alkaline phosphatase, AST, and ALT, and enlargement of the liver with dark color. Centrilobular swelling and degeneration of hepatocytes were observed in a dose-dependent fashion at 120 mg/kg/day and above in male mice, along with mild increases in liver enzymes at 240 mg/kg/day. (MRID # 40356601).

In a chronic toxicity/carcinogenicity study, triclopyr technical (98.0% a.i.) was administered in the diet to groups of male and female Fischer 344 rats (50/sex/dose) for 2 years at dose levels of 0, 3, 12, or 36 mg/kg/day. Additional groups of 10 rats/sex/dose received dietary exposure to triclopyr at the same dose levels for 6 and 12 months (MRID # 40107701).

Mortality in treated groups of male rats was lower than that in the control group. Cumulative mortality was stated as 50%, 32%, 26%, and 36% for control, low, mid, and high dose level male rats. Red cell count, hemoglobin, and hematocrit in male rats was numerically decreased at the high dose at 6, 12, and 24 months. Statistical significance was achieved for the decrease in red cells at 12 months, for hemoglobin at 6 months, and for hematocrit at 6 and 12 months. Absolute and relative kidney weight was significantly increased (10-17%) at the high dose in male rats, with an apparent dose-related trend at 12 months. Female rats showed an increased incidence of pigmentation of the proximal descending tubule at all dose levels compared to control, while male rats in the 6-month satellite group showed increased incidence of proximal tubule degeneration at the 12 and 36 mg/kg/day dose levels compared to control.

For chronic toxicity, the NOEL was 12 mg/kg/day for males and 36 mg/kg/day for females. The LOEL for males was 36 mg/kg/day based on marginal increases in proximal tubular degeneration at 6 months.

There were no significant increasing trends in tumor incidence for male rats. There were significant pair-wise differences vs control at 3 and 12 mg/kg triclopyr in the incidence of adrenal gland benign pheochromocytomas and benign and/or malignant pheochromocytomas combined, and in the incidence of skin fibromas at 3 and 12 mg/kg, with $p < 0.05$ for all comparisons except the incidence of pheochromocytoma (benign + combined) at 12 mg/kg, ($p < 0.01$ vs control).

Female rats had significant increasing trends in mammary gland adenocarcinomas at $p < 0.05$ and in adenomas and/or adenocarcinomas combined at $p < 0.01$. There was a significant difference in the pair-wise comparison of the 36 mg/kg/day dose group with the controls for mammary gland adenomas and/or adenocarcinomas combined at $p < 0.05$. There were no significant pair-wise comparisons or trends for the incidence of adrenal gland pheochromocytoma in female rats.

e. Developmental Toxicity

A developmental toxicity study was conducted with the butoxyethyl ester (BEE) form of triclopyr in rabbits. In this study, (MRID# 43217601; HED document # 011107), triclopyr BEE technical (96.9% a.i.) was administered at doses of 0, 10, 30, and 100 mg/kg/day to pregnant New Zealand White rabbits on gestation days 6 through 18 inclusive.

Maternal toxicity was evident at the 100 mg/kg dose level in the form of mortality during test article administration. In addition, cesarean section data showed a decrease in total number of live fetuses, live fetuses/dam, an increase in post-implantation loss ($p < 0.05$), and an increase in total fetal deaths at 100 mg/kg/day. The maternal LEL = 100 mg/kg based on the increase in mortality at this dose. The maternal NOEL = 30 mg/kg.

Developmental toxicity was evident at the 100 mg/kg dose level in the form of a decreased total number of live fetuses, increased total fetal deaths, increased fetal incidence of additional sternbral centers, increased incidence of reduced ossification of the digital bones, and an increase in the percentage of fetuses with 13 ribs. The developmental LOEL = 100 mg/kg, based on the cesarean section observations of decreased total live fetuses and increased total fetal deaths, as well as the observations of increased fetal and/or litter incidence of skeletal anomalies and variants observed at this dose. The developmental NOEL = 30 mg/kg.

A developmental toxicity study was conducted with the triethylamine (TEA) salt of triclopyr in rats. In this study, (MRID 43217602; HED document # 011107), triclopyr TEA technical (46.5% a.i.) was administered to timed-mated Crl:CD(SD) BR VAF/Plus female rats on gestation days 6 through 15 inclusive. Doses used were 0, 30, 100, or 300 mg/kg, corrected for compound purity.

Maternal toxicity was suggested at the 300 mg/kg dose level from the increased incidence of clinical signs (salivation) and mortality (1 death). Cesarean section data showed no toxicologically significant alterations in any parameter in treated rats vs control. The maternal LOEL = 300 mg/kg based on the increased incidence of salivation and mortality. The maternal NOEL = 100 mg/kg.

Developmental toxicity was evident in this study at the 300 mg/kg dose level, and included decreased mean fetal body weight, increased fetal and litter incidence of skeletal anomalies (reduced ossification of one or more cranial centers and sacrocaudal vertebral arches) and an increase in the number of fetuses with unossified sternbrae. The developmental LOEL = 300 mg/kg based on decreased mean fetal weight, increased fetal and litter incidence of skeletal anomalies, and increased fetal incidence of unossified sternbrae. The developmental NOEL = 100 mg/kg.

A developmental toxicity study was conducted with the TEA salt of triclopyr in rabbits. In this study, (MRID 43217603), triclopyr TEA technical (46.5% a.i.) was administered to pregnant New Zealand White rabbits on gestation days 6 through 18 inclusive. Doses used were 0, 10, 30, or 100 mg/kg, corrected for compound purity. Insemination was by natural means.

Maternal toxicity was evident at the 100 mg/kg dose level in the form of increased mortality during test article administration, decreased body weight gain and food efficiency, and increased liver and kidney weights. Based on these observations, The maternal LOEL = 100 mg/kg based on the decreased body weight gain, decreased food efficiency, and increased liver and kidney weight. The maternal NOEL = 30 mg/kg.

Developmental toxicity was evident at the 100 mg/kg dose level in the form of reduced number of litters, reduced number of corpora lutea, reduced number of total implants, reduced total live fetuses, increased embryonic deaths and deaths/dam, and increased pre-implantation loss. The developmental LOEL = 100 mg/kg based on the decreased number of live implants, decreased live fetuses, and increased embryonic deaths. The developmental NOEL = 30 mg/kg.

f. Reproductive Toxicity

In a two-generation reproductive toxicity study with the acid form of triclopyr, (MRID # 435457-01; HED document # 011882), male and female Sprague-Dawley rats (30 males/dose; 30 females/dose), received triclopyr technical (99.4% a.i.) in the diet at nominal doses of 0, 5, 25, or 250 mg/kg/day (P₁ high dose males received 100 mg/kg/day for the first 29 days of the study). The P₁ generation received triclopyr in the diet for 10 weeks prior to breeding. After 10 weeks, the P₁ animals were mated on a 1:1 ratio. Following weaning of the F₁ litters, 30 males and 30 females from each treatment group were selected as parents for the next generation. Selected F₁ rats were treated for 12 weeks with technical triclopyr and then bred to produce the F₂ litter.

Significant systemic toxicity was observed at the 250 mg/kg/day dose level in the P₁ and P₂ parental rats, and included decreased body weight and weight gain during pre-mating for males and females, and decreased body weight and weight gain during gestation for P₁ and P₂ females. For the P₁ parental rats at 250 mg/kg/day, decreased mean litter size was observed as was mean pup weight on days 1, 4, and 21 post-partum; an increased incidence of pup deaths was also observed at 250 mg/kg/day. In the P₂ parental generation, decreased number of litters, mean litter size, number of live pups, and pup weight were significantly decreased at 250 mg/kg/day. In the F₁ and F₂ litters, survival at 250 mg/kg/day was significantly decreased vs. control, as was mean litter size and body weight and weight gain.

At the 25 mg/kg/day dose, an increased incidence of degeneration of the proximal tubules of the kidney was observed in the P₁ and P₂ parental rats of both sexes. The increase at 25 mg/kg/day was dose-related.

The Parental Systemic Toxicity NOEL = 5 mg/kg/day (males and females); the Parental Systemic Toxicity LOEL = 25 mg/kg/day, based on increased incidence of proximal tubular degeneration in male and female P₁ and P₂ rats.

The Reproductive/Systemic Toxicity NOEL = 25 mg/kg/day; the Reproductive / Systemic Toxicity LOEL = 250 mg/kg/day, based on decreased litter size, decreased body weight and weight gain, and decreased survival in the F1 and F2 litters.

g. Mutagenicity

The mutagenic potential of triclopyr has been adequately evaluated in a range of assays in vivo and in vitro. These assays demonstrate triclopyr is non-mutagenic in vivo and in vitro. These studies are summarized below.

In an Ames mutagenicity assay (MRID # 41732202), triclopyr BEE (98% a.i.) was found to be non-mutagenic in the four tester strains of *Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537) in the presence or absence of metabolic activation at the concentrations tested (50-5000 $\mu\text{g}/\text{plate}$). In an in vivo micronucleus assay in mice, triclopyr BEE was not clastogenic in the mouse micronucleus test at the dose levels tested (0, 60, 200, or 600 mg/kg) [EPA MRID # 41747101]. In an unscheduled DNA synthesis (UDS) assay in rat hepatocytes, triclopyr BEE did not cause DNA damage or inducible repair in the rat hepatocyte unscheduled DNA synthesis assay at the concentrations of test article used in this study (1.0-1000 $\mu\text{g}/\text{ml}$) [EPA MRID # 41747102].

The mutagenicity of triclopyr technical acid was evaluated in a recombination repair system using rec- assay mutant (H17) and recombination repair deficient mutant (M45) of B. subtilis and was also tested in the reverse mutation assay using *Salmonella* strains TA 98 and TA 100. Concentrations used in the rec- assay were 20-2000 $\mu\text{g}/\text{disk}$, and 1-5000 $\mu\text{g}/\text{plate}$ in the reversion assay.

In the rec- assay, there was no evidence of growth inhibition for the repair competent or repair deficient bacterial strains employed. In the reversion assay, there were no increases in number of revertant colonies in the absence or presence of liver S-9 for the strains of *Salmonella* employed [EPA MRID # 00038408]. In an Ames assay, the mutagenic potential of triclopyr technical (98.0% a.i.) was assessed in *Salmonella* tester strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100 in the absence and presence of metabolic activation (rat liver S-9). Concentrations used were 10, 1000, and 10,000 $\mu\text{g}/\text{plate}$. There were no significant increases in the number of revertant colonies for any of the tester strains employed in this study in the absence or presence of metabolic activation [EPA MRID # 00031939].

In a dominant lethal assay, groups of 30 male mice were maintained on dietary levels of triclopyr of 0, 3, 15, or 70 mg/kg/day for 9 consecutive weeks. Immediately following treatment, each male was mated to 4 untreated mature virgin females for 7 consecutive days. Two of the 4 females in each group were held for the dominant lethal study. Ten days following the last day of cohabitation, females were sacrificed and uteri examined for live and dead implants. There were no significant toxic effects observed in treated male mice, and no significant differences in body weights. There were no significant effects on fertility index, average number of implantations,

average number of resorptions, average resorption rate, or average litter size in any of the untreated female mice bred to treated males at all dose levels of triclopyr tested [EPA MRID # 00028996].

In a dominant lethal assay, triclopyr at doses of 0.7, 7.0, and 70.0 mg/kg, triethylene melamine (positive control) at a dose of 0.3 mg/kg, or negative control (corn oil plus saline) were administered orally to separate groups of 10 male Sprague-Dawley rats. Males were sequentially mated to 2 untreated females per week for 7 weeks. Females were killed at 14±2 days after mating. There was an apparent decrease in mating index during week 1 at the 7 and 70 mg/kg dose levels. A trend towards an increase in average number of resorptions was evident at the 7 and 70 mg/kg dose levels, but statistical significance (by t-test) was apparent only at week 4 at the 7 mg/kg dose, week 5 at the 70 mg/kg dose, and week 7 at the 70 mg/kg dose. Statistical comparison by t-test is not appropriate in this type of experimental design. The proportion of females with one or more dead implantations also appeared increased at the 70 mg/kg dose level over negative control. The ratio of dead implants to total implants was also increased at the 7 and 70 mg/kg dose levels, but the increases were numeric in most of the cases [EPA MRID # 00057087].

In an unscheduled DNA synthesis assay, rat primary hepatocyte cultures were exposed to triclopyr at concentrations of 5×10^{-3} , 1.56×10^{-3} , 5×10^{-4} , 5×10^{-5} , 1.56×10^{-5} , and 5×10^{-6} M for 18 hours in the presence of $10 \mu\text{Ci/ml}$ ^3H -thymidine. Triclopyr failed to induce any increase in net nuclear grain counts at any of the concentrations tested. Hepatocyte toxicity was demonstrated at 5×10^{-3} triclopyr (OPP 84-2; MRID # 40055702).

In a host-mediated assay, triclopyr was administered orally at doses of 0, 0.7, 7.0, or 70.0 mg/kg to groups of 10 male ICR random bred mice. In the acute test, the indicator organism (*Salmonella* TA-1530, *Salmonella* G-46, and *Saccharomyces* D-3) was injected i.p. immediately after administration of test material. In subacute tests, the indicator organism was injected 1/2 hour after the last of 5 administrations of test material (5 times at 24 hour intervals). Intraperitoneal fluid was recovered, diluted, and plated for determination of revertants and recombinants. Triclopyr in this study induced no significant increases over negative control in mutant or recombinant frequencies at the dose levels used in this study [EPA MRID #00057085].

In an in vivo cytogenetics study in rats, triclopyr was administered to groups of 5 Sprague-Dawley rats as single doses of 0.7, 7.0 , and 70.0 mg/kg, or for 5 days to additional groups of 5 rats at the same dose levels. In the single dose study, rats were sacrificed at 6, 24, and 48 hours after test administration, while in the repeated dose study, rats were sacrificed at 5 days after the last dose. Examination of bone marrow cells for chromosomal aberrations from the acute and subacute groups showed no cells with chromosomal aberrations [EPA MRID # 00057086].

h. Metabolism

Disposition and metabolism of ^{14}C -triclopyr acid (98.8% a.i.) was investigated in male and female rats at a low oral dose (3 mg/kg), repeated low oral doses (3 mg/kg x 14 days), and a high dose (60 mg/kg) [MRID # 41353001]. Comparison of disposition data in intravenously dosed and orally dosed rats demonstrated that triclopyr was well absorbed after oral administration. Excretion was relatively rapid at the low dose, with a majority of radioactivity eliminated in the urine by 24 hours. At 60 mg/kg, urinary elimination of ^{14}C -triclopyr derived radioactivity was decreased in male and female rats from 0-12 hours, due to apparent saturation of renal elimination mechanisms. Fecal elimination of ^{14}C -triclopyr derived radioactivity was a minor route of excretion, as was elimination via exhaled air. No significant effect was observed on metabolism or disposition of ^{14}C -triclopyr from repeated low oral dosing in male or female rats.

Residual ^{14}C -triclopyr derived radioactivity was minimal in all dose groups, but measurable levels of tissue radioactivity were detected in perirenal fat of both sexes and ovaries of female rats which apparently increased with dose. Thus, potential accumulation of ^{14}C -triclopyr derived radioactivity may occur in these tissues.

Urinary metabolites of ^{14}C -triclopyr were isolated and identified by HPLC and GC/MS. Unmetabolized parent chemical represented >90% of urinary radioactivity, with the remainder accounted for by the metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), and possible glucuronide and/or sulfate conjugates of 3,5,6-TCP.

Plasma elimination following intravenous administration of ^{14}C -triclopyr was consistent with a one-compartment model with an elimination half-life of 3.6hr and zero-order kinetics from 0-12 hours at the 60 mg/kg dose. Kinetic parameters were optimized using SIMUSOLV modeling software. The model showed an apparent “flip-flop” phenomenon, in which absorption at the 3 mg/kg dose was rate limiting in elimination of ^{14}C -triclopyr derived radioactivity, but renal excretion was saturated and therefore limiting in elimination of ^{14}C -triclopyr derived radioactivity at the 60 mg/kg dose.

2. Dose Response Assessment

a. Reference Dose

The Reference Dose (RfD) for triclopyr was established at 0.05 mg/kg/day, based upon the 2-generation reproduction toxicity study in rats (83-4, MRID # 43545701) with a NOEL of 5.0 mg/kg/day, the lowest dose tested (RfD Peer Review Report of triclopyr, January 12, 1995). At the next dose level (25 mg/kg/day), an increased incidence of proximal tubular degeneration of the kidneys was observed in P1 and P2 parental rats in this study. An uncertainty factor of 10 for interspecies differences in response and an uncertainty factor of 10 for intraspecies differences in response was applied.

b. Dermal Absorption

Percent absorbed: Blood levels and urinary excretion of triclopyr were monitored in five human volunteers who received 3.7 mg/kg triclopyr BEE on the forearm for a duration of 8 hours. Dermal absorption from this study was calculated to be 1.65% of the applied dose (Carmichael, N.G. Et al. (1989): Oral and Dermal Pharmacokinetics of triclopyr in Human Volunteers. Human Toxicol. **8**, 431-437.).

Also, in a rabbit dermal absorption study (Accession # 259680, comprised of MRID # 00153805 and 00153807), 1.5% of an applied dose of triclopyr acid (2 g/kg) was reported to be absorbed through the skin. This study was graded core supplementary.

c. Other Toxicological Endpoints

The Agency's Toxicology Endpoint Selection Committee (TESC) considered the available toxicology data for triclopyr at a meeting held on June 11, 1996. Toxicity endpoints and dose levels of concern were identified for use in risk assessment corresponding to acute dietary exposure, short and intermediate term occupational or residential exposure, and chronic occupational or residential exposure.

Acute Dietary

To estimate acute dietary risk a dose level of 30 mg/kg/day was identified as the NOEL from a developmental toxicity study in rabbits (MRID # 43217601) administered triclopyr BEE. This NOEL was selected, based on toxicity noted at the next highest dose of 100 mg/kg in which decreased number of live fetuses, increased total fetal deaths, increased resorptions, increased fetal incidence of additional sternebral centers, increased litter incidence of reduced ossification of digital bones, and increased percentage of fetuses with 13 ribs was reported.

Short and Intermediate Term Occupational and Residential

In a 21-day dermal toxicity study in rabbits (MRID #42212701), signs of systemic toxicity were limited to decreased alkaline phosphatase in male and female rabbits at 1000 mg/kg/day and increased absolute and relative liver weight in male rabbits at 1000 mg/kg/day. These effects were considered marginal and not of toxicological significance.

The TESC recommended that risk assessments for **short- and intermediate** term exposure were not required since the NOEL was \geq 1000 mg/kg/day (limit dose) in a 21-day dermal toxicity study in rabbits.

Chronic Occupational and Residential (non-cancer)

For **chronic** (non-cancer) occupational or residential exposure risk assessment, a dose level of 5 mg/kg/day was identified as the NOEL for parental/systemic toxicity in a 2-generation reproduction toxicity study in rats (MRID # 43545701). This NOEL was selected based on the

observation of proximal tubular degeneration of the kidneys of P1 and P2 parental rats at the next highest dose of 25 mg/kg/day.

Inhalation Exposure (any time period)

In an acute inhalation toxicity study (MRID # 41443303), the acute inhalation LC₅₀ was determined to be >2.6 mg/L in male and female rats, with a Toxicity Category of IV. The Committee concluded that a separate risk assessment for this route of exposure is not required based on the placement of triclopyr in Toxicity Category IV. Significant toxicity resulting from inhalation exposure is not expected.

d. Cancer Classification

As a result of the August 9, 1995 meeting of the Agency's Carcinogenicity Peer Review Committee (CPRC), triclopyr was classified as a Group D chemical (not classifiable as to human carcinogenicity). This decision was based on increases in mammary tumors in both the female rat and mouse, and adrenal pheochromocytomas in the male rat, which the majority of the CPRC believed to be only marginal. Overall the majority of the CPRC felt that the animal evidence was marginal (not entirely negative, but yet not convincing). Therefore, the consensus of the CPRC was to classify triclopyr as a Group D chemical, based on what was considered only marginal response and the absence of additional support from structural analogs or genotoxicity.

3. Exposure Assessment

a. Dietary Exposure From Food

The only current direct food use of triclopyr is on rice. However, triclopyr is also used on a variety of sites, such as pasture and rangeland, where livestock graze. Thus, dietary exposure is also possible from meat, milk and other animal products. The following is a summary of the nature and magnitude of residues likely to be found in or on various food commodities, and the methods used to detect those residues.

Plant Metabolism

The qualitative nature of the residue is adequately understood based on two studies with [¹⁴C]triclopyr on grasses. The terminal residue of concern in/on grass and rice commodities is triclopyr *per se*. No significant levels of the metabolites 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine were detected.

Animal Metabolism

Adequate goat and poultry metabolism studies are available. The major residue in milk, poultry and eggs is triclopyr *per se*. No significant levels of 2-methoxy-3,5,6-trichloropyridine

were detected in any animal commodities. The metabolite 3,5,6-trichloro-2-pyridinol (TCP) comprised a significant portion of the residue in meat, meat byproducts and fat but no significant levels were detectable in any other animal commodities.

Residue Analytical Methods - Plants and Animals

Enforcement methods: Adequate methodology is available for the enforcement of tolerances for triclopyr residues of concern in/on grass, rice and animal commodities. Two GC methods (Methods I and II) with electron capture detection (GC/ECD) are available for the determination of triclopyr residues of concern. Method I (Dow Chemical Co. Method ACR 77.4) separately determines residues of triclopyr, 3,5,6-trichloro-2-pyridinol, and 2-methoxy-3,5,6-trichloropyridine and has successfully undergone an Agency method validation using grass commodities. The detection limits of Method I ranged from 0.01 to 1 ppm depending on the compound being analyzed. Method II (Dow Chemical Co. Method ACR 77.2) determines residues of triclopyr *per se* in milk, cream, and tissues, and has detection limits of 0.05-0.1 ppm. Another GC/ECD method is available for the enforcement of tolerances of 3,5,6-trichloro-2-pyridinol in meat; the method is listed in PAM Volume II as Method V under chlorpyrifos. All of the above PAM II methods use diazomethane as a derivatizing agent and benzene as a solvent. The Phase 4 Review stated that the registrant planned to revise the methods to substitute less hazardous reagents.

Data collection methods: Samples of grass commodities collected in response to reregistration requirements were analyzed using Methods ACR 84.2 for triclopyr and ACR 84.4 for 3,5,6-trichloro-2-pyridinol. These methods differ slightly from the enforcement methods listed in PAM Volume II, involving extraction with sodium hydroxide:water:methanol, but eliminating the use of diazomethane and benzene. Method ACR 84.2 has undergone successful radiovalidation using grass samples from the plant metabolism study.

Multiresidue methods: The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix I) indicates that triclopyr is completely recovered (>80%) using multiresidue method PAM Vol. I Section 402. Data pertaining to multiresidue methods testing of triclopyr and its metabolites through Protocols B, C, D, and E have been submitted and forwarded to FDA.

Storage Stability

The available storage stability data are adequate for the reregistration of triclopyr uses on grasses and rice. Analytical data used in support of reregistration of triclopyr are supported by available storage stability data.

Magnitude of the Residue in Plants

Adequate field trial data were submitted in conjunction with PP#1F03991 to support the reregistration of the use on rice.

For the reregistration of triclopyr uses on grasses, the requirements for magnitude of the residue in plants are fulfilled pending compliance by the registrant in adopting the required label amendments and tolerance revisions.

Adequate field trial data, reflecting postemergence use of the registered 4 lb ae/gal BEE EC and 3 lb ae/gal TEA SC/L formulations of triclopyr, are available from the original grass tolerance petition (PP#1F2508); these data are sufficient to reassess the established tolerances for an application rate of 1 lb ae/A. The existing tolerances of 500 ppm for triclopyr residues of concern in/on grass forage and hay were established based on a maximum allowable rate of 1 lb ae/A. Adequate field trial data are not available in support of application rates higher than 1 lb ae/A.

The available data indicate that the residues of triclopyr in/on grass forage collected immediately (0-day) following a single postemergence application of a representative BEE or TEA triclopyr formulation at 1 lb ae/A are below 500 ppm. For comparison purposes, limited field trial data reflecting application rates up to 9 lb ae/A indicate that the maximum residues of triclopyr in/on grass forage collected immediately (0-day posttreatment) were as high as 3333 ppm. The reassessed tolerance on grass forage will remain at 500 ppm; however, all labels must be amended to reflect the available data that support this tolerance, i.e., the maximum yearly use rate must be restricted to 1 lb ae/A.

For grass hay, the Agency allows the establishment of reasonable PHIs for the cutting of the hay. The available data indicate that the residues of triclopyr in/on grass hay collected 14 days following a single postemergence application of a representative BEE or TEA triclopyr formulation at 1 lb ae/A will not exceed 200 ppm. The reassessed tolerance for grass hay is 200 ppm based on a 14-day PHI.

The Agency currently considers feeding restrictions and preharvest intervals (PHIs) to be impractical for forage of pasture and rangeland grasses (Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, issued 9/95). Grass forage tolerances are set using 0-day posttreatment interval data. However, reasonable PHIs are allowed for the cutting of grass hay. Accordingly, label amendments are required to remove all PHIs for grass forage and to specify a 14-day PHI for grass hay, based on the reassessed tolerance for this commodity. The established 3-day preslaughter interval must be retained. A restriction against grazing lactating dairy animals until the next growing season, as currently found on triclopyr labels, must be retained. All other grazing restrictions are unacceptable and must be removed from triclopyr labels.

Magnitude of the Residue in Processed Food/Feed

There are no processed food/feed items associated with triclopyr uses on grasses; therefore, no grass processing data are required. An acceptable rice processing study has been submitted and evaluated in conjunction with a petition (PP#1F03991) for the establishment of triclopyr tolerances for rice and poultry commodities. This study indicates that neither triclopyr nor its TCP and 2-methoxy-3,5,6-trichloropyridine metabolites concentrate in rice processed fractions.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The requirements for studies depicting magnitude of the residue in milk, fat, meat, and meat byproducts of livestock animals are fulfilled pending compliance by the registrant in adapting the recommended label amendments and tolerance revisions/proposals. An acceptable poultry feeding study has been submitted and evaluated in conjunction with a petition (PP#1F03991) for the establishment of triclopyr tolerances for rice and poultry commodities.

An acceptable dairy cattle feeding study has been submitted/evaluated in support of the original grass tolerance petition (PP#1F2508). The existing tolerances for milk (0.01 ppm), for fat, meat, meat byproducts except liver and kidney (0.05 ppm), and for liver and kidney (0.5 ppm) are supported by these data provided the labels are amended to comply with the requirements noted in this document.

Nature and Magnitude of the Residue in Water, Fish and Irrigated Crops

Triclopyr is registered for use on rice. It is not currently registered for any other direct use on water. However, data are currently under review in connection with PP#1F03935 for the registration of triclopyr on aquatic sites.

Magnitude of the Residue in Food-Handling Establishments

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

Confined/Field Rotational Crops

An adequate confined rotational crop study has been submitted to support the triclopyr use on rice, including a rotational crop plant-back restriction of 4 months for all crops other than rice. No further data are required in support of the existing label restriction.

b. Dietary Exposure from Drinking Water

Triclopyr is not currently regulated under the Safe Drinking Water Act (SDWA), therefore, a Maximum Contaminant Level (MCL) is not established. Public water supply systems are not required to sample and analyze for triclopyr.

A temporary Allowable Residue Level in Drinking Water (ARLDW) in potable water of 0.5 ppm was established under PP#6G3306 will expire in March of 1998. Petitions for the registration of triclopyr in aquatic areas (PP#1F03935) are currently pending.

In accordance with the FQPA, the Agency is in the process of developing procedures and methods for determining whether or not a pesticide is likely to be found in drinking water and, if so, at what levels. Currently, in order to assess the potential for drinking water exposure from both ground water and surface water sources, EPA first considers the physical properties and environmental fate of the chemical and its metabolites. EPA also considers available monitoring data and surface water modeling estimates. A more detailed discussion of the environmental fate, monitoring data, and modeling results available for triclopyr can be found in section III.C.2.(c) of this document.

It should be noted that the modeling results presented in section III.C are worst-case estimates of residues of triclopyr in pond waters, not in raw or finished drinking water. The chronic (average) and acute (maximum) exposures calculated below using the model estimates are not expected to occur in drinking water, but are presented as upper bound estimates for residues of triclopyr in surface waters for use in calculating chronic and acute exposures and risks. Limited surface water monitoring data presented in section III.C indicate that triclopyr residues may occur in streams treated by direct injection at concentrations greater than the model estimates, but that these residues then dissipate rapidly within hours or a few days to non-detectable levels. All other monitoring data indicate that residues of triclopyr are orders of magnitude less than that predicted by the model.

The chronic exposure for adult females and children calculated for use in the chronic drinking water risk equation is based on the predicted concentration of triclopyr residues in surface water 56 days after application of triclopyr at the maximum rate. The GENEEC model estimates that 233 ppb of triclopyr may occur.

$$\text{Chronic exposure (adult female)} = 0.233 \text{ mg/L} \times 2 \text{ L/day} \div 60 \text{ kg} = 7.7 \times 10^{-3} \text{ mg/kg/day}$$

$$\text{Chronic exposure (child)} = 0.233 \text{ mg/L} \times 1 \text{ L} \div 10 \text{ kg} = 2.3 \times 10^{-2} \text{ mg/kg/day}$$

The acute exposure for adult females and children calculated for use in the acute drinking water risk equation is based on the maximum (peak) concentration of triclopyr residues from the maximum application rate as estimated using the GENEEC model (364 ppb).

Acute exposure (adult female) = $0.364 \text{ mg/kg/day} \times 2 \text{ L/day} \div 60 \text{ kg} = 1.2 \times 10^{-2} \text{ mg/kg/day}$

Acute exposure (children) = $0.364 \text{ mg/kg/day} \times 1 \text{ L/day} \div 10 \text{ kg} = 3.6 \times 10^{-2} \text{ mg/kg/day}$

c. Occupational Exposure

Summary of Use Patterns and Formulations

Triclopyr is formulated as an emulsifiable concentrate (16.5 to 61.6 percent active ingredient), a liquid-ready to use (13.6 to 16.7 percent active ingredient), a soluble concentrate (32.5 percent active ingredient), a granular (0.18 to 0.5 percent active ingredient), and as a manufacturing product/liquid (61.6 to 96 percent active ingredient). Triclopyr is used for bark treatment, broadcast, direct spray, foliar treatment, soil treatment, spot treatment and stump treatment. The following equipment is used to apply triclopyr: fixed-wing aircraft, helicopter, hand held spray wand, hand held sprayer, knapsack sprayer, low volume sprayer, power sprayer, groundboom sprayer, foliar pump sprayer, handgun, and hose-end sprayer.

Triclopyr is applied to the following sites: terrestrial feed crops (e.g., pastures and rangelands); terrestrial non-food sites (e.g., airports/landing fields, industrial areas, nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedge rows, nonagricultural uncultivated areas/soils; recreational and outdoor residential (e.g., ornamental lawns and turf); and forestry sites.

Occupational-use products and homeowner use products

At this time, products containing triclopyr are intended for both occupational uses and homeowner uses.

Incident Reports

A review of pesticide poisoning incident data was completed on June 26, 1996. Numerous databases were searched for incident data for triclopyr (active ingredient 116001), triethylamine triclopyr (active ingredient 116002), and triclopyr butoxyethyl ester (active ingredient 116004). A literature review of possible human and animal adverse effects after exposure to triclopyr was also conducted, although the available literature on these effects proved to be scant.

In summary, there were a total of 72 incident reports in the Incident Data System for triclopyr (PC Codes 116001, 116002, and 116004); 42 reports involved humans, 20 domestic animals and 10 environmental effects. The majority of the incidents resulted after exposure to multiple pesticides and a causal relationship to triclopyr could not be established. Skin and eye irritation were reported in approximately 12 humans either handling or exposed by drift to triclopyr alone. Available evidence indicates that these effects were not severe and they are

consistent with the known toxicity of the chemical. The labeling for triclopyr products contains warnings against contact with eyes and skin and these warnings must be retained on all products.

There were a total of 9 illnesses reported to the California Department of Pesticide Regulation from 1982 through 1993 as a result of exposure to triclopyr alone. Seven were incidents of eye or skin effects.

Triclopyr was Number 49 on the Top 200 Active Ingredients for which the National Pesticide Telecommunications Network (a toll-free information service supported by EPA's Office of Pesticide Programs) received calls from 1982-1991. There were 624 calls reporting 125 incidents; 82 were in humans, 21 in animals and 22 others.

Residential Exposure

The Agency has determined that there are potential exposures to triclopyr during application. These involve application of triclopyr-containing products by means of pump spray bottles, aerosol cans, squeeze bottles, "weed sticks," hose end sprayers, paint brush, rotary and drop spreaders. It is unlikely that power sprayers would be used by homeowners. This sort of special equipment is more apt to be used by agricultural or commercial applicators.

The Agency does not believe that homeowner exposure or risk will be significant for the following reasons:

- No effects of toxicological concern were observed at the highest dose tested (1000 mg/kg/day) in a 21-day dermal toxicity study in rabbits. Dermal absorption is low (< 2%).

- No significant toxicity resulting from inhalation exposure to triclopyr is expected. Both triclopyr BEE (TGAI) and TEA (44.4% ai) are classified as Toxicity Category IV for effects via the inhalation route of exposure.

- The percent ai in products intended for homeowner use is less than that in products intended for agricultural and commercial use. Homeowner products range from 0.5 to 8.0% ai, whereas products for the agricultural and commercial market range from 13.0 to 61.6% ai. Application rates for homeowner products are 0.6 lbs/ai/A or less, whereas typical agricultural and commercial rates range from 4-6 lbs/ai/A.

- All homeowner products are for outdoor use. Most homeowner product applications are directed via spray or weed sticks (wand) at individual pest plants or limited areas. Only the 0.5% ai granular product is applied by broadcast.

Because no toxicological endpoints of concern have been identified for short or intermediate dermal or inhalation exposures to homeowners, no exposure or risk assessments

have been conducted. No chronic exposure is anticipated for homeowner use of triclopyr products.

Occupational Mixer/Loader/Applicator Exposure

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with triclopyr. Based on the use patterns 12 major exposure scenarios were identified for triclopyr: (1a) mixing/loading liquids for aerial application; (1b) mixing/loading liquids for groundboom and handgun application; (2) aerial application of liquids (fixed-wing); (3) aerial application of liquids (helicopter); (4) groundboom application of liquids; (5) handgun sprayer application of liquids; (6) mixing/loading/applying liquids with a backpack sprayer; (7) mixing/loading/applying liquids with a low pressure handwand; (8) applying liquids with an aerosol can; (9) mixing/loading/applying granulars with a push-type spreader; (10) mixing/loading/applying liquids with a hand pump sprayer; (11) mixing/loading/applying liquid with a hose-end sprayer; and, (12) flagging for liquid aerial applications.

Short-term and intermediate-term dermal and inhalation exposure assessments are not required because there are no toxicological endpoints of concern. At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios is likely to result in chronic exposure.

Post-Application/Reentry Exposure

EPA has determined that there are potential exposures to persons entering treated sites after application is complete. These include exposures (1) to persons, including children, in recreational (playground) and residential turfgrass areas (2) to workers and other persons in commercial forests, and (3) to workers and other persons in rights-of-ways and other non-crop areas. Because of the toxicological characteristics of triclopyr (very low dermal and inhalation toxicity), EPA has determined that a post-application exposure assessment is not warranted at this time.

However, it should be noted that EPA Region 9 is working with the California Department of Pesticide Regulation, the US Forest Service and Native American tribes in California to determine the potential exposure to forestry herbicides, including triclopyr, that may be occurring to Native Americans through their use of forest plant materials. Native Americans use these plant materials in their diets, in the making of traditional basketry, for medicinal purposes, and in ceremonial activities. Phase one of the joint project developed sampling and analytical methodologies. Phase two will determine the dissipation rate and frequency of occurrence of three herbicides (glyphosate, hexazinone, and triclopyr) in plants of interest to Native Americans. The objective of this joint effort is to characterize these unique exposure scenarios which, because of their unique and localized nature, are not reflected in the current assessment.

Restricted-Entry Intervals (REIs) 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 the dermal toxicity, eye irritation potential, and skin irritation potential are used in determining the WPS REI. If one or more of the three acute toxicity effects are in the Toxicity Category I, the 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 REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim REI is established at 12 hours. Interim REIs established for triclopyr-containing products range from 12 to 48 hours. As noted in PR Notice 93-7, Labeling Revisions Required by the Worker Protection Standard, EPA considers, during the reregistration process, all relevant active ingredient and product-specific information to decide whether there is reason to shorten or lengthen the previously established REI. The REI for triclopyr is further addressed in Section IV of this document.

4. Risk Characterization

a. Dietary Risk

Chronic Dietary Risk using TMRC

A chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

Existing tolerances result in a TMRC which represents 0.81% of the RfD for the U.S. general population. The sub population with the highest potential exposure, non-nursing Infants (<1 year old) occupies 2.65% of the RfD.

The chronic analysis for triclopyr is a worst case estimate of dietary exposure calculated with all residues at tolerance level and 100 percent of the commodities assumed to be treated with triclopyr. Because the percent of the RfD occupied is far below 100, even using worst case exposure assumptions, EPA considers the chronic dietary risk of triclopyr from food sources to be minimal.

Acute Dietary Risk

Since the toxicological endpoint to which exposure is being compared in this analysis is a developmental NOEL (30 mg/kg/day), pregnant females (13+ years) is the sub-population of particular interest.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 present no dietary concern. The high end MOE

value of 2500 (see below) is within the acceptable range and demonstrates no acute dietary concern.

Pregnant Females (13+ Years):

Where RDV = relative dose value
and X = estimated percentage of population user-days with residue contribution exceeding X times the RDV.

$$\begin{aligned} \text{Exposure} &= \text{RDV} \times X \\ &= 0.01 \times 1.2 \end{aligned}$$

$$\text{High End Exposure} = 0.012 \text{ mg/kg/day}$$

$$\begin{aligned} \text{MOE} &= \text{NOEL/exposure} \\ &= 30.0 \text{ mg/kg/day} / 0.012 \text{ mg/kg/day} \\ \text{MOE} &= 2500 \end{aligned}$$

b. Drinking Water Risk

The calculations presented below are based on an acute NOEL = 30 mg/kg/day, and a chronic NOEL = 5 mg/kg/day. The Reference Dose has been established as 0.05 mg/kg/day.

Chronic Drinking Water Risk

For a 10 kg child consuming 1 Liter of water a day the chronic drinking water risk is calculated as a percent of the RfD:

$$\text{Percent of RfD} = (2.3 \times 10^{-2} \text{ mg/kg/day} \div 0.05 \text{ mg/kg/day}) \times 100 = 46\%$$

For a 60 kg pregnant female consuming 2 Liters of water a day the chronic drinking water risk is calculated as a percent of the RfD:

$$\text{Percent of RfD} = (7.7 \times 10^{-3} \text{ mg/kg/day} \div 0.05 \text{ mg/kg/day}) \times 100 = 15\%$$

Acute Drinking Water Risk

For a 10 kg child consuming 1 Liter of water a day the acute drinking water risk is calculated as a Margin of Exposure (MOE):

$$\text{MOE} = 30 \text{ mg/kg/day} \div 3.6 \times 10^{-2} \text{ mg/kg/day} = 825$$

For a 60 kg pregnant female consuming 2 Liters of water a day the acute drinking water risk is calculated as a MOE:

$$\text{MOE} = 30 \text{ mg/kg/day} \div 1.2 \times 10^{-2} \text{ mg/kg/day} = 2,500$$

c. Occupational Risk

Risk From Handler Exposures

Short-term and Intermediate-term Risk: No short- or intermediate-term risk assessment was required for handler exposures to triclopyr because no toxicological endpoints of concern were identified in a 21 day dermal toxicity study in rabbits at the highest dose (1000 mg/kg/day) indicating very low toxicity via the dermal route of exposure. Furthermore, no significant toxicity is expected from inhalation exposure.

Chronic Risk: At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios is likely to result in chronic exposure.

Risk From Post-Application Exposures

Short-term and Intermediate-term Risk: No short- or intermediate-term risk assessment was required for post-application exposures to triclopyr because there are no toxicological endpoints of concern identified at this time.

Chronic Risk: At this time, no chronic risk assessment is required for post-application exposures to triclopyr, since none of the current post-application exposure scenarios is likely to result in chronic exposure.

Additional Occupational/Residential Exposure Studies

Handler Studies

Handler exposure studies are not required at this time, since there are no toxicological endpoints of concern identified at this time.

Post-Application Studies

Post-application exposure studies are not required at this time, since there are no toxicological endpoints of concern identified at this time.

d. FQPA Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the

susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) require EPA to apply an uncertainty (safety) factor of up to 10 fold, unless reliable data demonstrate that a lesser uncertainty factor will be sufficiently protective of infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought and other substances that have a common mechanism of toxicity.

Potential Risk to 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 data base, the nature of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For the purpose of assessing the pre- and post-natal toxicity of triclopyr, EPA has evaluated three developmental and one reproduction study. The results of these studies are reported in Section III.B.e. and III.B.f. Based on current data requirements, these studies when considered along with other required toxicity studies, constitute a complete data base for evaluating pre- and post-natal effects for triclopyr. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

The developmental and reproductive data for triclopyr indicate that developmental and reproductive effects occurred only at doses that are the same as or higher than doses which caused maternal or parental effects. Generally, the Agency would be concerned when developmental/reproductive effects are seen at doses lower than those that cause maternal effects.

Based on reliable data indicating no special sensitivity of young organisms to triclopyr, the Agency concludes that an uncertainty factor of 100 is adequate for the triclopyr chronic and acute risk assessments.

Aggregate Exposure/Risk

In examining aggregate risk, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure include drinking water, and exposure from uses in and around the home. Triclopyr shares a common metabolite, TCP, with the insecticide chlorpyrifos. EPA has assessed the combined likely exposures to TCP from both triclopyr and chlorpyrifos (below) using very high exposure assumptions, and found no risks of concern.

Because triclopyr has food uses, specific consideration of potential risks to infants and children, as well as cumulative and aggregate exposures, is warranted.

Aggregate Risk

Because of the toxicological characteristics of triclopyr (no dermal endpoint of concern identified at this time), EPA determined that a post-application exposure assessment was not necessary. Residential exposure is considered to be negligible (no dermal endpoint of concern identified at this time). Therefore, no significant non-occupational exposure is expected.

Exposure levels to triclopyr based on upper bound estimates of triclopyr residues in surface waters derived from modeling are not expected to occur in drinking water. They are presented here to indicate that even in the most extreme circumstances, the total risk associated with triclopyr residues in the diet (food + water) is below the Agency's level of concern. By comparison, exposures to triclopyr based on available ground water monitoring data result in chronic drinking water risks <1% of the RfD (for adults and children), and an acute MOE >1,000,000 for females, 13+ years.

Acute Aggregate Risk

The acute aggregate dietary MOE includes potential exposure to triclopyr in food and drinking water. It is calculated below for females 13+ years. The MOE calculation is based on a maternal NOEL of 30 mg/kg/day selected from a developmental study in rabbits for use in acute dietary risk calculations. Because the endpoint selected for acute dietary exposure and risk is from a developmental study and is a maternal NOEL, the sub-population, females 13+ years, is the subgroup of interest and the subject of the acute aggregate risk calculations below. The aggregate acute dietary MOE was calculated to be 1250. This risk assessment assumed 100% crop treated with tolerance level residues on all treated crops consumed, and an upper bound estimate of triclopyr residues in drinking water, resulting in a significant over-estimate of dietary exposure. The high acute aggregate dietary MOE provides assurance that there is a reasonable certainty of no harm for the sub-population of females 13+ years as well as the general population including infants and children.

13+ Pregnant Females Dietary + Drinking Water

Acute aggregate exposure = 0.012 mg/kg/day (food) + 0.012 mg/kg/day (water) = 0.024 mg/kg/day

Acute MOE (aggregate) = 30 mg/kg/day ÷ 2.4 10⁻² mg/kg/day = 1250

Chronic Aggregate Risk

Using the conservative exposure assumptions described above, the Agency finds that the percentage of the RfD that will be utilized by aggregate exposure to residues of triclopyr for the sub-population, females 13+ years approximates 16% and for the sub-population, non-nursing infants (< 1 year old) approximates 49%.

Females 13+ years (pregnant) Dietary + Drinking Water

Percent of RfD (food) = 0.0003 mg/kg/day ÷ 0.05 mg/kg/day x 100 = 0.6% RfD

Percent of RfD (water) = (7.7 x 10⁻³ mg/kg/day ÷ 0.05) X 100 = 15% RfD

Chronic aggregate exposure = 0.6% (food) + 15% (water) = 15.6% RfD

Non-Nursing Infants (< 1 year old)

Percent of RfD (food) = 0.0013 mg/kg/day ÷ 0.05 mg/kg/day x 100 = 2.6% RfD

Percent of RfD (water) = 2.3 x 10⁻² mg/kg/day ÷ 0.05 mg/kg/day) X 100 = 46% RfD

Chronic aggregate exposure = 2.6% (food) + 46% (water) = 48.6% RfD

Aggregate Risk from TCP

Triclopyr shares a common metabolite, 3,5,6-trichloro-2-pyridinol (TCP), with the insecticide chlorpyrifos. EPA's assessment of the likely exposure and risks associated with TCP follows.

Toxicity Endpoints

TCP is comparable in toxicity to triclopyr. Whereas the acute toxicity endpoint for triclopyr is 30 mg/kg/day based on a developmental study, the acute toxicity endpoint for TCP is **25 mg/kg/day**, also based on a developmental study (Redden 9/97).

The chronic endpoint for triclopyr is the RfD of 0.05 mg/kg/day based on a reproductive study in rats. A RfD has not been set for TCP but for purposes of this risk assessment, EPA proposes that a provisional RfD of **0.03 mg/kg/day** be used based on a 1-year dog study with a

NOEL of 3 mg/kg/day (Redden 9/97) and an uncertainty factor of 100 for intra and interspecies variability. This RfD is 10-fold higher than the RfD of 0.003 mg/kg/day for chlorpyrifos based on cholinesterase inhibition.

Acute Exposure

No DRES runs have been done for TCP, however, the DRES runs for triclopyr and chlorpyrifos can be used for this analysis. The DRES run for triclopyr indicates that $\geq 99.5\%$ of females (13+ years) are exposed to 0.012 mg/kg/day or less. The triclopyr run assumes 100% crop treated and all residues at tolerance levels. If we assume that all triclopyr residues could be converted to TCP (clearly a worse case assumption since TCP is considered a significant component of the residue only in meat and meat byproducts), acute dietary exposure to TCP from use of triclopyr is highly unlikely to exceed 0.012 mg/kg/day.

From the chlorpyrifos DRES run, $\geq 99.5\%$ of females (13+ years) are exposed to 0.016 mg/kg/day or less of chlorpyrifos. The chlorpyrifos run made use of percent crop treated and anticipated residue information to generate a more realistic estimate of dietary exposure to chlorpyrifos. Assuming that all chlorpyrifos residues would be converted to TCP prior to consumption¹, acute dietary exposure to TCP from all uses of chlorpyrifos is not likely to exceed 0.016 mg/kg/day.

Realistic estimates of TCP in drinking water from use of triclopyr and chlorpyrifos are not available. Based on modeling, an upper bound estimate of acute drinking water exposure to triclopyr of 0.012 mg/kg/day was done for the triclopyr RED (Eiden 7/7/97). Assuming as we did above that all triclopyr in drinking water is hydrolyzed to TCP prior to consumption, the upper bound estimate of acute drinking water exposure to TCP is 0.012 mg/kg/day.

From the draft chlorpyrifos RED, the highest level of chlorpyrifos found in drinking water was 2 ppm in a well associated with a house treated for termites. There is no way to know how high TCP levels might have been under these conditions (the half-life for hydrolysis of chlorpyrifos to TCP ranges from 4-10 weeks) without direct monitoring, but TCP levels could possibly be higher than chlorpyrifos levels. If TCP levels were at 2 ppm, the corresponding dose would be 0.0067 mg/kg/day.

For residential uses of chlorpyrifos, no data are available to estimate potential exposures to TCP.

¹ A tolerance reassessment for chlorpyrifos was performed at some time after TCP was removed from the tolerance expression for those commodities where TCP residues could be distinguished from chlorpyrifos residues. It is apparent from the reassessment that TCP was usually not the major component of the total residue (Knizner 9/15/94). Therefore, using chlorpyrifos residues as a surrogate for TCP residues is unlikely to underestimate residues of TCP in commodities.

Acute Aggregate Risk

Acute dietary exposure to TCP resulting from triclopyr use is unlikely to exceed 0.012 mg/kg/day, and acute dietary exposure to TCP from chlorpyrifos is unlikely to exceed 0.016 mg/kg/day. Combined dietary exposure is unlikely to exceed 0.028 mg/kg/day and the corresponding MOE is $25 \text{ mg/kg/day} \div 0.028 \text{ mg/kg/day}$ or ≥ 900 .

If the upper bound estimate of 0.012 mg/kg/day for acute drinking water exposure to TCP from uses of triclopyr is added to the dietary estimate, the combined exposure is 0.040 mg/kg/day and the MOE is ≥ 600 .

An estimate for acute drinking water exposure to TCP from uses of chlorpyrifos is not feasible; however, residues of TCP in drinking water from uses of chlorpyrifos would have to exceed 6 ppm for the MOE to be less than the recommended 100. Based on the water monitoring data for chlorpyrifos, this is likely to be a rare event.

Chronic Exposure and Risk

The DRES run for triclopyr indicates that for non-nursing infants <1 year old, chronic dietary exposure to triclopyr is equivalent to 2.65% of the RfD of 0.05 mg/kg/day or 0.001325 mg/kg/day. Using the worst case assumption that all triclopyr residues could be converted to TCP, then for non-nursing infants <1 year old, chronic dietary exposure to TCP from uses of triclopyr would occupy 4.4% of the provisional TCP RfD of 0.03 mg/kg/day.

The DRES run for chlorpyrifos indicates that for non-nursing infants <1 year old, chronic dietary exposure to chlorpyrifos and TCP (before TCP was removed from the tolerance expression for some commodities) is equivalent to 91% of the RfD of 0.003 mg/kg/day or 0.00273 mg/kg/day. Assuming that the total residue was converted to TCP prior to ingestion then for non-nursing infants <1 year old, chronic dietary exposure to TCP from uses of chlorpyrifos would occupy 9.1% of the provisional TCP RfD of 0.03 mg/kg/day.

For non-nursing infants <1 year old, total chronic dietary exposure is unlikely to exceed 4.4% plus 9.1% or 13.5% of the provisional RfD for TCP. Based on a GENECC estimate for non-nursing infants < 1 year old (Eiden 7/7/97), chronic drinking water exposure to triclopyr was estimated to be 0.023 mg/kg/day. For non-nursing infants <1 year old, total chronic exposure from diet and drinking water is $0.023 + 0.00273 + 0.001325 \text{ mg/kg/day}$ or 0.027 mg/kg/day or 90% of the provisional RfD. Possible chronic drinking water exposure to TCP from use of chlorpyrifos has not been included in the calculation because there are no supporting data. Qualitatively, it is conceivable that termiticide use of chlorpyrifos may result in chronic drinking water exposures to TCP that exceed the provisional RfD but this situation is not likely to be common.

Based on its analysis, the Agency concludes that the existing uses of triclopyr and chlorpyrifos are unlikely to result in acute or chronic dietary risks from TCP. Based on limited available data and modeling estimates, with less certainty, the Agency concludes that existing uses of triclopyr and chlorpyrifos are unlikely to result in acute or chronic drinking water risks from TCP. Acute and chronic aggregate risks of concern are also unlikely to result from existing uses of triclopyr and chlorpyrifos.

Potentially the greatest (and least certain) source of exposure to TCP is from drinking water associated with use of chlorpyrifos as a termiticide. Risks associated with this use will be considered in the chlorpyrifos RED. Additional restrictions on the use of triclopyr are unlikely to have any effect in reducing aggregate risk from TCP.

Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Triclopyr shares a common metabolite, TCP, with the insecticide chlorpyrifos. EPA has assessed the combined likely exposures to TCP from both triclopyr and chlorpyrifos (above) using very high exposure assumptions, and found no risks of concern.

Additionally, DowElanco has submitted information to the Agency comparing the chemical structure and toxicity of triclopyr to other related compounds including another pyridinyloxyacetic acid, fluroxypyr and two pyridinecarboxylic acids, clopyralid and picloram (MRID 44385901). However, at this time the Agency has not yet made a final decision concerning a possible mechanism of toxicity for triclopyr and other compounds. Therefore, for

the purposes of the tolerance reassessments in this RED document, EPA has performed risk assessments for triclopyr and TCP only.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to birds. The preferred test species is either mallard duck or bobwhite quail. Results of this test are tabulated below.

Table 5: Avian Acute Oral Toxicity - Triclopyr Acid

Species	% A.I.	LD ₅₀ (mg/kg)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirement
Mallard Duck (<i>Anas platyrhynchos</i>)	technical	1,698	slightly toxic	40346401 Dow Chemical/1976	yes (core)

These results indicate that triclopyr acid is slightly toxic to avian species on an acute oral basis. The guideline requirement (71-1) is fulfilled (MRID # 40346401).

Table 6: Avian Acute Oral Toxicity-Triclopyr Triethylamine (TEA)

Species	% A.I.	LD ₅₀ (mg/kg)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Mallard Duck (<i>Anas platyrhynchos</i>)	64.7	2055 ¹	practically non-toxic	40346501 Fink/1978	yes (core)

¹ This a.i. value is from 3176 mg/kg x 64.7% formulation.

These results indicate that triclopyr - triethylamine (TEA) is practically non-toxic to slightly toxic to avian species on an acute oral basis. The guideline requirement (71-1) is fulfilled (MRID # 40346501).

Table 7: Avian Acute Oral Toxicity -Triclopyr Butoxyethyl Ester (BEE)

Species	% A.I.	LD ₅₀ (mg/kg)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	96.1	735	slightly toxic	41902002	yes (core)
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	62.9	849 ¹	slightly toxic	41902003	yes (core)

¹ This a.i. value is from 1350 mg/kg x 62.9% formulation.

These results indicate that triclopyr - butoxyethyl ester (BEE) is slightly toxic to avian species on an acute oral basis. The guideline requirement (71-1) is fulfilled (MRID # 41902003). Data on the toxicity of the triclopyr degradate, 3,5,6-trichloro-2-pyridinol (TCP) to wildlife, are currently being reviewed in the context of the chlorpyrifos RED since TCP is also a degradate of chlorpyrifos. These data indicate that TCP is slightly toxic or practically non-toxic acutely to the bird species tested.

Two subacute dietary studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to birds. The preferred test species are mallard duck (a waterfowl) and bobwhite quail (an upland gamebird). Results of these tests are tabulated below.

Table 8: Avian Subacute Dietary Toxicity - Triclopyr Acid

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Cortunix Quail	technical	3,272	slightly toxic	00049638 Dow Chemical/1973	no, supplemental
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	technical	2,934	slightly toxic	40346403 Dow Chemical/1976	yes (core)
Mallard Duck (<i>Anas platyrhynchos</i>)	99.0	5,620	practically non- toxic	0031249 Wildlife Int'l/1979	yes (core)

These results indicate that triclopyr acid is slightly toxic to practically non-toxic to avian species on a subacute dietary basis. The guideline requirement 71-2 is fulfilled (MRID # 0031249 and 40346403).

Table 9: Avian Subacute Dietary Toxicity-Triclopyr TEA

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	64.7	11,622	practically non-toxic	40346503 Fink/1978	yes (core)
Mallard Duck (<i>Anas platyrhynchos</i>)	64.7	>10,000	practically non-toxic	40346502 Fink/1977	yes (core)

These results indicate that triclopyr TEA is practically non-toxic to avian species on a subacute dietary basis. The guideline requirement 71-2 is fulfilled (MRID # 40346503, 40346502).

Table 10: Avian Subacute Dietary Toxicity Triclopyr Butoxyethyl Ester (BEE)

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	93	9026	practically non-toxic	00134180 Wildlife Int'l/1978	yes (core)
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	96.1	5401	practically non-toxic	41905501 Lynn/1991	yes (core)
Mallard Duck (<i>Anas platyrhynchos</i>)	93	>10,000	practically non-toxic	00134179 Wildlife Int'l/1977	yes (core)
Mallard Duck (<i>Anas platyrhynchos</i>)	96.1	>5,401	practically non-toxic	41905502 Lynn/1991	yes (core)

These results indicate that triclopyr BEE is practically non-toxic to avian species on a subacute dietary basis. The guideline requirement 71-2 is fulfilled (MRID # 41905501, 41905502, 00134179, 00134180). Available data on the degrade TCP suggest low toxicity to birds on a subacute dietary basis.

(2) Birds, Chronic

Avian reproduction studies are required for triclopyr because: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season; (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed; ($t_{1/2}$ of 8 to 18 days). Results of these tests are tabulated below.

Table 11: Avian Reproduction - Triclopyr Acid

Species	% A.I.	NOEC/LOEC (ppm)	Endpoints Affected	MRID No. Author/Year	Fulfills Guideline Requirement?
Northern Bobwhite Quail (<i>Colinus virginianus</i>)	98.9	NOEC 500 LOEC>500	N/A	00031251 Beavers/1979	yes (core)
Mallard Duck (<i>Anas platyrhynchos</i>)	98.9	NOEC 100 LOEC 200	number of 14 day old survivors	00031250 Beavers/1979	yes (core)

Based on the data provided, reproduction of birds may be affected at levels greater than 100 ppm. The guideline requirement (71-4 (a) & (b)) is fulfilled for triclopyr acid (MRID # 00031250 and 00031251).

The discussion of exposure and chronic effects to birds from triclopyr BEE and TEA is in the ecological exposure and risk assessment section and indicated that an avian reproduction study is not needed for triclopyr BEE and TEA.

(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. Results from acute oral rat toxicity studies substitute for wild mammal testing. These toxicity values are reported in the table below.

Table 12: Wild Mammalian Toxicity

Species	Test Type	Endpoint (Mg/kg/day)	MRID NO.
Rat	Acute oral LD ₅₀	LD ₅₀ = 729 (Males) LD ₅₀ = 630 (Females)	00031940
Rat	Two-Generation Reproduction Study Guideline (83-4)	Reproductive/Systemic NOEL = 25 Reproductive/Systemic LEL = 250	43545701

The results indicate that triclopyr acid is practically non-toxic to small mammals on an acute oral basis.

The 2-Generation rat reproduction study showed that the reproductive/systemic toxicity LEL of 250 mg/kg/day was based on decreased litter size, decreased body weight and weight gain, and decreased survival of the F₁ and F₂ litters.

(4) Insects

A honey bee acute contact study using the technical grade of the active ingredient is required if the proposed use will result in honey bee exposure. Results of this test are tabulated below.

Table 13: Nontarget Insect Acute Contact Toxicity-Triclopyr Acid

Species	% A.I.	LD ₅₀ (µg/bee)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirement?
Honey Bee (<i>Apis mellifera</i>)	99.2	> 100	practically non-toxic	40356602 Dingledine/1985	yes (core)

The results indicate that triclopyr acid is practically non-toxic to bees on an acute contact basis. The guideline requirement (141-1) is fulfilled (MRID # 40356602).

Table 14: Nontarget Insect Acute Contact Toxicity Triclopyr TEA

Species	% A.I.	LD ₅₀ (µg/bee)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Honey Bee (<i>Apis mellifera</i>)	99.2	>100	practically non-toxic	40356602 Dingledine/1985	yes (core)

The results indicate that triclopyr TEA is relatively non-toxic to bees on an acute contact basis. The guideline requirement (141-1) is fulfilled (MRID # 40356602).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

Two freshwater fish toxicity studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to fish. The preferred test species are rainbow trout (a cold-water fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 15: Freshwater Fish Acute Toxicity Triclopyr Acid

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Rainbow trout (<i>Oncorhynchus mykiss</i>)	technical (Dowco 233)	117	practically non-toxic	00049637 Dow Chemical/1973	yes (core)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	technical (Dowco 233)	148	practically non-toxic	0049637 Dow Chemical/1973	yes (core)

The results indicate that triclopyr acid is practically non-toxic to freshwater fish on an acute basis. The guideline requirement 72-1 is fulfilled (MRID # 00049637).

Table 16: Freshwater Fish Acute Toxicity Triclopyr TEA

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Rainbow trout (<i>Oncorhynchus mykiss</i>)	64.7	613 (flow-through)	practically non-toxic	00151956 McCarty/1978	yes (core)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	47.8 (M3724)	240 (flow-through)	practically non-toxic	00049637 Dow Chemical/1973	yes, (core for formulated product)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	64.7	893 (flow-through)	practically non-toxic	00151956 McCarty/1978	yes (core)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	47.8 (M3724)	471 (flow-through)	practically non-toxic	00049637 Dow Chemical/1973	yes, (core for formulated product)
Fathead minnow (<i>Pimephales promelas</i>)	64.7	947 (flow-through)	practically non-toxic	00151956 McCarty/1978	yes (core)
Fathead minnow (<i>Pimephales promelas</i>)	44.9	544 (static)	practically non-toxic	00151958 Mayes/1983	yes (core)
Fathead minnow (<i>Pimephales promelas</i>)	44.9	279 (flow-through)	practically non-toxic	00151958 Mayes/1983	yes (core)

The results indicate that triclopyr TEA is practically non-toxic to freshwater fish on an acute basis. The guideline requirement (72-1) is fulfilled (MRID # 00151956 and 00151958).

Table 17: Freshwater Fish Acute Toxicity Triclopyr BEE

Species	% A.I.	LC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirement?
Rainbow trout (<i>Oncorhynchus mykiss</i>)	96.98	0.65	highly toxic	42884501 Woodburn/1992	yes (core)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	formulated	1.29	moderately toxic	00134181	yes (core)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	62.9	0.77 - 2.7 (24 hrs)	highly to moderately toxic	41971603 Gorzinski/1991	no, supplemental
Bluegill sunfish (<i>Lepomis macrochirus</i>)	formulated	1.46	moderately toxic	00134181	yes (core)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	96.98	0.36	highly toxic	42917901 Woodburn/1993	yes (core)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	62.9	1.3 (24 hrs)	moderately	41971604 Gorzinski/1991	no, supplemental
Coho salmon (<i>Oncorhynchus kisutch</i>)	99	Yolk-sac fry: 0.45-0.47 Juvenile fry: 1.4	Yok-sac fry: highly toxic Juvenile fry: moderately toxic	41736304 Barron/1987	no, supplemental
Fathead minnow (<i>Pimephales promelas</i>)	96.4	2.4 (24 hrs)	moderately toxic	00151963 Batchelder/1980	no, supplemental
Fathead minnow (<i>Pimephales promelas</i>)	96	2.31 (24 hrs)	moderately toxic	00151965 Batchelder/1981	no, supplemental

The results indicate that triclopyr BEE is moderately to highly toxic to freshwater fish on an acute basis. The guideline requirement (72-1) is fulfilled (MRID # 42884501, 00134181, 42917901, 41736304, 41971603, 41971604, 00151963, 00151965).

Available data on the degradate TCP from the literature and data supplied by the registrant in the context of the reregistration of chlopyrifos suggest slight to moderate acute toxicity to freshwater warm- and cold-water fish species. These data are summarized below.

Table 18: TCP (3,5,6-TC-2-P) Acute Toxicity to Freshwater Fish

Species	% AI	LC ⁵⁰ (ppm)	MRID No. Author/Year	Toxicity Category
Bluegill sunfish	99.9%	12.5	41829003 ¹	slightly toxic
Rainbow trout	99.9%	12.6	41829004 ¹	slightly toxic
Rainbow trout	99.7%	1.5	Wan, 1987 ²	moderately toxic
Coho salmon	99.7%	1.8	Wan, 1987	moderately toxic
Chum salmon	99.7%	1.8	Wan, 1987	moderately toxic
Sockeye salmon	99.7%	2.5	Wan, 1987	moderately toxic
Chinook salmon	99.7%	2.1	Wan, 1987	moderately toxic
Pink salmon	99.7%	2.7	Wan, 1987	moderately toxic

1 Data are currently under review for the ecological risk assessment for the chlorpyrifos RED.(Gorzinski, Mayes & Ormond, 1991)

2 Wan, et al. Bull. Environ. Contam. Toxicol 39:721-728 (1987)

(2) Freshwater Fish, Chronic

A fish early-life stage test is required for triclopyr because (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; (2) there are acute LC₅₀s less than 1 mg/L. Results of these tests are tabulated below.

Table 19: Freshwater Fish Early Life Stage Toxicity-Triclopyr TEA

Species	% A.I.	NOEC/LOEC (ppm)	MATC (ppm)	Endpoints Affected	MRID No. Author/Year	Fulfills Guideline Requirements
Fathead minnow (<i>Pimephales promelas</i>)	44.9	NOEC >104 LOEC <162	130	length	00151958 Mayes/1983	yes (core)

The results indicate that triclopyr TEA may affect fish lengths at levels greater than 104 ppm. The guideline requirement (72-4) is partially fulfilled for triclopyr TEA (MRID # 00151958).

The triclopyr degradate, TCP, is considered to be persistent in aquatic environments and aquatic concentrations of TCP may exceed 0.01 of the LC₅₀ for fish. Therefore, an additional freshwater fish early lifestage toxicity study with TCP using rainbow trout (the most sensitive species) or chum or coho salmon is required.

(3) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess the toxicity of a pesticide to invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 20: Aquatic Invertebrate Toxicity - Tricloppyr Acid

Species	% AI	LC ₅₀ or EC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fullfills Guideline Requirements
Waterflea (<i>Daphnia Magna</i>)	99.5	132.9	Practically non-toxic	40346504 McCarty/1977	yes (core)

Table 21: Aquatic Invertebrate Toxicity - Triclopyr TEA

Species	% AI	LC ₅₀ or EC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fullfills Guideline Requirements
Waterflea <i>Daphnia Magna</i>	44.9	1,496	Practically non- toxic	00151959 Gersich/1982	yes (core)

The results indicate that triclopyr TEA is practically non-toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2) is fulfilled (MRID # 00151959).

Table 22: Freshwater Invertebrate Toxicity Triclopyr BEE

Species	% A.I.	LC ₅₀ / EC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fullfills Guideline Requirements
Waterflea (<i>Daphnia magna</i>)	96.4	1.7 (nominal conc.)	moderately toxic	00151963 Batchelder/1980	no, supplemental
Waterflea (<i>Daphnia magna</i>)	96.4	12.0	slightly toxic	00151965 Milazzo/1981	yes (core)

The results indicate that triclopyr BEE is slightly to moderately toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2) is fulfilled (MRID # 151963)

and 00151965). Available data suggest that the triclopyr degradate, TCP, is slightly toxic to freshwater invertebrates on an acute basis.

(4) Freshwater Invertebrates, Chronic

An aquatic invertebrate life-cycle test is required for triclopyr because the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent. Results of this test are tabulated below.

Table 23: Freshwater Aquatic Invertebrate Life Cycle Toxicity-Triclopyr TEA

Species	% A.I.	NOEC/L OEC (ppm)	MATC (ppm)	Endpoints Affected	MRID No. .Author/Year	Fulfills Guideline Requirements
Daphnid (<i>Daphnia magna</i>)	44.9	NOEC 80.7 LOEC 149.0	110	total young and mean brood size	00151959 Gersish/1982	yes (core)

The results indicate that aquatic invertebrate reproductive impairment may occur at levels greater than 80.7 ppm. The guideline requirement 72-4(b) is fulfilled for triclopyr TEA (MRID # 00151959).

This guideline study requirement 72-4 (b) is not needed for triclopyr BEE because a valid fish early life-stage study 72-4(a) fulfills this data requirement.

(5) Estuarine and Marine Animals

Estuarine/marine acute toxicity testing is required for triclopyr because of forestry, rights-of-way, rice, and turf uses. The preferred test species are sheepshead minnow, mysid shrimp and eastern oyster. Results of these tests are tabulated below.

Table 24: Estuarine/Marine Acute Toxicity- Triclopyr TEA

Species	% A.I.	LC ₅₀ /EC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Eastern oyster (shell deposition) (<i>Crassostrea virginica</i>)	46.09	58	slightly	42646101 Kowalski/1992	yes (core), for formulated product
Eastern oyster (embryo- larvae) (<i>Crassostrea virginica</i>)	43.8	>56 <87ppm (48 hr EC ₅₀)	100% abnormal development at 87 ppm	0062623 EG&G/1975	yes (core), for formulated product
Fiddler crab (<i>Uca pugilator</i>)	43.8	>1000	practically non- toxic	0062623 EG&G/1975	no, supplemental
Grass shrimp (<i>Palaemonetes pugio</i>)	46.09	326	practically non- toxic	42646102 Kowalski/1992	yes (core), for formulated product
Pink shrimp (<i>Penaeus duorarum</i>)	43.8	895	practically non- toxic	0062623 EG&G/1975	no, supplemental
Tidewater silverside (<i>Menidia beryllina</i>)	44.7	130	practically non- toxic	41633703 Ward/1989	yes (core), for formulated product

The results indicate that triclopyr TEA is slightly toxic to practically non-toxic to estuarine/marine invertebrates on an acute basis and practically non-toxic to estuarine/marine fish on an acute basis. The guideline requirement (72-3 (d) & (e)) is fulfilled (MRID # 42646101, 42646102, 41633703, 0062623).

Table 25: Estuarine/Marine Toxicity-Triclopyr BEE

Species	% A.I.	LC ₅₀ /EC ₅₀ (ppm)	Toxicity Category	MRID No. Author/Year	Fulfills Guideline Requirements
Eastern oyster (shell deposition) (<i>Crassostrea virginica</i>)	96.1	Species	highly toxic	41971602 Boeri/1991	yes (core)
Eastern oyster (shell deposition) (<i>Crassostrea virginica</i>)	62.9 (Garlon 4)	0.32	highly toxic	41969903 Boeri/1991	yes (core for formulated product)
Estuarine (Grass) shrimp (<i>Palaemonetes pugio</i>)	96.1	2.47	moderately toxic	41971601 Boeri/1991	yes (core)
Estuarine (Grass) shrimp (<i>Palaemonetes pugio</i>)	62.4 (Garlon 4)	1.7	moderately toxic	41969902 Ward/1991	yes (core for formulated product)
Tidewater silverside (<i>Menidia beryllina</i>)	96.1	0.45	highly toxic	42053901 Ward/1991	yes (core)
Tidewater silverside(<i>Menidia beryllina</i>)	62.9 (Garlon 4)	0.76	highly toxic	41969901 Ward/1991	yes (core for formulated product)

The results indicate that triclopyr BEE is moderately to highly toxic to estuarine/marine invertebrates on an acute basis and highly toxic to estuarine/marine fish on an acute basis. The guideline requirement (72-3 (a), (b), (c), (d), (e), & (f)) is fulfilled (MRID # 41971602, 41969903, 41971601, 41969902, 42053901, 41969901).

(6) Estuarine and Marine Animals, Chronic

Chronic estuarine/marine studies are not required for triclopyr TEA and BEE because they are not expected to be continuous or recurrent in the estuarine/marine ecosystem.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (GLN #122-1, 123-1) is required for triclopyr TEA and BEE. These herbicides have terrestrial non-residential outdoor use patterns and may move off the application site by runoff or spray drift.

For seed germination, seedling emergence and vegetative vigor testing the following plant species and groups must be tested: (1) six species of at least four dicotyledonous families, which

should include soybean (*Glycine max*) and one root crop species, and (2) four species of at least two monocotyledonous families, one of which must be corn (*Zea mays*).

Tier I tests (122-1) are designed to show if the plants are inhibited at less than 25% when compared to the control. If the plants show 25% or greater inhibition, then Tier II level testing (123-1) is required.

Tier I results for triclopyr TEA and BEE show that except for seed germination in corn, all species tested showed greater than 25% inhibition for seed germination (MRID 41734301), seedling emergence (MRID 41734301), and vegetative vigor (MRID 41784401), thereby triggering the need for Tier II testing for all ten species.

Results from the Tier II (Guideline 123-1) testing for triclopyr TEA of the most sensitive species are reported below.

Table 26: Terrestrial Non-Target Plant Toxicity-Triclopyr TEA

Type of Test Percent ai	Most sensitive species	parameter	EC ₂₅ lb ai/A	NOEL lb ai/A	MRID# Author/year	Fulfills Guideline Requirement
Seed Germination 45.2% triclopyr	sugar beet	radicle length	0.0007 ppm ¹	0.0002 ppm ¹	43129801 Schwab/1993	yes, (core)
	corn	radicle length	0.0116 ppm ¹	0.0123 ppm ¹		
Seedling Emergence 45.2% triclopyr	corn	% emergence and shoot length	>0.333	0.3330	43129801 Schwab/1993	yes (core)
	radish	% emergence and shoot length	> 1.0	0.3330		
Vegetative Vigor 45.2% triclopyr	onion	shoot weight	0.1660	0.1110	43129801 Schwab/1993	yes (core)
	sunflower	shoot length	0.0076	0.0041		

¹ The endpoints from the seed germination study are in ppm instead of lb ai/A because the seeds are tested in a solution rather than sprayed.

In seed germination studies, triclopyr TEA was most toxic to sugar beet and corn, with EC₂₅s of 0.0007 and 0.0116 ppm, and NOELs of 0.0002 and 0.0123 ppm, respectively.

In seedling emergence studies, triclopyr TEA was most toxic to corn and radish, with EC₂₅s of >0.0333 and >1 lb ai/A, respectively. The NOEL for both corn and radish was ≥ 0.333 lb ai/A.

In vegetative vigor studies, triclopyr TEA was most toxic to onion and sunflower, with EC₂₅s of 0.166 and 0.0076 lb ai/A, and NOELs of 0.111 and 0.0041 lb ai/A, respectively.

Results from the Tier II (Guideline 123-1) testing for triclopyr BEE of the most sensitive species are reported below. A seedling germination study had been conducted for triclopyr BEE, however, it was invalid; a new test is not required (based on current guidelines).

Table 27: Terrestrial Non-Target Plant Toxicity-Triclopyr BEE

Type of Test Percent ai	Most sensitive species	parameter	EC ₂₅ lb ai/A	NOEL or EC ₀₅ lb ai/A	MRID# Author/year	Fulfills Guideline Requirements
Seedling Emergence 62.2% Triclopyr	onion	shoot weight	0.0732	0.0030	43650001 Schwab, 1995	yes, core
	alfalfa	emergence	0.0622	0.0036		
Vegetative Vigor 62.2% Triclopyr	onion	shoot weight	0.0888	<0.088	43650001 Schwab, 1995	yes, (core)
	sunflower	shoot weight	0.0089	0.0039		

In seedling emergence studies, triclopyr BEE was most toxic to alfalfa and onion, with EC₂₅s of 0.0622 and 0.0732 lb ai/A and NOELs of < 0.0622 and 0.0030 lb ai/A, respectively.

In vegetative vigor studies, triclopyr BEE was most toxic to sunflower and onion, with EC₂₅s of 0.0089 and 0.0883 lb ai/A and NOELs of 0.0039 and <0.088 lb ai/A, respectively.

2. Aquatic

Aquatic plant testing is required for triclopyr because aerial application and outdoor non-residential use will expose non-target aquatic plants to triclopyr. The following species should be tested at Tier II: *Kirchneria subcapitata* (*Selenastrum capicornutum*), *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Results of Tier II (Guideline 123-2) toxicity testing on the technical/TEP materials are tabulated below.

Table 28: Non-Target Aquatic Plant Toxicity-Triclopyr TEA

Species	% A.I.	EC ₅₀ (ppm ai)	EC ₀₅ or NOEC (ppm ai)	MRID No. Author/Year	Fulfills Guideline Requirement
<i>Skeletonema costatum</i>	45.01%	6.70	0.40	41633707 Cowgill, 1987	yes, core
<i>Lemna gibba</i>	45.01%	8.80	3.5	41633709 Cowgill, 1987	yes, core
<i>Lemna gibba</i>	45.00%	11.00	3.5	41736302 Cowgill, 1988	yes, core
<i>Anabaena flos-aquae</i>	45.0%	5.90	2.0	41633706 Cowgill, 1987	yes, cor
<i>Kirchneria subcapitata</i> (<i>Selenastrum capicornutum</i>)	45.01%	7.60	11.3	41633705 Cowgill, 1987	yes, core
<i>Navicula pelliculosa</i>	45.0%	15.30	8.0	41633708 Cowgill, 1987	yes, core
<i>Selenastrum capicornutum</i>	98.8% triclopyr acid	32.5	7.0	41736303 Cowgill/1989	no, supplemental

These results indicate that exposure levels of 8.80 or greater ppm ai triclopyr TEA may cause detrimental effects to the growth and reproduction of vascular aquatic plant species. Algae or diatoms may be affected from exposure levels of greater than 5.9 ppm ai triclopyr TEA or 32.45 ppm ai of triclopyr acid. The guideline requirement (123-2) is fulfilled. (MRID# 41633705, 41633706, 41633707, 41633708, 41633709, 41736302, 41736303).

Table 29: Non-Target Aquatic Plant Toxicity-Triclopyr BEE

Species	% A.I.	EC ₅₀ (ppm ai)	EC ₀₅ or NOEC (ppm ai)	MRID No. Author/Year	Fulfills Guideline Requirement
<i>Kirchneria subcapitata</i> (<i>Selenastrum capicornutum</i>)	61.3%	3.40	2.3	41633704, 42090422 Cowgill, 1989	yes, core
<i>Lemna gibba</i>	96.98%	0.88	≤0.16	42719101 Milazzo, 1993	yes, core
<i>Skeletonema costatum</i>	96.98%	1.17	0.209	42721103 Hughes, 1993	yes, core
<i>Anabaena flos-aquae</i>	96.98%	1.97	0.52	42721101 Hughes, 1993	yes, core
<i>Navicula pelliculosa</i>	96.98%	0.10	0.002	42721102 Hughes, 1993	yes, core

These results indicate that exposure levels of 0.88 ppm ai or greater of triclopyr BEE may cause detrimental effects to the growth and reproduction of vascular aquatic plant species. Algae or diatoms may be affected from exposure levels of greater than 0.10 ppm ai of triclopyr BEE. The guideline requirement (123-2) is fulfilled. (MRID# 41633704, 42090422, 42719101, 42721101, 42721102, 42721103).

3. Environmental Fate

a. Environmental Fate Assessment

Triclopyr TEA rapidly dissociates in water to the triclopyr acid/anion and triethanolamine. Triclopyr BEE rapidly hydrolyses in the environment to the triclopyr acid/anion and butoxyethanol. Both triethanolamine and butoxyethanol are rapidly dissipated by microbial degradation. Triclopyr acid is a weak acid which will dissociate completely to the triclopyr anion at pHs > 5 (dissociation constant pKa 2.93). Therefore, triclopyr anion will be the predominant moiety present in the environment when products containing either triclopyr BEE or triclopyr TEA are used. Triclopyr acid/anion is somewhat persistent, but is mobile. The predominant degradation pathway for triclopyr in water is photodegradation. The predominant degradation pathway in soil is microbial degradation to the major degradate 3,5,6-trichloro-2-pyridinol (TCP), which is both persistent and mobile.

Triclopyr acid is non-volatile (vapor pressure 1.26×10^{-6} mm Hg) and highly soluble (water solubility of 430 mg/L [WSSA, 1989]). Triclopyr TEA is a non-volatile, very soluble salt (vapor

pressure $< 1 \times 10^{-8}$; solubility 4.12×10^5 mg/L at pH 7). Triclopyr BEE is non-volatile (vapor pressure 3.6×10^{-6} mm Hg) and shows relatively low solubility (6.8 ppm).

Triclopyr TEA will not persist as the salt under normal environmental conditions. In measurements of conductance of a solution of triclopyr TEA in water as a function of time, triclopyr TEA dissolved and dissociated completely to the acid within one minute.

Triclopyr BEE will persist in the environment as the ester for only a limited duration. Triclopyr BEE hydrolyzed quickly to triclopyr acid in natural waters (pH 6.7; half-life of 0.5 days). Supplemental information indicates that triclopyr BEE degrades to triclopyr acid with a half-life of about three hours when applied to silty clay loam, silt loam, and sandy loam soils. In all three soils, less than 3.2% of the applied triclopyr BEE remained after 48 hours. This behavior was also observed in the field. The half-life of triclopyr BEE in a terrestrial field dissipation study was 1.1 days, while total triclopyr (BEE plus triclopyr) half-life was 10.6 days.

Triclopyr acid is a weak acid which will dissociate completely to the triclopyr anion at pHs > 5 (dissociation constant pKa 2.93). Therefore, triclopyr anion will be the moiety present in the environment when products containing either triclopyr BEE and triclopyr TEA are used.

Based on laboratory studies, triclopyr acid is stable to hydrolysis and anaerobic aquatic metabolism; it degrades slowly under aerobic aquatic conditions. Triclopyr acid does not bioaccumulate in aquatic organisms.

It appears that aqueous photolysis is a predominant degradation mechanism in aquatic media. Photodegradation of triclopyr acid was rapid; the half-life was less than 1 day in sterile solutions and approximately 1 day in natural water. The major photodegradation product observed in sterile solutions was 5-chloro-3,6-dihydroxy-2-pyridinoloxycetic acid (TCP); oxamic acid was the major degradation product in natural river water.

The aquatic dissipation half-lives observed in the field are consistent with the shorter half-lives observed in the photolysis in water studies. In general, results of the available studies suggest that triclopyr acid is rapidly dissipated under aquatic conditions in the field ($t_{1/2} = 0.5$ -3.5 days in Lake Seminole, Georgia in an Aquatic Field Dissipation study; and 5 days in pond water in a Forestry Field Dissipation study). Some factors that could affect the rate of dissipation in cases where aqueous photolysis is an important dissipation factor include vegetative cover, type of vegetation, depth of the plot, and suspended sediment.

In soil, the predominant degradation mechanism for triclopyr acid is biotic metabolism. Triclopyr acid degraded in aerobic soil with half-lives of 8 to 18 days to intermediate degradates 3,5,6-trichloro-2-pyridinol (TCP) and 3,5,6-trichloro-2-methoxypyridine (TMP); the ultimate degradate is carbon dioxide. TCP was also observed as a minor degradate in the aerobic aquatic metabolism study.

Total triclopyr residues did not persist in field dissipation studies. When triclopyr BEE was applied to bare soil in North Carolina, triclopyr BEE degraded to triclopyr acid with a half-life of 1.1 days; total triclopyr residues dissipated with a half-life of 10.4 days. Half-lives of total triclopyr in bare-ground and vegetated plots in California were approximately two weeks and 33 days, respectively.

Based on adsorption/desorption studies, triclopyr acid and its major degradate TCP are expected to be very mobile in soils. Freundlich K_{ads} for triclopyr were 0.165-0.975 mL/g; values for TCP were 0.53-1.95 mL/g. In the field dissipation studies, low concentrations of triclopyr were found in soil depths of up to 45 cm, however, triclopyr did not persist.

The degradation products TCP and TMP were recovered in the terrestrial field dissipation studies, with TCP found at higher concentrations than TMP in both the bare and vegetated soil plots. TCP was detected up to 36 weeks after treatment in vegetated soil; it represented a considerable amount (0.131 ppm) at 63 weeks (last test interval) in bare soil. In the forestry studies, TCP was generally limited to the upper 30 cm of the soil, with sporadic detections in deeper soil depths. Based on these observations it appears that TCP is persistent and mobile in the field.

The primary degradation pathway for triclopyr TEA is dissociation to the triclopyr acid and triethanolamine. Triethanolamine is then degraded by aerobic microbial processes to CO_2 (soil half-life 5.6 -13.7 days). In aquatic conditions it is stable (half life 14-18 days) and then proceeds to rapid degradation. However, triethanolamine is stable to degradation under anaerobic aquatic conditions (half-life > 2 years). Because of the rapid microbial degradation under aerobic conditions, it is not expected that volatilization, photodegradation, or bioaccumulation in fish will contribute significantly to the dissipation of triethanolamine.

The primary degradation pathway for triclopyr BEE is hydrolysis to triclopyr acid and 2-butoxyethanol, with hydrolysis occurring more rapidly at higher pHs. 2-Butoxyethanol is then rapidly degraded by microbial processes (aerobic soil and aquatic) to 2-butoxyacetic acid (half-lives of 0.375 - 0.058 days in soil; half-life of 0.6-3.4 days in a sediment/water mixture), with the final degradate as CO_2 . 2-Butoxyethanol and 2-butoxyacetic acid are somewhat more persistent under anaerobic aquatic conditions (half-lives of 1.4 and 73.3 days respectively in an anaerobic sediment/water mixture) with the final degradate as CO_2 . 2-Butoxyethanol (also known as ethylene glycol monobutyl ether) has a perceptible vapor pressure (0.76 mm at 20 °C; Condensed Chemical Dictionary, 10th edition); however, because of the rapid microbial degradation, it is not expected that volatilization will contribute significantly to the dissipation of 2-butoxyethanol. Because of the rapid microbial degradation, it is not expected that photodegradation or bioaccumulation in fish will contribute significantly to the dissipation of butoxyethanol.

Triclopyr is moderately persistent, with persistence increasing as it reaches deeper soil levels and anaerobic conditions; it is also very mobile. Because triclopyr is not expected to reach high concentrations in ground water and it is not toxic, EFED concludes that it is not a concern

for drinking water that is derived from ground water sources. However, both triclopyr BEE and triclopyr TEA may produce TCP which is relatively mobile and persistent and has the potential to degrade groundwater. Therefore, the Agency continues to recommend a ground water label advisory and to keep the ground water study in reserve. Triclopyr and TCP do not adsorb to soil and sediment particles, and may be transported in surface runoff waters. Although, triclopyr is not predicted to persist in surface waters, information from two aquatic field dissipation studies conducted on rice indicates that following application of triclopyr, TCP can persist in flood waters. Triclopyr is not currently regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) is not established. Public water supply systems are not required to sample and analyze for triclopyr.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

Triclopyr **acid** is stable to hydrolysis at pH 5, 7, and 9 in sterile buffered solutions. The guideline requirement for triclopyr acid is fulfilled (GLN 161-1; MRID 41879601).

The hydrolysis of triclopyr **BEE** is pH dependent, with rate of hydrolysis increasing with increasing pH. Triclopyr BEE hydrolyzed in sterile buffered solutions at pH's of 5, 7 and 9 with calculated half-lives of 84.0, 8.7 and 0.3 days, respectively. It hydrolyzed in natural water (Black Creek, Chippewa, Michigan; pH 6.7) with a calculated half-life of 0.5 days. The major identified degradate in all cases was triclopyr acid, which is stable to hydrolysis (see above). The guideline requirement for triclopyr BEE is fulfilled (GLN 161-1; MRID 00134174).

Photodegradation

Photodegradation in water:

Triclopyr acid photodegraded in sterile aqueous buffered solutions (pH 7) with half-lives of 0.6 days (8-9 hours) using natural light (August in Michigan) and 0.36 days using filtered Hg lamps (samples irradiated continuously). The half-lives in river water using natural and artificial light sources were 1.7 and 0.7 days, respectively. Triclopyr acid did not degrade in similar solutions incubated in the dark for up to 3 days. Identified degradates in both sterile solutions and river water were 5-chloro-3,6-dihydroxy-2-pyridinyloxyacetic acid and oxamic acid; 5-chloro-3,6-dihydroxy-2-pyridinyloxyacetic acid was the major degradate in the sterile solutions (up to 48% of the applied), while oxamic acid predominated in the river water (up to 16% of the applied). The guideline requirement for triclopyr acid is fulfilled (GLN 161-2; MRIDs 41732201 and 42411804).

[¹⁴C]Triclopyr BEE (pyridine ring labeled in the 2 and 6 position), at 1.0 ppm, photodegraded with a registrant-calculated half-life of 6.6 days in sterile pH 5 aqueous buffer solutions that were irradiated outdoors in California for 30 days. Triclopyr BEE was stable (<10% degradation) in the dark controls. The major degradate was ¹⁴CO₂, which totaled 29.4% of the applied in the exposed samples at 30 days, and 1.5% in the dark controls. The following non-volatile degradates were identified in the irradiated solutions after 30 days: (5/6)-chloro-3-hydroxy-s-pyridinone, was 17% of the applied; and dichloropyridinyloxyacetic acid, 2-hydroxy ethyl ester, was approximately 6% of the applied. At least 15 additional non-volatile compounds were isolated at 10% of the applied but were not identified. Organic volatiles were 1.6% of the applied. The guideline requirement for triclopyr BEE is fulfilled (GLN 161-2; MRID 43007601).

Photodegradation on soil:

The Agency has no acceptable data on photodegradation on soil for either the acid, BEE or TEA. Information on the photodegradation on soil is required for the acid; data are currently in review. This data requirement has been waived for BEE and TEA since both quickly degrade to the acid. Information on the acid will fulfill the 161-3 data requirement.

Photodegradation in air:

No data were reviewed for photodegradation in air (GLN 161-4). The requirement for this environmental fate study was waived due to the low vapor pressures of technical triclopyr, triclopyr BEE, and triclopyr TEA. These are 1.26 x 10⁻⁶ Torr [WSSA, 1989], 3.6 x 10⁻⁶ Torr [MRIDs 40557003 and 42443402], and < 1 x 10⁻⁸ mm Hg [MRID 41219104], respectively. The low vapor pressures and the small Henry's Law constants (which are indicators of the low tendency for the material to volatilize from water; estimated to be 9.65 x 10⁻¹⁰, 2.47 x 10⁻⁷, and 1.15 x 10⁻¹⁴ atm-m³ mol⁻¹ for triclopyr, triclopyr BEE, and triclopyr TEA, respectively) indicate that volatilization and subsequent photodegradation in air would not be a significant route of dissipation for triclopyr TEA and BEE.

Aerobic Soil Metabolism

Under aerobic soil metabolism conditions, **triclopyr acid**, at 1 ppm, degraded with half-lives of 8 and 18 days in silty clay loam and silt loam soils, respectively. The non-volatile degradates observed during the study were 3,5,6-trichloro-2-pyridinol (TCP) and 3,5,6-trichloro-2-methoxypyridine (TMP); they were not persistent (maximum concentrations of 26 and 8%, respectively, were seen after <30 days of incubation. The ultimate degradate was carbon dioxide (at 300 days posttreatment, approximately 70 and 80% of the applied radioactivity in the silt loam and silty clay soils, respectively). The guideline requirement for the triclopyr acid is fulfilled (GLN 162-1, MRID 40346304).

[¹⁴C-1-ethyl]triethylamine hydrochloride, at 5.03 µg/g degraded with first order half-lives of 5.6 and 13.7 days from a sandy loam and a silt loam soil, respectively, incubated under aerobic conditions at 25 °C for 182 days. The major degradation product was ¹⁴CO₂, which was >60% of the applied by 24 days after treatment in the sandy loam and 91 days after treatment in the silt loam. A second degradate was observed at a maximum of 8% at 7 days after treatment in the sandy loam and 37% at 24 days after treatment in the silt loam. This metabolite decreased rapidly to low (<2.5%) levels in both soils. Efforts to obtain a definitive identification for this metabolite were unsuccessful. The guideline requirement for the **TEA moiety** is fulfilled (GLN 162-1, MRID 43837501).

Radiolabeled [¹⁴C-1-butyl] **2-butoxyethanol**, at 6 µg/g, degraded with calculated first-order half-lives of 0.9 hours (0.375 days) from Hanford sandy loam and 1.4 hours (0.058 days) from Commerce silt loam incubated under aerobic conditions at 25 °C for 4 and 10 days, respectively. The intermediate metabolite was 2-butoxyacetic acid, which comprised 85.1-101.0% of the applied at 4-24 hours posttreatment. It was rapidly metabolized to the major degradation product, ¹⁴CO₂, which reached a maximum of approximately 50% of the applied by 96 hours (4 days) after treatment in the Hanford sandy loam and approximately 50% of the applied by 10 days after treatment in the Commerce silt loam. Unextracted [¹⁴C]residues were a maximum of 19% in both soils at 4 and 10 days, respectively. The guideline requirement for the **BEE moiety** is fulfilled (GLN 162-1, MRID 43799101).

Anaerobic Soil Metabolism

This data requirement is fulfilled by the 162-3 study (see below).

Anaerobic Aquatic Metabolism

Triclopyr BEE degraded quantitatively to triclopyr acid in less than one day (approximately 5 hours) in two sandy loam soils incubated anaerobically (flooding plus nitrogen) for 30 days prior to pesticide addition. **Triclopyr acid** was then persistent under anaerobic conditions, decreasing to approximately 80% of the applied after 365 days. The registrant calculated a half-life of 1300 days; however, confidence in this value is limited because of the extrapolation outside the duration of the study. The only identified degradate was TCP at maximum concentrations of approximately 25% of the applied at 365 days posttreatment; the majority of the radioactivity was associated with the floodwater. The guideline requirements for **both triclopyr acid and BEE triclopyr** are fulfilled by this study (GLN 162-3; MRID 00151967).

[¹⁴C-1-ethyl]Triethylamine hydrochloride (TEA-HCl), applied at a nominal concentration of 1.36 µg/mL in water, degraded with a calculated half-life of 2 years in an anaerobic (flooding plus nitrogen atmosphere; E_{h7} values of -139 to -296 mV) sediment-water system. TEA was equally distributed between the water and sediment extracts; 10-19% of the applied [¹⁴C] remained bound to the sediment after extraction with organic solvents. Volatiles

were less than 1% of the applied radioactivity through 6 months (the duration of the study). The guideline requirement for the **TEA moiety** is fulfilled (GLN 162-3; MRID 43837502).

Radiolabeled [¹⁴C-1-butyl] **2-butoxyethanol** degraded with a calculated first order half-life of 1.4 days in a sediment/water mixture (554.1 µg 2-butoxyethanol in 50 g sediment/129.9 mL pond water) incubated under anaerobic conditions (flooded plus nitrogen atmosphere; dissolved oxygen content 0.3 mg/L, E_{h7} -200 mV) at 25 °C for 193 days. The intermediate metabolite, 2-butoxyacetic acid, comprised a maximum of 71.8% of the applied at 7 days posttreatment, and declined with an observed half-life of 73.3 days. The ultimate degradation product was ¹⁴CO₂, which was 57.4% of the applied at the termination of the study (193 days after treatment). Unextracted [¹⁴C]residues were a maximum of 9.9% at 29 days posttreatment. The guideline requirement for the **BEE moiety** is fulfilled (GLN 162-3, MRID 43799103).

Aerobic Aquatic Metabolism

Triclopyr acid degraded slowly (t_{1/2} = 142 days) in a silty clay soil:water system incubated aerobically for 30 days. The only degradate observed was 3,5,6-trichloro-2-pyridinol (TCP) at <5% of the amount applied at 30 days; however, the study was not conducted for a sufficient duration to adequately describe the formation and decline of the degradate TCP. Additional information on the aerobic aquatic metabolism of TCP is required. The guideline requirement for **triclopyr acid** is partially fulfilled (GLN 162-4; MRID 40479101).

[¹⁴C-1-Ethyl]**triethylamine hydrochloride** (TEA-HCl; nominal concentration of 1.33 µg/mL in water) did not appreciably degrade during the first 14 days after application to an aerobic sediment-water system. By 18 days posttreatment (the next sampling interval), TEA-HCl had decreased to approximately 5% of the initial application. In addition, up until 14 days posttreatment, <2% of the radioactivity had been evolved as ¹⁴CO₂, and < 5% was unextractable residues. By 18 days posttreatment (the next sampling interval), >60% of the radioactivity had evolved as ¹⁴CO₂, and approximately 25% was bound to sediment. Dissolved O₂ levels decreased substantially at the beginning of the study from 6.5-6.7 ppm at 0 days after treatment to <2 ppm at 1-7 days after treatment. The guideline requirement for the **TEA moiety** is partially fulfilled (GLN 162-4, MRID 43837503).

Radiolabeled [¹⁴C-1-butyl] **2-butoxyethanol**, at an application rate of 427 µg 2-butoxyethanol added to 10 g sediment plus 106 mL water, degraded with a first order half-life of 0.6-3.4 days in a moist sediment/water mixture incubated under aerobic conditions at 25 °C for 10 days. The intermediate metabolite, 2-butoxyacetic acid, comprised a maximum of 53.9% of the applied at 3 days posttreatment, and declined with an observed half-life of approximately 1 day. The ultimate degradation product was ¹⁴CO₂, which was 69.0% of the applied at 10 days after treatment. Unextracted [¹⁴C]residues were a maximum of 9.9% at 10 days posttreatment. The guideline requirement for the **BEE moiety** is partially fulfilled (GLN 162-4, MRID 43799106).

c. Mobility

Mobility studies are not required for the TEA or BEE moieties because of their rapid degradation in soils.

Adsorption/desorption studies

Based on adsorption/desorption studies using sand, sandy loam, silt loam, and clay loam soils, unaged **triclopyr acid** was very mobile. Freundlich K_{ads} values ranged from 0.165 to 0.975 mL/g; K_{oc} s were 25-384 mL/g. Adsorption was not correlated with CEC or organic carbon content. The guideline requirement for unaged triclopyr acid is fulfilled (GLN 163-1; MRID 40749801).

Supplemental information from this same study indicate that **triclopyr acid residues** were also very mobile after 15 and 30 days aging periods. Estimated K_{oc} values for the degradate 3,5,6-trichloro-2-pyridinol (TCP) ranged from 14 to 86 mL/g (MRID 40749801).

3,5,6-Trichloro-2-pyridinol (TCP), a major degradate of triclopyr, was very mobile in sand, sandy loam, silt loam, and clay loam soils with Freundlich K_{ads} values of 0.53-1.95 mL/g. The guideline requirement for aged triclopyr acid is fulfilled (GLN 163-1; MRID 42493901).

Volatility studies

No laboratory volatility (GLN 163-2) or field volatility (GLN 163-3) studies were reviewed for triclopyr derivatives (there are no end use products containing triclopyr acid). The requirement for this environmental fate study was waived due to the low vapor pressures of technical triclopyr, triclopyr BEE, and triclopyr TEA (1.26×10^{-6} Torr [WSSA, 1989], 3.6×10^{-6} Torr [MRIDs 40557003 and 42443402], and $< 1 \times 10^{-8}$ mm Hg [MRID 41219104], respectively). The low vapor pressures and the small Henry's Law constants (which are indicators of the low tendency for the material to volatilize from water; estimated to be 9.65×10^{-10} , 2.47×10^{-7} , and 1.15×10^{-14} atm-m³ mol⁻¹ for triclopyr, triclopyr BEE, and triclopyr TEA, respectively) indicate that volatilization would not be a significant route of dissipation for triclopyr derivatives.

(1) Accumulation

No fully acceptable laboratory bioaccumulation in fish (GLN 165-4) or accumulation in aquatic non-target organisms (GLN 165-5) studies have been reviewed for triclopyr derivatives.

However, the requirement for these environmental fate studies were waived for triclopyr TEA due to its low octanol/water partition coefficient ($K_{ow} < 5$, MRID 41219101). In addition, since triclopyr BEE degrades rapidly to the acid in natural waters (half-life 0.5 days; MRID 00134174), it can also be assumed to not bioaccumulate. Information contained in supplemental studies (Acc.nos. 073872 and 229782) showed that only slight bioaccumulation (<10x) was

observed for triclopyr acid and its degradate TCP. The data requirement has therefore also been waived for triclopyr BEE.

(2) Field Dissipation

Field dissipation studies are not required for triclopyr acid since there are currently no registered end use products containing triclopyr acid.

Terrestrial - Triclopyr BEE

Triclopyr BEE was applied at 8.1 lb ae/A (Garlon 4, 44.3% EC) to a bareground plot of sandy loam soil in North Carolina. Triclopyr BEE degraded to triclopyr acid with a registrant-calculated half-life of 1.1 days from the 0- to 7.5-cm soil depth. Triclopyr BEE was detected only in the 0- to 7.5-cm depth and only until 7 days posttreatment. Total triclopyr (triclopyr BEE plus triclopyr acid) dissipated from the 0- to 7.5-cm soil depth with a registrant-calculated half-life of 10.6 days. Total triclopyr was detected at up to 0.14 ppm in the 15- to 30-cm depth at 4 weeks posttreatment; at all later sampling intervals, concentrations were 0.02 ppm. Total triclopyr was detected in the 30- to 45-cm depth at 7 days posttreatment at 0.04 ppm, declined to 0.03 ppm at 2 weeks posttreatment, and was not detected thereafter. Total triclopyr was not detected at depths greater than 45 cm.

Two degradates were monitored and recovered from the soil samples. 3,5,6-Trichloro-2-pyridinol (TCP, pyridinol) was 0.04-1.40 ppm immediately posttreatment and 0.11-0.49 ppm at 7 days in the 0- to 7.5-cm soil depth. TCP was first detected in the 7.5-to 15-cm depth at 3 days posttreatment at up to 0.11 ppm and was present at up to 0.13 ppm at 7 days. At two weeks posttreatment, the 0- to 15-cm segments contained up to 0.18 ppm TCP, increased to 0.33 ppm at 4 weeks, and then decreased to 0.06-0.09 ppm at 8 weeks. TCP then decreased slowly in the 0-15 cm soil depth to 0.02-0.03 at 52 weeks posttreatment. TCP was not detected below the 30-cm soil depth. 3,5,6-Trichloro-2-methoxypyridine (TMP, methoxypyridine) was 0.15-0.35 ppm immediately posttreatment and 0.05-0.17 ppm at 7 days in the 0- to 7.5-cm soil depth. TCP was first detected in the 7.5-to 15-cm depth at 3 days posttreatment at up to 0.05 ppm and was present at up to 0.04 ppm at 7 days. At two weeks posttreatment, the 0- to 15-cm segments contained up to 0.08 ppm TMP, increased to 0.09 ppm at 4 weeks, and then decreased to 0.03-0.05 ppm at 8 weeks. TCP then decreased slowly in the 0-15 cm soil depth to 0.02 at 52 weeks posttreatment. TMP was not detected below the 30-cm soil depth. (GLN 164-1, (MRID 43033401).

Total triclopyr (triclopyr BEE plus triclopyr acid) dissipated with an observed half-life of approximately 2 weeks in the 0- to 6-inch depth of a bare ground loam soil plot located in California that was treated with triclopyr butoxyethyl ester (TBEE; Garlon 4, 44.3% ae EC) at 6.4 lb ae/A. In the upper 6 inches of a "native short grass"-covered plot at the same site, total triclopyr dissipated with an observed half-life of 4-8 weeks and a "best fit" registrant-calculated half-life of 33 days. Two degradates were recovered from the soil: 3,5,6-trichloro-2-pyridinol

(TCP; pyridinol) and 3,5,6-trichloro-2-methoxypyridine (TMP; methoxypyridine). In the upper 6 inches TCP was a maximum of 0.067 ppm at 28 weeks in the unvegetated soil plot; TMP was a 0.05 ppm at all test intervals. In general, neither triclopyr nor its degradates were detected below the 6-inch soil depth. TCP and TMP residues generally averaged 0.01 ppm in soil segments collected from both the unvegetated and grassed plots below the 6-inch soil depth at all sampling intervals, with only one exception. (MRIDs 42730601 and 44039301). The guideline requirement for the use of triclopyr BEE on terrestrial field sites is fulfilled with these studies (GLN 164-1, MRID 43033401, and MRIDs 42730601 and 44039301).

Aquatic - Triclopyr TEA

Triclopyr (applied as the TEA salt at 27-30 lb ae/A) dissipated with half-lives of < 1 day in the surface and bottom water of plots (660 x 500 feet) located in Banks Lake, Washington, following surface (boat) and aerial (helicopter) application. The degradate 3,5,6-trichloro-2-pyridinol (TCP) was not detected (<0.05 ppm) in surface (1-foot depth) or bottom (3 feet above the bottom) waters at any sampling interval. Triclopyr and TCP were not detected in the sediment (<0.10 ppm and <0.05 ppm, respectively) at any interval. Samples were not analyzed for the degradate 3,5,6-trichloro-2-methoxypyridine (TMP; methoxypyridine). This study was declared scientifically sound, but it could not be used to fulfill data requirements because sustained high winds (10-15 mph, gusting to 20 mph) occurred immediately posttreatment. This was not representative of conditions that normally occur, and the atypical weather conditions possibly accelerated the dissipation and degradation of the test substance (MRID 41714305).

Triclopyr acid (applied as the TEA salt at 27-30 lb ae/A) dissipated with calculated half-lives of 0.5 and 3.5 days in the surface waters of 10-acre plots located in the Spring Creek arm of Lake Seminole, Georgia, following surface and aerial applications, respectively. The plots were approximately 65-75% covered with vegetation at time of application. The degradate 3,5,6-trichloro-2-pyridinol (TCP) was detected at 0.06-0.18 ppm in surface (1-foot depth) and bottom (3 feet above the bottom) waters 1 to 8 hours after application, but was not detected (<0.05 ppm) in surface or bottom water after 1 day posttreatment. Triclopyr was detected at up to 0.64 ppm in the sediment layer (up to 5-10 cm deep) immediately posttreatment, but was <0.10 ppm (detection limit) at all other sampling intervals; TCP was not detected in the sediment (<0.05 ppm) at any interval. Samples were not analyzed for the degradate 3,5,6-trichloro-2-methoxypyridine (TMP; methoxypyridine). Different rates of dissipation may have been due to water movement through the plots (the plot receiving the surface application was open on all sides and was < 0.5 miles from the main channel, while the plot receiving the aerial application was bounded on two sides by land and was 0.5-1.5 miles from the main channel. The guideline requirement for use of triclopyr TEA on aquatic weeds is partially fulfilled (GLN 164-2; MRIDs 41714304 and 42821301).

Triclopyr dissipated with observed half-lives of less than 12 days in the soil and less than 8 days in the flood waters of rice plots that were treated twice at 0.375 lb ae/A each time with the triethylamine salt of triclopyr (3,5,6-trichloro-2-pyridyloxyacetic acid). In May-June, 1994, rice

plots in Louisiana and Arkansas were treated at the 3-to-4 leaf stage (not flooded at time of application) and at 1/2-inch internode elongation (28 days after the first application; flooded). In the **flood waters** (plots flooded 5 days after first application), triclopyr dissipated with a "best fit" calculated half-life of 7.6 days at the AR site and 2.2 days at the LA site. At both sites, maximum residues of triclopyr in the flood water were found immediately after the second, direct application; calculated half-lives for dissipation following the second application were 1.8 days at the AR site and 3.4 days at the LA site. Triclopyr residues in the flood water by the end of the flood period were 0.015 ug/mL at the Arkansas site and 0.006 ug/mL at the Louisiana site. In the top 3 inches of the **soil**, triclopyr dissipated with a "best fit" registrant-calculated half-life of 7.6 days at the AR site and 2.9 days at the LA site. Soil concentrations were lower following the second, flooded application; calculated half-lives for triclopyr in the top 3 inches of flooded soil following the second application were 11.6 days at the AR site and 11.7 days at the LA site. Triclopyr residues in the soil by the end of the flood period were 0.026 ug/g at the Arkansas site and < LOQ (0.01 ppm) at the Louisiana site.

Two degradates, 3,5,6-trichloro-2-pyridinol (TCP; pyridinol) and 3,5,6-trichloro-2-methoxypyridine (TMP; methoxypyridine), were recovered from the water and the soil. The concentrations of pyridinol and methoxypyridine were greater in the flood waters following the second application of triclopyr TEA. Concentrations of pyridinol were approximately ten times greater than those of methoxypyridine at all sampling intervals. TCP persisted in the flood water of rice fields for up to 59 days following the second application of triclopyr TEA; TMP dissipated more rapidly. Pyridinol was found deeper in the soil in Arkansas than in Louisiana (down to 12 inches versus 9 inches); however, at all times, concentrations in the lower depths were near the limit of quantitation (0.01 ppm). The guideline requirement for the use of triclopyr TEA on rice is fulfilled. (GLN 164-2; MRIDs 43955901 and 44198101).

Forestry

Triclopyr BEE was aerially applied at a nominal rate of 3.84 kg ae/ha (Garlon 4, 480 g ae/L EC) to forested sites (trembling aspen and balsam poplar) in Ontario, Canada. Residues were recovered from water as triclopyr BEE, from sediment as triclopyr acid, and as total triclopyr (triclopyr BEE plus triclopyr) from foliage, soil, litter, aquatic plants, and fish. The degradate 3,5,6-trichloro-2-pyridinol (TCP) was detected on the foliage and in the soil, litter, aquatic plants and fish; TCP was not detected in water at any time. The degradate 2-methoxy-3,5,6-trichloropyridine (methoxypyridine) was detected only in the soil, and then only rarely at or near the detection limit (0.01 ppm).

Total triclopyr in foliage was >500 ppm at day 0; it decreased to approximately 200 ppm and stayed there for the next 29 days (last sampling interval), but variable data thereafter prevented calculation of a half-life. Total triclopyr (triclopyr BEE plus triclopyr) and TCP dissipated from the soil with half-lives of 26 and 85 days, respectively; in the soil, total triclopyr and TCP were detected as deep as 90 cm, and 2-methoxy-3,5,6-trichloropyridine was detected as deep as 30 cm.

Triclopyr BEE present due to overspray of the stream and transported between sampling locations in stream water hydrolyzed to triclopyr acid in a matter of hours (4-6 hours); the maximum observed concentration of triclopyr BEE was 0.35 ppm. Total triclopyr in aquatic plants decreased with a half-life of 4-11 days; TCP was very low. Total triclopyr depurated from fish with a half-life of 0.6 days; the maximum observed concentration of total triclopyr was 43 ppm in whole fish at day 0. No quantifiable levels of triclopyr BEE or TCP were found in sediment; triclopyr acid was not seen after day 3. (MRIDs 41445001 and 44039302)

Triclopyr BEE was aerially applied by helicopter to clearcut timberland in southwest Washington at a rate of 6 lb ae/A (Garlon 4; 4 lb ai/gallon EC) in 1991. Total triclopyr residues (triclopyr BEE + triclopyr) and its degradates 3,5,6-trichloro-2-pyridinol (TCP) and 3,5,6-trichloro-2-methoxypyridine (TMP) were detected on the foliage, leaf litter, pond sediment, and in scarified and litter-covered soil; only total triclopyr residues and TCP were found in stream sediment. Samples were not specifically analyzed for triclopyr BEE. Only total triclopyr residues were detected in the pond and stream waters. The registrant estimated half-lives for total triclopyr residues to be 96 days in exposed soil, and 37 days in unexposed soil. In the litter covered soil, there were sporadic detections of triclopyr acid through the 12-30 inch soil depth (approximately 30-76 cm); there were no detections below 30 inches throughout the study. TCP was detected through the 12-18 inch (30-46 cm) depth; there were no detections below 18 inches throughout the study. TMP was detected at up to approximately 0.4 ppm in the 0- to 6-inch soil depth, up to 0.05 ppm in the 6- to 12-inch soil depth, and was not detected below 12 inches in the litter covered or the scarified soils. Total triclopyr in foliage was 206-475 ppm at day 0; the estimated half-life for total triclopyr residues was 15 days. Other half-lives were 5 days in pond water, 24 days in pond sediment, and 20 days in leaf litter. The guideline requirement is fulfilled (GLN 164-3; MRIDs 41445001 and 44039302, and 43011601 and 44039301).

(3) Spray Drift

No spray drift data are required for the triclopyr acid because the registrant is not supporting the registration of any typical end use products containing the acid. No TEA- or BEE-triclopyr-specific studies were reviewed. Droplet size spectrum (GLN 201-1) and drift field evaluation (GLN 202-1) studies are required for triclopyr derivatives, since the different formulations may be applied by aircraft and it is estimated that there will be detrimental effects to non-target organisms due to drift. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. The Agency is evaluating these studies. In the interim and for this assessment of triclopyr derivatives, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The estimated drift rates at 100 feet downwind of the treated sites are 1% at the applied spray volume from ground applications and 5% from aerial

applications. After review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks of the application of products containing triclopyr TEA or BEE.

d. Water Resources

While triclopyr TEA and BEE are the forms applied, both readily form the acid. The acid and its degradate TCP are of concern in the ground water assessment. Triclopyr acid is somewhat persistent, with persistence increasing as it reaches deeper soil levels, where there are anaerobic conditions; it is also very mobile. TCP is both mobile and persistent. Pesticides with similar properties have been found in ground water. Due to the environmental fate characteristics of triclopyr acid, the Agency believes this chemical has a potential to leach to ground water.

(1) Ground Water

The Office of Pesticide Programs (OPP) evaluates the persistence and mobility of each pesticide for ground water concerns. If the data indicate that the parent and/or degradates are persistent and mobile, then a small-scale prospective ground water study may be requested. The basic triggering criteria include: 1) weight of the evidence from laboratory and field dissipation studies indicating that the pesticide has properties and characteristics similar to pesticides that are known to leach or have been detected in ground water; 2) movement of the parent or degradates 75-90 centimeters through the soil profile or plow layer in a field dissipation study or; 3) reports of detections in ground water from other monitoring studies and information about toxicity. In addition, use patterns, application rates, timing of application, potential acreage treated, depth to ground water, soil types, hydraulic gradient, and climate are also evaluated as part of the triggering criteria.

Persistence, mobility, and detections in ground water are also used to evaluate a chemical to determine whether its use should be restricted. A pesticide may be recommended for restricted use for ground water concerns if it exceeds one or more characteristics for each of the three factors (persistence, mobility, and detections).

Persistence and Mobility

Triclopyr was evaluated for persistence and mobility in relation to its potential to leach to ground water. Below is a summary of that evaluation.

Table 30: Mobility and Persistence of Triclopyr Relative to Restricted Use Criteria

Factors	Characteristic	Restricted use Criteria	Triclopyr BEE	Triclopyr TEA	TCP (degradate)
Persistence	Field dissipation half-life	> 3 weeks or	0.2 wks (1.1 d)	NA	> 3 weeks
	Lab-derived aerobic soil metabolism half-life	> 3 weeks or		1.1, 2.6 wks (8, 18 d.)	> 1 year
	Hydrolysis half-life	< 10% in 30 days or	18, 172, 5,000 % in 30 days	Stable	Stable
	Photolysis half-life (soil)	< 10% in 30 days and	NA	NA	< 1 day
Mobility	Soil adsorption: K_d	5 ml/g or		0.165 - 0.975 ml/g	0.53 - 1.95 ml/g
	Soil adsorption: K_{oc}	500 ml/g or		25 - 134 ml/g	77 - 242 ml/g
	Depth of leaching in field dissipation study	75 cm	45 cm		46, 90 cm

Shaded area indicates that parameter exceeds trigger.

NA indicates No Acceptable data

Ground Water Detections

To date, there has been limited monitoring for triclopyr in ground water in the United States. The "Pesticides in Ground Water Database" (Hoheisel et al., 1992) reports sampling for triclopyr in Maine, Texas, Virginia, and Vermont. A total of 379 wells were reported sampled in four states and 5 wells were found to contain triclopyr residues. One well in Texas contained 0.58 ppb triclopyr and four wells in Virginia were found to contain 0.006 to 0.018 ppb of triclopyr. A summary of this is presented below.

Table 31: Summary of Ground Water Detections

Factor	Characteristic	Restricted Use Criteria	Reported Detections
Detections	Number of wells per state with detections	25 wells in 4 or more states or	5 wells in 2 states
	Number of counties with detections > 10% of reference point	3 counties at >10% of MCL or HAL	No MCL or HA Established

Shaded area indicates that parameter exceeds trigger.

General Conclusions on Ground-Water Quality

Although the environmental fate data are incomplete, triclopyr exceeded the triggers for mobility and persistence used to recommend restricted use based on ground water concerns. Triclopyr does not meet the detection triggers for recommending restricted use because of limited monitoring data. To date, there has been limited monitoring for triclopyr residues in ground water in the United States (Hoheisel, et al., 1992). Three hundred and seventy-nine wells were reported as sampled for triclopyr. Five detections of triclopyr residues in ground water have been reported in two states. All were very low, the maximum concentration reported was 0.58 ppb.

Ground Water Reference Points

Triclopyr is currently not regulated under the Safe Drinking Water Act (SDWA). EPA's Office of Water has not established a Maximum Contaminant Level (MCL) or a Drinking Water Lifetime Health Advisory Level (HAL) for triclopyr in drinking water. An estimated HAL can be calculated from the Reference Dose. EFED estimates the Lifetime Adult HA for triclopyr to be 350 ppb. Public water supply systems are not required to sample and analyze for triclopyr.

Field Dissipation Study Summaries

A field dissipation study conducted in North Carolina found triclopyr residues at 30-40 ppb in the 30-45 cm soil sampling interval at 7 days and 2 weeks after treatment. In the same study, TCP residues were found at 30 ppb at the 30-45 cm soil sampling interval at 8 weeks after treatment. A California field dissipation study found the majority of the triclopyr residues in the 0-6 inch sampling interval, however there were also detections of the degradate TCP in all five composite samples at the 24-30 inch depth. Residues in these deeper samples ranged from 50 to 120 ppb. This data suggests there may be limited leaching of triclopyr and TCP under some conditions, however, this evidence is not strong enough to require a ground water study.

(2) Surface Water

Information from acceptable environmental fate studies discussed previously indicates triclopyr is non-persistent in surface waters (aquatic field dissipation half-lives of 0.5 and 3.5 days for surface and aerial applications, respectively for Lake Seminole, Georgia). In aqueous environments, triclopyr TEA salt dissolves rapidly (less than one minute) to triethanolamine and triclopyr acid, and triclopyr acid then dissociates to form the triclopyr anion ($pK_a = 2.93$). Laboratory studies indicate triclopyr is non-persistent (aqueous photolysis half-life of 8-9 hours for pH 7 sterile buffered solution; half-lives in river water ranging from 0.7-1.7 days). In aqueous systems, the hydrolysis of triclopyr BEE is base-catalyzed and varies from stable at acidic conditions (half-life of 84 days in sterile pH 5 solution) with decreased stability (half-life of 7 hours) observed under basic (pH 9) conditions. In natural waters, triclopyr BEE hydrolyzed rapidly (half-life of 0.5 days at pH 6.7) to triclopyr acid.

Triclopyr acid is stable to abiotic hydrolysis at pH 5, 7, and 9; however, photolytic degradation in aquatic environments is rapid. The vapor pressure and Henry's Law constant indicate triclopyr should not readily volatilize from surface water environments. Based on the Freundlich adsorption coefficients (K_{ads} range: 0.165-0.975 mL/g), triclopyr does not adsorb to soil and sediment particles, and may be transported in surface runoff waters. However, triclopyr is not predicted to persist in surface waters because of the rapid photolytic degradation in aquatic environments.

Monitoring information is not available from Storet, however there is partially acceptable and supplemental information from two forestry studies. Limited surface water monitoring data for triclopyr in stream and pond water was reported in a southwest Washington forestry dissipation field study (MRID #43011601). At 3 days post-treatment, triclopyr was measured at 23.2-25.1 $\mu\text{g/L}$ in stream water which was not directly treated. These data suggest triclopyr was transported to the stream location through spray drift associated with the aerial application. Triclopyr and its degradates TCP and TMP were not detected (detection limit of 10 $\mu\text{g/L}$ acid equivalents) at any other sampling intervals in the stream water. Two sediment samples contained 10.7-14.9 $\mu\text{g/Kg}$ at 3 days post-treatment. Triclopyr was measured in sediments at 26.4 and 12.6 $\mu\text{g/Kg}$ at 4 weeks and 3 months, respectively. For the pond water that was directly oversprayed with triclopyr, concentrations were 1.99-2.10 mg/L immediately posttreatment, 0.492 -0.776 mg/L at 7 days, 0.0345-0.0380 mg/L at 4 weeks, and <0.0100 mg/L (detection limit) from 3-8 months. In the pond sediment, triclopyr was 0.467-0.830 mg/Kg immediately posttreatment, 0.613-1.55 mg/Kg at 3 days post-application, 0.369-1.22 mg/Kg at 14 days, and 0.270-0.334 mg/Kg at 4 weeks.

Triclopyr BEE was aerially applied at a nominal rate of 3.84 kg ae/ha (Garlon 4, 480 g ae/L EC) to forested sites (trembling aspen and balsam poplar) in Ontario, Canada. Residues were recovered from water as triclopyr BEE, from sediment as triclopyr acid, and as r) from foliage, soil, litter, aquatic plants, and fish. The degradate 3,5,6-trichloro-2-pyridinol (TCP) was detected on the foliage and in the soil, litter, aquatic plants and fish; TCP was not detected in

water at any time. The degradate 2-methoxy-3,5,6-trichloropyridine (methoxypyridine) was detected only in the soil, and then only rarely at or near the detection limit (0.01 ppm).

Triclopyr BEE present due to overspray of the stream and transported between sampling locations in stream water hydrolyzed to triclopyr acid in a matter of hours (4-6 hours); the maximum observed concentration of triclopyr BEE was 0.35 ppm. Total triclopyr in aquatic plants decreased with a half-life of 4-11 days; TCP was very low. No quantifiable levels of triclopyr BEE or TCP were found in sediment; triclopyr acid was not seen after day 3.

In a supplemental journal article (Thompson et al., 1995) the environmental fate and ecological effects of triclopyr BEE were studied in a first-order forest stream in Ontario, Canada. Maximum concentrations of triclopyr BEE in stream water samples were 0.848 and 0.949 $\mu\text{g}/\text{mL}$ at two sampling locations at 10 and 20 minutes after direct injection into the stream. Triclopyr BEE dissipated rapidly, with stream water concentrations decreasing to below 0.1 $\mu\text{g}/\text{mL}$ within 60-70 minutes following injection. The study authors concluded flowing water systems such as the forested watershed monitored in this study would result in rapid dissipation of triclopyr BEE and triclopyr acid.

Expected Aquatic Concentrations

The Agency calculated generic EECs using the GENeric EXpected Environmental Concentration Program (GENEEC). These generic EECs are designed as a coarse screen and estimate expected concentrations from a few basic chemical parameters and pesticide product label application information. These estimated environmental concentrations are then used as an estimate of the exposure to nontarget aquatic animals in a first-tier screen for risk assessment (section C.3.(a)(2)).

GENEEC is a model designed to mimic a PRZM-EXAMS simulation. It uses a chemical's soil/water partition coefficient and various degradation and metabolic half-life values to estimate runoff from a 10-hectare field into a 1-hectare water body, 2 meters deep. GENEEC calculates generic estimated environmental concentration (GEEC) values that are used for both acute and chronic risk assessments. It considers reduction in dissolved pesticide concentration due to soil incorporation, degradation in soil before a rainfall event, adsorption of pesticide to soil or sediment, and degradation of the pesticide within the water body. It also accounts for direct deposition of spray drift onto the water body.

Input values were obtained from studies submitted to the Agency and the open literature and are discussed earlier in this document. The Agency assumed all applications were a single application at the maximum use rate for a site, with no soil incorporation. Spray drift at 100 feet downwind is assumed to be 1% of the application rate for ground applications and 5% of the application rate for aerial applications.

Because the TEA salt dissociates to the triclopyr acid and TEA within one minute of dissolving in water, it is expected that only the acid will be present in runoff from areas treated with triclopyr TEA. It is therefore appropriate to use the chemical and environmental fate data for triclopyr acid in the GENEEC program. The K_{oc} was estimated from the arithmetic mean of high and low values for triclopyr acid; the value for the aerobic soil metabolism half-life was the longer of the two available.

The following data were used for input into the GENEEC Program for the **TEA salt**:

- Soil Organic Carbon Partitioning Coefficient (K_{oc}): 204.
- Aerobic soil metabolism half-life: 18 days.
- Aerobic aquatic metabolism half-life: 142 days.
- Photolysis Half-life (at pH 7): 0.6 days.
- Water Solubility: 440 ppm.

Table 32: Estimated Environmental Concentrations (EEC) for Triclopyr TEA

Ground Application			
RATE (lbs ae/A)	PEAK EEC (ppb)	DAY 21 EEC (ppb)	Day 56 EEC (ppb)
1.0	30	25	19
3.158	95	80	61
9.0	270	227	173
12.12	364	305	233
Aerial Application			
6.0	186	156	119

The environmental fate data set is incomplete for the BEE ester; no data were available for either the aerobic soil or aerobic aquatic metabolism half-life. However, it was possible to generate GENEEC values by making the worst-case assumption that triclopyr BEE was stable to aerobic soil metabolism. The K_{oc} was a reported estimate for triclopyr BEE (Meylan and Howard, 1992).

The following values were used for input into the GENEEC Program for the **BEE ester**:

- Soil Organic Carbon Partitioning Coefficient (K_{oc}): 560
- Aerobic soil metabolism half-life: Stable (GENEEC input = 0)
- Aerobic aquatic metabolism half-life: No available data (GENEEC input = 0)
- Abiotic hydrolysis half-life (at pH 7): 8.7 days.
- Photolysis Half-life: 6.6 days.
- Water Solubility: 6.84 ppm.

Table 33: GENEEC Aquatic Estimated Environmental Concentrations for Triclopyr BEE

Ground Application	
RATE (lbs ae/A)	PEAK EEC (ppb)
1.0	19
3.0	57
8.0	152
12.0	228
Aerial Application	
1.5	30
8.0	160

In order to run GENEEC, a minimal input data set is required. An essential data input is the aerobic soil metabolism half-life. Since this value was not available for the BEE, the EECs in the above table reflect the assumption that triclopyr BEE was stable to aerobic soil metabolism. We know from other laboratory and field data that triclopyr BEE degrades in soil to triclopyr with a half-life of less than a day (half-life of 3 hours in laboratory soil, supplemental info from MRID 00134174; half-life of 1.1 days in field soil, MRID 43033401). These observations would indicate that the predicted peak EEC values for triclopyr BEE listed above are higher than what would be expected to occur in the environment.

In addition, as calculated above, any decrease in the estimated aquatic concentrations of triclopyr BEE with time would be due only to abiotic hydrolysis and photodegradation. We know that triclopyr BEE hydrolyzed to triclopyr acid/anion very rapidly in natural waters in the dark (half-life of 0.5 days, MRID 00134174); therefore, it is not expected that there will be any triclopyr BEE remaining in the model water body after only a few days. Therefore, the 21- and 56-day GEEC values generated during the running of GENEEC with the above parameters were not reported in the table above.

4. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Risk Quotients (RQs) and the Levels of Concern (LOCs):

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

$$\text{RISK QUOTIENT} = \frac{\text{EXPOSURE}}{\text{ECOTOXICITY}}$$

Risk quotients are then compared to OPP established levels of concern. These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. More specifically, the criteria indicate that a pesticide, when used as directed, has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories:

- o **acute high risk** - potential for acute risk is high; regulatory action may be warranted in addition to restricted use classification
- o **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification
- o **acute endangered species** - the potential for acute risk to endangered species is high; regulatory action may be warranted
- o **chronic risk** - the potential for chronic risk is high; regulatory action may be warranted

Currently, the Agency has no procedures for assessing chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

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 the results of short-term laboratory studies which assess acute effects are:

- LC₅₀ (fish and birds)
- LD₅₀ (birds and mammals)
- EC₅₀ (aquatic plants and invertebrates)

- EC₂₅ (terrestrial plants)
- EC₀₅ or NOEC (endangered plants)

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

- LOEC (birds, fish, and aquatic invertebrates)
- NOEC (birds, fish and aquatic invertebrates)
- MATC (fish and aquatic invertebrates)

Generally, 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, if the measured end point is reproduction or survivability then the NOEC is used.

Risk presumptions, along with the corresponding risk quotients and levels of concern, are tabulated below.

Table 34: Ecological Risk Presumptions, Risk Quotients and Levels of Concern

Risk Presumption	Risk Quotient	Level of Concern
Birds		
Acute High Risk	EEC^1/LC_{50} or $LD_{50}/sqft^{(2)}$ or LD_{50}/day^3	0.5
Acute Restricted Use	EEC/LC_{50} or $LD_{50}/sqft$ or LD_{50}/day (or $LD_{50} < 50$ mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or $LD_{50}/sqft$ or LD_{50}/day	0.1
Chronic Risk	$EEC/NOEC$	1
Wild Mammals		
Acute High Risk	EEC/LC_{50} or $LD_{50}/sqft$ or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or $LD_{50}/sqft$ or LD_{50}/day (or $LD_{50} < 50$ mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or $LD_{50}/sqft$ or LD_{50}/day	0.1
Chronic Risk	$EEC/NOEC$	1

¹ abbreviation for Estimated Environmental Concentration; designated as ppm in avian/mammalian food items

² $\frac{mg/ft^2}{LD_{50} * wt. of bird}$

³ $\frac{mg \text{ of toxicant consumed/day}}{LD_{50} * wt. of bird}$

Table 35: Aquatic Animals Risk Presumptions and Levels of Concern

Risk Presumption	Risk Quotient	Level of Concern
Acute High Risk	EEC ¹ /LC ₅₀ or EC ₅₀	0.5
Acute Restricted Use	EEC/LC ₅₀ or EC ₅₀	0.1
Acute Endangered Species	EEC/LC ₅₀ or EC ₅₀	0.05
Chronic Risk	EEC/MATC or NOEC	1

¹ abbreviation for Estimated Environmental Concentration; designated ppb/ppm in water

Table 36: Terrestrial and Semi-Aquatic Plant Risk Presumptions and LOCs

Risk Presumption	Risk Quotient	Level of Concern
Acute High Risk	EEC ¹ /EC ₂₅	1
Acute Endangered Species	EEC/EC ₀₅ or NOEC	1
Aquatic Plants		
Acute High Risk	EEC ² /EC ₅₀	1
Acute Endangered Species	EEC/EC ₀₅ or NOEC	1

¹ abbreviation for Estimated Environmental Concentration; designated lb ae/A

² abbreviation for Estimated Environmental Concentration; designated ppb/ppm in water

(1). Exposure and Risk to Nontarget Terrestrial Animals

For pesticides, such as triclopyr TEA and BEE, applied as a non-granular product (e.g. liquid, dust), the estimated environmental concentrations (EEC) on food items following product application are compared to LC₅₀ values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb ae/A are tabulated below.

Table 37: Predicted Environmental Concentrations on Terrestrial Foods

Food Items	EEC(ppm) Predicted Maximum Residue	EEC (ppm) Predicted Mean Residue
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants, and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

¹ Predicted maximum and mean residues are based upon a 1 lb ae/a application rate and are based on Hoerger and Kenaga (1973) as modified by Fletcher et al (1994).

For pesticides, such as triclopyr TEA, applied as a granular formulation, the estimated environmental concentrations (EEC) following product application is compared to LD₅₀s/ft² values to assess risk. Birds may be exposed to granular pesticides by intentionally or inadvertently ingesting granules when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules. The risk quotient for granular pesticides is calculated by dividing the milligrams active ingredient per square foot (mg ai/ft²) by the LD50 mg/ai/bird. Risk quotients are calculated by using a 178-gram bobwhite quail (Dunning 1984).

(a). Birds

Acute Risk

The acute risk quotients (RQ) for broadcast applications of non-granular products are tabulated below.

Table 38: EECs and Dietary Risk Quotients with Triclopyr TEA for Birds

Food Items	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
	1.0 lbs ae/A		1.5 lbs ae/A		3.185 lbsae/A		6.0 lbs ae/A		9.0 lbs ae/A		12.12 lbs ae/A	
Short Grass	240	0.04	360	0.07	757	0.14	1440	0.27	2160	0.40	2908	0.54
Long Grass	110	0.01	165	0.03	347	0.06	660	0.12	990	0.18	1333	0.25
Broad leaf Plants and Small Insects	135	0.02	202	0.04	426	0.08	810	0.15	1215	0.23	1636	0.31
Fruits, Pods, Seeds, Large Insects	15	0.00	22	0.00	47	0.01	90	0.02	135	0.02	181	0.03

Notes:

EECs are given in parts per million (PPM).

EECs reflect maximum predicted residues based on 1 lb ae/A application rate , based on hoerger and Kenage (1973) as modified by Fletcher, et al. (1994).

Most sensitive bird species (quail) LC50 = 11,622 ppm = 5357 ppm ae

Factor for conversion of ai to ae is 0.7125 , based upon the percentages of active ingredient to acid equivalents specified on product labels.

To calculate acid equivalents:

$$11,622 \text{ (LC50 most sensitive species)} \times 0.647 \text{ (\% ai in formulated product)} \times 0.7125 = 5357 \text{ ppm ae.}$$

The results for triclopyr TEA applications indicate the following :

" Acute levels of concern (LOC) were exceeded only for birds feeding on short grass with application of 12.12 lb ae/A.

" LOCs are exceeded for endangered species of birds at rates ≥ 3.185 lb ae/A for birds that feed on short grass and ≥ 6.0 lb ae/A for birds feeding on long grass, broadleaf plants, and small insects.

"LOCs are exceeded for restricted use candidate at rates of application ≥ 6.0 lb ae/A.

Table 39: EECs and Dietary RQs for Birds with Triclopyr BEE

Food Items	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
	1.0 lbs ae/A		1.5 lbs ae/A		8.0 lbs ae/A		12.0 lbs ae/A	
Short Grasses	240	0.06	360	0.09	1920	0.49	2880	0.74
Long Grasses	110	0.03	165	0.04	880	0.23	1320	0.34
Broadleaf Plants and Small Insects	135	0.03	202	0.05	1080	0.27	1620	0.42
Fruits, Pods, Seeds, Large Insects	15	0.00	22	0.01	120	0.03	180	0.05

Notes:

EECs are given in parts per million (ppm).

LC50 = 5401 ppm, equivalent to 3884 ppm ae.

Predicted maximum residues are based upon a 1 lb ae/a application rate and are based on Hoerger and Kenaga (1973) as modified by Fletcher et al (1994).

Factor for conversion of ai to ae is 0.7192, based upon the ratio of percentages of active ingredient to acid equivalents as specified on product labels.

The results for triclopyr BEE applications indicate the following:

" No acute levels of concern for avian species, on an acute dietary basis, are exceeded at ≤ 1.5 lbs ae/A application rates.

" The 8 lbs ae/A use rate exceeds the level of concern for restricted use on short grasses, long grasses, and broadleaf plants/small insects. Additionally, triclopyr BEE exceeds the levels of concern on short grasses, long grasses, and broadleaf plants/small insects for acute risk to endangered avian species.

" The 12 lbs ae/A use rate on short grasses exceeds the level of concern for high acute risk to non-target avian species. Additionally triclopyr BEE concentrations on long grasses, broadleaf plants and small insects exceed the level of concern for restricted use criteria. Triclopyr BEE concentrations on short and long grasses, broadleaf plants and small insects exceed the levels of concern for acute risk to endangered avian species.

Acute Exposure to Birds from Granular Formulation of Triclopyr TEA

The granular formulation of triclopyr TEA is used at 0.54 lb ae/A on turf (based on LUIS report) as a weed and feed formulation that is broadcast applied. The most sensitive single dose

LD₅₀ for triclopyr TEA was 2055 (3176 mg/kg x 64.7% formulation) mg ai/kg (1464 mg ae/kg) for the mallard duck.

The weight of a mallard duck is 1.082 kg (Dunning, 1984). LD₅₀ in mg ae/bird is 1,584 mg ae/bird as shown below.

$$\begin{aligned} \text{LD}_{50} &= 1464 \text{ mg ae/kg} \\ 1.082 \text{ kg} &= \text{mallard weight} \\ 1464 \text{ mg ae/kg} \times 1.082 \text{ kg/bird} &= 1,584 \text{ mg ae/mallard duck} \end{aligned}$$

The **milligrams per square foot** is calculated as follows:

$$0.54 \text{ lb ae/A for turf} \times (453590 \text{ mg/lb} \div 43560 \text{ ft}^2/\text{A}) = 5.6 \text{ mg/ft}^2$$

The **single dose LD₅₀ per square foot** is calculated as follows:

$$5.6 \text{ mg/ft}^2 / (1464 \text{ mg ae/kg} \times 1.082 \text{ kg/bird}) = 0.004 \text{ LD}_{50}/\text{ft}^2 \text{ per mallard bird}$$

The single dose LD₅₀/ft² of 0.004 does not exceed any level of concern.

Chronic Risk for TEA and BEE

The chronic risk quotients for broadcast applications of non-granular products are tabulated below.

Table 40: EECs and Chronic RQs with Triclopyr TEA for Birds

Food Items	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
	1.0 lbs ae/A		1.5 lbs ae/A		3.185 lbs ae/A		6.0 lbs ae/A		9.0 lbs ae/A		12.12 lbs ae/A	
Short Grasses	240	2.4	360	3.6	758	7.6	1440	14.4	2160	21.6	2908	29.1
Long Grasses	110	1.1	165	1.65	347	3.5	660	6.6	990	9.9	1333	13.3
Broadleaf Plants and Small Insects	135	1.35	202	2.0	426	4.3	810	8.1	1215	12.2	1636	16.4
Fruits, Pods, seeds, Large Insects	15	0.15	22	0.2	47	0.5	90	0.9	135	1.35	181	1.8

Notes:

EECs are given as parts per million (ppm).

Calculations are based on triclopyr acid NOEC = 100 ppm ae.

Predicted maximum residues are based upon a 1 lb ae/a application rate and are based on Hoerger and Kenaga (1973) as modified by Fletcher et al (1994).

The results for triclopyr TEA applications indicate the following:

" The chronic level of concern was exceeded for ≥ 9.0 lbs ae/A use rates for birds feeding on the fruits, pods, seeds, and large insect food items. However the chronic level of concern was exceeded for birds feeding on the other food items at all use rates.

" Chronic risk from granulars can not be estimated due to the uncertainties related to exposure. For example, no data are available to characterize the release rate of the pesticide from the granular base material (carrier).

Although there will be an initial level of triclopyr BEE that birds may be exposed to, triclopyr BEE rapidly hydrolyzes to triclopyr acid/anion in the environment. Chronic effects from a limited duration of exposure to triclopyr BEE are unknown. However, any effects from long term exposure due to the use of triclopyr in any form is probably due to the acid/anion. Therefore, the risk assessment will use the values for the triclopyr TEA (equivalent to the acid/anion) to estimate the chronic risk quotients for triclopyr BEE.

An avian reproduction study is not needed for triclopyr BEE.

(b). Mammals

Granular Products - Acute and Chronic Risk

The granular formulation of triclopyr TEA is used at 0.54 lb ae/A on turf (based on use information) as a weed and feed formulation that is broadcast applied. Mammalian data indicate that mammals are less sensitive to triclopyr than birds. Since it was determined that there is no risk to birds from the use of currently labeled granular products of triclopyr TEA, it is reasonable to assume that there will be no acute risk to mammal species from the use of the above granular products.

Chronic risk from granulars can not be estimated due to the reasons stated above.

Non-granular Products - Acute Risk

The assumptions of this analysis are:

The various forms of triclopyr are considered bioequivalent with regard to toxicity to mammals. Therefore, the rat LD₅₀ of 630 mg/kg will be used to assess acute risk to mammals for all forms of triclopyr.

Estimating the potential for adverse effects to wild mammals is based on a 1-day LC₅₀ calculated from the rat LD₅₀. The concentration of triclopyr in the diet which is expected to be acutely lethal to 50% of the test population (LC₅₀) is determined by dividing the LD₅₀ value (usually rat LD₅₀) by the percentage (decimal) of body weight consumed. It is assumed a young rat consumes approximately 10% of its body weight per day (Lehman, A. J., 1959). A risk quotient is then determined by dividing the EEC by the derived LC₅₀ value.

Exposure will be based on a nomograph developed from by Hoerger and Kenaga (1973) as modified by Fletcher et al. (1994).

Acute Assessment

The acute risk quotients for broadcast applications of non-granular products are tabulated below.

Table 41: Mammalian Acute RQ for Single Application of Triclopyr

Appl. Rate (lbs ae/A)	% Body Weight Consumed	1-Day LC ₅₀ (ppm)	EEC (PPM) Short Grass	EEC (PPM) Forage, Small Insects	EEC (PPM) Fruit, Pods, Large Insects	Acute RQ Short Grass	Acute RQ Forage & Small Insects	Acute RQ Fruit, Pods, Large Insects
12.12	10	6300	2,909	1,636	182	0.46	0.26	0.03

Table 41: Mammalian Acute RQ for Single Application of Triclopyr

Appl. Rate (lbs ae/A)	% Body Weight Consumed	1-Day LC ₅₀ (ppm)	EEC (PPM) Short Grass	EEC (PPM) Forage, Small Insects	EEC (PPM) Fruit, Pods, Large Insects	Acute RQ Short Grass	Acute RQ Forage & Small Insects	Acute RQ Fruit, Pods, Large Insects
9.0	10	6300	2,160	1,215	135	0.34	0.19	0.02
6.0	10	6300	1,440	810	90	0.23	0.13	0.01
3.185	10	6300	764	430	48	0.12	0.07	0.01
1.5	10	6300	360	203	23	0.06	0.03	0.00

Notes:

Calculations are based on a rat LD50 value of 630 mg/kg ae.

The equation for the RQ is:

$$\frac{EEC}{LC50} = \frac{EEC}{630 \text{ mg ae/kg/day} \times \left(\frac{0.10 \text{ kg body weight}}{0.010 \text{ kg food consumption}} \right)}$$

Small Mammal (herbivore/insectivore/granivore) Acute Assessment

- " The LOC for acute high risk for triclopyr is not exceeded at any of the rates of application.
- " There were LOC exceedences for the restricted use criteria on short grass at 12 lbs ae/A and on forage and small insects at use rates of 6 lbs ae/A and above.
- " There were LOC exceedences for acute risk to endangered species on short grass at the use rates of 3 lbs ae/A and above, and on forage and small insects at use rates of 6 lbs ae/A and above.
- " There were no LOC exceedences for fruits, pods, and large insects at any currently-registered use rate up to 12.12 lbs ae/A.

Mammalian Non-Granular Products Chronic Risk Assessment

The chronic risk quotients for broadcast applications of non-granular products are tabulated below.

Table 42: Mammalian Chronic RQs for Single Application of Triclopyr

Application Rate (lbs ae/A)	EEC (ppm) Short Grass	EEC (ppm) Forage, Small Insects	EEC (ppm) Fruit, Pods, Large Insects	Chronic RQ Short Grass	Chronic RQ Forage & Small Insects	Chronic RQ Fruit, Pods, Large Insects
12.12	2,909	1,636	182	11.64	6.54	0.73
9.0	2,160	1,215	135	8.64	4.86	0.54
6.0	1,440	810	90	5.76	3.24	0.36
3.185	764	430	48	3.06	1.72	0.19
1.5	360	203	23	1.44	0.81	0.09

Notes:

Calculations are based on a rat NOEL of 25 mg ae/kg/day (250 ppm/ae)

The equation for the RQ is:

$$\frac{\text{EEC}}{\text{LC50}} = \frac{\text{EEC}}{25 \text{ mg ae/kg/day} \times \left(\frac{0.10 \text{ kg body weight}}{0.010 \text{ kg food consumption}} \right)}$$

Conclusions - Small Mammal (herbivore/insectivore/granivore) Chronic Assessment

" The results, based on chronic RQ's on short grass, indicate that for broadcast applications of non-granular products, the chronic risk level of concern (1.0) is exceeded for small mammals at all use rates greater than and including the 1.5 lbs ae/A use rates.

" The results, based on chronic RQ's on forage and small insects, indicate that for broadcast applications of non-granular products the chronic risk level of concern (1.0) is exceeded at all use rates greater than and including the 3.185 lbs ae/A use rates.

" There were no chronic LOC exceedences for fruits, pods, and large insects at any currently-registered use rate up to 12.12 lbs ae/A.

(C). Insects

Currently, the Agency has no procedure for assessing risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions.

(2). Exposure and Risk to Nontarget Aquatic Animals

GENEEC:

The Agency calculated generic EECs using the GENeric Expected Environmental Concentration Program (GENEEC). The resultant GEECs are used as a first tier screen for assessing acute and chronic risks to aquatic organisms. Acute risk assessments are performed using either 0-day GEEC values (single application) or peak (GEEC) values (multiple application). Chronic risk assessments are performed using the 21-day GEECs for invertebrates and 56-day GEECs for fish. However, as discussed in section C.2.c.(3) under Expected Aquatic Concentrations, we do not expect any triclopyr BEE to remain in the water longer than a few days. Therefore, only acute assessment can be made for the triclopyr BEE. In all cases, a single application is assumed. GEECs are tabulated below.

Aquatic Exposure:

Triclopyr TEA has the following aquatic uses: Drainage systems, forestry, rights-of-way and rice. For these use patterns, EFED assumes simple dilution of the amount applied to a surface acre of water at depths varying from 6" to 6'. A 21-day and a 56-day EECs cannot be determined for the direct application to water scenarios.

Table 43: EECs for Aquatic Exposure to Triclopyr TEA

Site	Application Method	Application Rate (lbs ae/A)	Initial (PEAK) EEC (ppm)	21-day EEC (ppm)	56-day EEC (ppm)
GENEEC					
pastures, rangeland, non-agricultural rights-of ways, fencerows, hedgerows, nonagricultural uncultivated areas/soils	ground	12.12	0.364	0.305	0.233
non-agricultural rights-of-way, nonagricultural uncultivated areas/soils		9.0	0.270	0.277	0.173
pastures, rangeland		3.158	0.095	0.080	0.061
ornamental lawns and turf		1.5	0.045	0.0375	0.029
pastures, rangeland	aerial	6.0	0.185	0.156	0.11
DIRECT APPLICATION TO 6 INCHES OF WATER					
forest	aerial	4.0 ¹	2.936	N/A	N/A
drainage systems	ground ground	12 ¹	8.808	N/A	N/A
		9 ¹	6.606	N/A	N/A
rice	ground and aerial	0.375 ¹	0.275	N/A	N/A

1. EEC's are based on one direct application to 6 inches of water. EEC = use rate in lbs ae/A X 734 pbb

Table 44: EECs for Aquatic Exposure to Triclopyr BEE

Site	Application Method	Application Rate (lbs ae/A)	Initial (PEAK) EEC (ppm)
GENEEC			
agricultural/farm structures/buildings and equipment, fencerows/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.0	0.228
pastures, rangeland		8.0	0.152
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways/fencerows/hedgerows, non-agriculture uncultivated areas/soils		1.5	0.028
ornamental lawns and turf		1.0	0.019
non-agricultural rights-of-ways/fencerows/hedgerows	aerial	8.0	0.160
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways/fencerows/hedgerows, non-agriculture uncultivated areas/soils	aerial	1.5	0.03
DIRECT APPLICATION TO 6 INCHES OF WATER			
forest tree management/forest pest management	aerial, ground	3.0	2.202 ¹
forest tree management/forest pest management	aerial, ground	8.0	5.872 ¹
forest trees (all or unspecified)	ground	12.0	8.808 ¹
drainage systems	aerial	1.5	1.101 ¹
	ground	8	6.606 ¹
streams/rivers/channeled water	ground	12	8.808 ¹

1. EEC's are based on one direct application to 6 inches of water. EEC = use rate in lbs ae/A X 734 pbb

(a) Freshwater Fish

Acute and chronic risk quotients are tabulated below for Triclopyr TEA. A 21-day and a 56-day EECs cannot be determined for the direct application to water scenarios.

Table 45: Acute and Chronic RQs for Freshwater Fish with Triclopyr TEA

Site	Application Method	Application Rate in lbs ae/A	Peak EEC (ppm ae)	Acute RQ	56-day EEC (ppm ae)	Chronic RQ
pastures, rangeland, non-agricultural rights-of ways, fencerows, hedgerows, nonagricultural uncultivated areas/soils	ground	12.12	0.364	<0.05	0.233	< 1
non-agricultural rights-of-way, nonagricultural uncultivated areas/soils		9.0	0.270	<0.05	0.173	< 1
pastures, rangeland		3.158	0.095	<0.05	0.061	< 1
ornamental lawns and turf		1.5	0.045	<0.05	0.029	< 1
pastures, rangeland	aerial	6.0	0.185	<0.05	0.119	< 1
DIRECT APPLICATION TO 6 INCHES OF WATER						
forest	aerial	4.0	2.936	<0.05	N/A	N/A
drainage systems	ground	12 .0	8.808	<0.05	N/A	N/A
	ground	9.0	6.606	<0.05	N/A	N/A
rice	ground and aerial	0.375	0.275	<0.05	N/A	N/A

Notes:

Calculations based on fathead minnow LC50 = 279 ppm ai and MATC = 130 ppm ai, equivalent to 199 ppm ae and 93ppm ae, respectively.

Factor for conversion of ai to ae is 0.7125, based upon the ratio of percentages of active ingredient to acid equivalents as specified on product labels

Acute

The results indicate that acute high risk, restricted use, and endangered species levels of concern are not exceeded for freshwater fish at registered maximum application rates of Triclopyr TEA.

Chronic

Based on the MATC from the fathead minnow early life-stage (130 ppm (mg/L)) and the 56-day average GENEEC, no chronic risk levels of concern for freshwater fish are exceeded at any of these use application rates and use patterns.

Acute risk quotients are tabulated below for Triclopyr BEE.

Table 46: Acute Freshwater Fish RQs for Triclopyr BEE

Site	Application Method	Application Rate lbs ae/A	Peak EEC (ppm ae)	Acute RQ
agricultural/farm structures/buildings and equipment, fencerows/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.0	0.228	0.91
pastures, rangeland		8.0	0.152	0.61
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways/fencerows/hedgerows, non-agriculture uncultivated areas/soils		1.5	0.028	0.11
ornamental lawns and turf		1.0	0.019	0.08
non-agricultural rights-of-ways/fencerows/hedgerows	aerial	8.0	0.160	0.64
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways/fencerows/hedgerows, non-agriculture uncultivated areas/soils	aerial	1.5	0.03	0.1
DIRECT APPLICATION TO 6 INCHES OF WATER				
forest tree management/forest pest management	aerial, ground	3.0	2.202 ¹	8.81
forest tree management/forest pest management	aerial, ground	8.0	5.872 ¹	23.49
forest trees (all or unspecified)	ground	12.0	8.808 ¹	35.23
drainage systems	aerial	1.5	1.101 ¹	4.40
	ground	8	6.606 ¹	26.42
streams/rivers/channeled water	ground	12	8.808 ¹	35.23

1. EECs are based on one direct application to 6 inches of water. EEC = use rate in lbs ae/A X 734 pbb

Notes:

Calculations based on *L. macrochirus* LC50 of 0.36 ppm ai, equivalent to 0.25 ppm ae.

Factor for conversion of ai to ae is 0.7192, based upon the ratio of percentages of active ingredient to acid equivalents as specified on product labels.

Acute

The results indicate the acute high risk level of concern is exceeded for freshwater fish at the maximum application rates for all the forest and direct application to water uses of Triclopyr BEE. Additionally, the 8 lbs ae/A and 12 ae/A use rates for ground application, and the 8.0 lbs ae/A use rate for aerial application exceed the LOC for acute high risk.

The level of concern for risk that may be mitigated through restricted use was exceeded by the 1.5 lbs ae/A ground application rate, and the 1.5 lbs ae/A aerial application rate.

The level of concern for risk to endangered species was exceeded by the 1.0 lbs ae/A ground application rate.

Chronic

Although there is a calculated MATC available for the BEE for rainbow trout early life-stage (0.0388 ppm), the nature of the study design was that the organisms were continuously exposed to BEE at a constant concentration in a flow-thru system. Because BEE will not persist as such in the environment following a single application (see GENEEC discussion), the toxicity level found in this study does not reflect the probable effect of BEE on organisms in the environment. Chronic effects may be unlikely from a single application of triclopyr BEE. However, it is possible that the triclopyr degradate, TCP, may have a chronic adverse impact on fish species because laboratory and field data indicate that the TCP may be persistent in aqueous environments at concentrations greater than 1% of the LC₅₀.

(b). Freshwater Invertebrates

The acute and chronic risk quotients for triclopyr TEA are tabulated below.

Table 47: Acute and Chronic Freshwater Invertebrate RQs for Triclopyr TEA

Site	Application Method	Application Rate in lbs ae/A	Peak EEC (ppm ae)	21-day EEC (ppm ae)	Acute RQ	Chronic RQ
pastures, rangeland, non-agricultural rights-of ways, fencerows, hedgerows, nonagricultural uncultivated areas/soils	ground	12.12	0.364	0.305	0.05	1.00
non-agricultural rights-of-way, nonagricultural uncultivated areas/soils		9.0	0.270	0.277	0.05	1.00
pastures, rangeland		3.158	0.095	0.080	0.05	1.00
ornamental lawns and turf		1.5	0.045	0.0375	0.05	1.00
pastures, rangeland		aerial	6.0	0.185	0.156	0.05
DIRECT APPLICATION TO 6 INCHES OF WATER						
forest	aerial	4.0	2.936	N/A	0.05	N/A
drainage systems	ground	12.0	8.808	N/A	0.05	N/A
	ground	9.0	6.606	N/A	0.05	N/A
rice	ground and aerial	0.375	0.275	N/A	0.05	N/A

Notes:

Calculations based on *Daphnia magna* LC50 = 775 ppm ai and MATC = 110 ppm ai, equivalent to 357 ppm ae and 79 ppm ae, respectively.

Factor for conversion of ai to ae is 0.7125, based upon the ratio of percentages of active ingredient to acid equivalents as specified on product labels.

Acute

The results indicate that acute high risk, restricted use, and endangered species levels of concern are not exceeded for freshwater invertebrate at registered maximum application rates of Triclopyr TEA.

Chronic

Based on the MATC from the *Daphnia magna* aquatic invertebrate life-cycle study (110 ppm) and the 21-day average GENEEC, no chronic risk levels of concern for freshwater invertebrates are exceeded at any of these application rates and use patterns.

The acute risk quotients for triclopyr BEE are tabulated below:

Table 48: Acute Freshwater Invertebrate RQs for Triclopyr BEE

Site	Application Method	Application Rate lbs ae/A	Peak EEC (ppm ae)	Acute RQ
agricultural/farm structures/buildings and equipment, fencerows/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.0	0.228	0.03
pastures, rangeland		8.0	0.152	0.02
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agriculture uncultivated areas/soils		1.5	0.028	0.00
ornamental lawns and turf		1.0	0.019	0.00
non-agricultural rights-of-way/fencerows/hedgerows	aerial	8.0	0.160	0.02
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agriculture uncultivated areas/soils	aerial	1.5	0.03	0.00
DIRECT APPLICATION TO 6 INCHES OF WATER				
forest tree management/forest pest management	aerial, ground	3.0	2.202	0.26
forest tree management/forest pest management	aerial, ground	8.0	5.872	0.68
forest trees (all or unspecified)	ground	12.0	8.808	1.02
drainage systems	aerial	1.5	1.101	0.13
	ground	8.0	6.606	0.77
streams/rivers/channeled water	ground	12.0	8.808	1.02

Notes:

Calculations are based on *Daphnia magna* LC₅₀= 12.0 ppm ai; equivalent to 8.6 ppm ae.

EEC's are based on one direct application to 6 inches of water. EEC = use rate in lbs ae/A X 734 pbb.

Factor for conversion of ai to ae is 0.7192, based upon the ratio of percentages of active ingredient to acid equivalents as specified on product labels.

Acute

The results indicate that the high acute risk level of concern is exceeded for freshwater invertebrates at the application rates of 8.0 lbs ae/A and 12 lbs ae/A uses rate for forest trees (all

or unspecified), and the 8 lbs ae/A use rate for drainage systems and the 12 lbs ae/A use rate for streams/rivers/channeled water uses of Triclopyr BEE.

The level of concern for risk that may be mitigated through restricted use was exceeded at the 1.5 lbs ae/A use rate for forestry use and the 1.5 lbs ae/A use rate on drainage systems.

Chronic

A chronic risk assessment for triclopyr BEE was not done because BEE will not persist as such in the environment following a single application (see GENEEC discussion).

(c). Estuarine and Marine Animals

Triclopyr TEA is similar in acute and chronic toxicity to freshwater and estuarine/marine animals. Therefore, the acute and chronic risk is presumed to be similar to that for freshwater animals; i.e., the acute high risk, chronic risk, restricted use, and endangered species levels of concern are not exceeded for estuarine/marine invertebrates and fish at registered maximum application rates of Triclopyr TEA.

Triclopyr BEE is similar in acute toxicity to freshwater and estuarine/marine animals. Therefore, the acute risk to estuarine/marine organisms from triclopyr BEE is presumed to be similar to that for freshwater animals; i.e., the high acute risk level of concern is exceeded for freshwater fish at the maximum application rates for all the forest and direct application to water uses of Triclopyr BEE.

A chronic estuarine/marine risk assessment for triclopyr BEE was not done because BEE will not persist as such in the environment following a single application (see GENEEC discussion).

(3). Exposure and Risk to Nontarget Plants

Terrestrial and Semi-aquatic

a). Terrestrial and Semi-aquatic

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:

- based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one inch,

- characterized as "sheet runoff" (one treated acre to an adjacent acre) for terrestrial plants,
- characterized as "channelized runoff" (10 treated acres to a distant low-lying acre) for plants inhabiting semi-aquatic area, and
- based on % runoff values of 1, 2, and 5 for water solubility of <10 ppm, 10-100 ppm, and >100 ppm, respectively.

Spray drift exposure from ground application is assumed to be 1% of the application rate. Spray drift from aerial applications is assumed to be 5% of the application rate. EECs are calculated for unincorporated ground and aerial applications. Estimated environmental concentrations for terrestrial plants are tabulated below.

Table 49: EECs for Terrestrial and Semi-Aquatic Plants for Triclopyr TEA with 5% Runoff

Site	Method	Appl. Rate (lb ae/A)	Sheet Run-off (lb ae/A)	Channelized Run-off (lb ae/A)	Drift (lb ae/A)	Total Loading Adjacent Area (lb ae/A) ¹	Total Loading to Semi-aquatic Area (lb ae/A) ²
pastures, rangeland, fencerow/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground		0.61	6.10	0.12	0.73	6.22
non-agricultural rights-of-way, non-agriculture uncultivated areas/soils		9.0	0.45	4.50	0.09	0.54	4.59
pastures, rangeland		3.158	0.16	1.60	0.03	0.19	1.63
ornamental lawns and turf		1.5	0.08	0.80	0.02	0.10	0.82
pastures, rangeland	aerial	6.0	0.18	1.80	0.30	0.48	2.10
forestry	aerial	4.00	0.12	1.20	0.20	0.32	1.40
drainage systems	ground	12.0	0.60	6.00	0.12	0.72	6.12
	ground	9.0	0.45	4.50	0.09	0.54	4.59
rice	aerial	0.375	0.01	0.11	0.02	0.03	0.13
	ground	0.375	0.02	0.19	0.00	0.02	0.21

1. This total loading is comprised of Sheet Run-off + Drift.
2. This total loading is comprised of Channel Run-off + Drift.

Table 50: EECs for Terrestrial and Semi-Aquatic Plants for Triclopyr BEE with 1% Runoff

Site	Method	Appl. Rate (lb ae/A)	Sheet Run-off (lb ae/A)	Channel Run-off (lb ae/A)	Drift (lb ae/A)	Total Loading to Adjacent Area (lb ae/A) ¹	Total Loading to Semi-aquatic Area (lb ae/A) ²
agricultural/farm structures/ buildings and equipment, fencerow/ hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.0	0.12	1.20	0.12	0.24	1.32
pastures, rangeland		8.0	0.08	0.80	0.08	0.16	0.88
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agricultural uncultivated areas/soils		1.5	0.02	0.20	0.02	0.04	0.22
ornamental lawns and turf		1.0	0.01	0.10	0.01	0.02	0.11
non-agricultural rights-of-ways, fencerows/hedgerows	aerial	8.0	0.05	0.48	0.40	0.45	0.88
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways, fencerow/ hedgerows, non-agriculture uncultivated areas/soils		1.5	0.01	0.09	0.08	0.09	0.17
forest tree management/forest pest management	aerial	3.0	0.02	0.18	0.15	0.17	0.33
	ground	3.0	0.03	0.30	0.03	0.06	0.33
forest tree management/forest pest management	aerial	8.0	0.05	0.48	0.40	0.45	0.88
	ground	8.0	0.08	0.80	0.08	0.16	0.88
forest trees (all or unspecified)	ground	12.0	0.12	1.20	0.12	0.24	1.32
drainage systems	aerial	1.5	0.01	0.09	0.08	0.09	0.17
	ground	8.0	0.08	0.80	0.08	0.16	0.88
streams/rivers/channeled water	ground	12.0	0.12	1.20	0.12	0.24	1.32

1. This total loading is comprised of Sheet Run-off + Drift.
2. This total loading is comprised of Channelized Run-off + Drift.

The EC₂₅ value of the most sensitive species in the seedling emergence study is compared to runoff exposure to determine the risk quotient (EEC/toxicity value). The EC₂₅ value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the acute risk quotient.

Acute risk quotients are tabulated below.

Table 51: Acute RQs for Plants in Terrestrial and Semi-Aquatic Areas for Triclopyr TEA

Site	Appl. Method	Appl. Rate in lbs ae/A	Drift (lbs ae/A)	Total Loading to Adjacent Area (lbs ae/A)	Total Loading to Semi-aquatic Area (lb ae/A)	RQ of Runoff to Adjacent Area	RQ of Runoff to Semi-Aquatic Area	RQ of Spray Drift to Plant
pastures, rangeland, fencerow/hedge rows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.12	0.12	0.73	6.22	3.10	26.20	22.20
non-agricultural rights-of-way, non-agriculture uncultivated areas/soils		9.0	0.09	0.54	4.59	2.30	19.30	16.70
pastures, rangeland		3.185	0.03	0.19	1.63	0.80	6.90	5.60
ornamental lawns and turf		1.5	0.02	0.10	0.82	0.40	3.40	3.70
pastures, rangeland	aerial	6.0	0.30	0.48	2.10	2.00	8.80	55.60
forestry		4.0	0.20	0.32	1.40	1.30	5.90	37.00
drainage systems	ground	12.0	0.12	0.72	6.12	3.00	25.80	22.20
drainage systems		9.0	0.09	0.54	4.59	2.30	19.30	16.70
rice	aerial	0.375	0.02	0.03	0.13	0.10	0.50	3.70
rice	ground	0.375	0.00	0.02	0.21	0.10	0.90	1.00

Notes:

Calculations are based on seedling emergence endpoint value for corn = 0.333 lbs ai/A and a sunflower vegetative vigor endpoint = 0.0076 lbs ai/A, equivalent to 0.2373 lbs ae/A and 0.0054 lbs ae/A, respectively.

Factor for conversion of ai to ae is 0.7125 lb ae/A, based upon the ratio of percentages of active ingredients to acid equivalents as specified on product labels.

Table 52: Acute RQs for Plants in Terrestrial and Semi-Aquatic Areas for Triclopyr BEE

Site	Appl. Method	Application Rate in lbs ae/A	Drift (lb ae/A)	Total Loading to Adjacent Area (lb ae/A)	Total Loading to Semi-aquatic Area (lb ae/A)	RQ of Runoff to Adjacent Area	RQ of Runoff to Semi-Aquatic Area	RQ of Spray Drift to Plant
agricultural/farm structures/buildings and equipment, fencerow/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils	ground	12.0	0.12	0.24	1.32	5.40	29.50	18.80
pastures and rangeland		8.0	0.08	0.16	0.88	3.60	19.70	12.50
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways, fencerows, hedgerows, non-agriculture uncultivated areas/soils		1.5	0.02	0.04	0.22	0.90	4.90	3.10
ornamental lawns and turf		1.0	0.01	0.02	0.11	0.40	2.50	1.60
non-agricultural rights-of-ways, fencerows /hedgerows	aerial	8.0	0.40	0.45	0.88	10.10	19.60	62.50
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways, fencerow, hedgerows, non-agriculture uncultivated areas/soils		1.5	0.08	0.09	0.17	2.00	3.80	12.50
forest tree management/forest pest management		3.0	0.15	0.17	0.33	3.80	7.40	23.40
forest tree management/forest pest management	ground	3.0	0.03	0.06	0.33	1.30	7.40	4.70
forest tree management/forest pest management	aerial	8.0	0.40	0.45	0.88	10.10	19.60	62.50

Site	Appl. Method	Application Rate in lbs ae/A	Drift (lb ae/A)	Total Loading to Adjacent Area (lb ae/A)	Total Loading to Semi-aquatic Area (lb ae/A)	RQ of Runoff to Adjacent Area	RQ of Runoff to Semi-Aquatic Area	RQ of Spray Drift to Plant
forest tree management/forest pest management	ground	8.0	0.08	0.16	0.88	3.60	19.60	12.50
forest trees - all or specified	ground	12.0	0.12	0.08	1.32	5.40	29.50	18.80
drainage systems	aerial	1.5	0.08	0.09	0.17	2.00	3.80	12.50
drainage systems	ground	8.0	0.08	0.16	0.88	3.60	19.60	12.50
streams/rivers/channel ed water	ground	12.0	0.12	0.24	1.32	5.40	29.50	18.80

Notes:

Calculations are based on seedling emergence value for alfalfa of 0.0622 lbs ai/A and a sunflower vegetative vigor endpoint value of 0.0089 lbs ai/A, equivalent to 0.0447 lbs ae/A and 0.0064 lbs ae/A, respectively.

Factor for conversion of ai to ae is 0.7192 lb ae/A, based upon the ratio of percentages of active ingredients to acid equivalents as specified on product labels.

Terrestrial Plant Assessment

Triclopyr TEA

Ground application results indicate that acute risk and endangered plant species' levels of concern from runoff are exceeded for non-target terrestrial plants at rates of application equal to or above 9.0 lb ae/A inhabiting adjacent acreage and 1.5 lb ae/A or higher inhabiting semi-aquatic areas. The 1% drift from ground application exceeds LOCs to non-target terrestrial plants at application rates of 1.5 lb ae/A or higher and to endangered plant species at rates of 0.315 lb ae/A or higher.

Aerial application results show LOCs for non-target plants and endangered plant species inhabiting adjacent areas and semi-aquatic areas being exceeded at application rates of 4.0 lb ae/A or higher. Risk quotients for 5% spray drift from aerial application exceeds the LOC for non-target and endangered species of plants at application rates of 0.315 lb ae/A or higher.

Triclopyr BEE

Ground application results indicate that non-target terrestrial plant acute risk levels of concern from runoff are exceeded at rates of application equal to or above 3.0 lb ae/A inhabiting adjacent acreage and 1.0 lb ae/A or higher inhabiting semi-aquatic areas. Risk quotients using 1% drift from ground application to non-target terrestrial plants exceed LOCs at application rates of

1.0 lb ae/A or higher. Endangered plant species inhabiting adjacent areas and semi-aquatic areas may be affected at all application rates of triclopyr BEE.

Aerial application results show LOCs from runoff being exceeded at application rates of 1.5 lb ae/A or higher to non-target plants inhabiting adjacent areas and semi-aquatic areas. Level of concern to non-target plants was exceeded when 5% that was applied drifted. Endangered plant species may be affected from aerial application of triclopyr BEE.

(b). Aquatic

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from such uses as aquatic weed or mosquito larvae control. An aquatic plant risk assessment is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Non-vascular aquatic plant risk assessments are performed using either algae or a diatom, whichever is the most sensitive species. Runoff and drift exposure is computed from GENEEC. For aerial application to forestry, rice, drainage systems, and rights-of-way, direct application to six inches of water is assumed. The risk quotient is determined by dividing the pesticide's initial concentration in water by the plant EC₅₀ value.

Acute risk quotients for vascular and non-vascular plants are tabulated below.

Table 53: Acute RQs for Aquatic Plants for Triclopyr TEA

Site and Rate of Application (lb ae/A)	Appl. Method	Test Species	EC ₅₀ (ppm ae)	EC ₀₅ or NOEC (ppm ae)	EEC (ppm ae)	Acute RQ ²	Endang. RQ ³
pastures, rangeland, fencerow/hedgerows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils (12.12 lb ae/A)	Ground	duckweed	6.27	2.49	0.364	<1.0	< 1.0
		algae or diatom	4.20	n/a	0.364	<1.0	n/a ⁴
non-agricultural rights-of-way, non-agriculture uncultivated areas/soils (9.0 lb ae/A)	Ground	duckweed	6.27	2.49	0.270	<1.0	< 1.0
		algae or diatom	4.20	n/a	0.270	<1.0	n/a
pastures, rangeland (3.158 lb ae/A)	Ground	duckweed	6.27	2.49	0.095	<1.0	< 1.0
		algae or diatom	4.20	n/a	0.095	<1.0	n/a
Ornamental Lawns and Turf (1.5 lb ae/A)	Ground	duckweed	6.27	2.49	0.045	<1.0	< 1.0

Table 53: Acute RQs for Aquatic Plants for Triclopyr TEA

Site and Rate of Application (lb ae/A)	Appl. Method	Test Species	EC ₅₀ (ppm ae)	EC ₀₅ or NOEC (ppm ae)	EEC (ppm ae)	Acute RQ ²	Endang. RQ ³
		algae or diatom	4.20	n/a	0.045	<1.0	n/a
Pastures and Rangeland (6.0 lb ae/A)	Aerial	duckweed	6.27	2.49	0.185	<1.0	< 1.0
		algae or diatom	4.20	n/a	0.185	<1.0	n/a
DIRECT APPLICATION TO 6 INCHES OF WATER							
Forestry (4.0 lb ae/A)	Aerial	duckweed	6.27	2.49	2.936	<1.0	1.2
		algae or diatom	4.20	n/a	2.936	<1.0	n/a
drainage systems (12.0 lb ae/A)	ground	duckweed	6.27	2.49	8.808	1.4	3.5
		algae or diatom	4.20	n/a	8.808	2.1	n/a
drainage systems (9.0 lb ae/A)	Ground	duckweed	6.27	2.49	6.606	<1.0	2.7
		algae or diatom	4.20	n/a	6.606	1.6	n/a
Rice (0.375 lb ae/A)	Ground and aerial	duckweed	6.27	2.49	0.275	<1.0	< 1.0
		algae or diatom	4.20	n/a	0.275	<1.0	n/a

Notes:

¹ Factor for conversion of ai to ae is 0.7125 lb ae/A, based upon the ratio of percentages of active ingredients to acid equivalents as specified on product labels. The Endangered Species RQ is calculated from the EEC/EC₀₅ or NOEC value. Calculations are based upon a duckweed (*Lemna gibba*) EC₅₀ of 8.8 ppm ai and a non vascular plant (*Anabaena flos-aquae*) EC₅₀ of 5.9 ppm ai. (equivalent to 6.27 ppm ae and 4.20 ppm ae, respectively)¹

² The acute RQ is calculated from the EEC/EC₅₀.

³ The Endangered Species RQ is calculated from the EEC/EC₀₅ or the NOEC value.

⁴ There are no listed endangered species of algae or diatoms.

Table 54: Acute RQs for Aquatic Plants for Triclopyr BEE)¹

Site and Rate of Appl. (lb ae/A)	Appl. Method	Test Species	EC ₅₀ (ppm ae)	EC ₀₅ or NOEC (ppm ae)	EEC (ppm ae)	Acute RQ ²	Endangered Species RQ ³
agricultural//farm structures/ buildings and equipment, fencerow/hedge rows, non-agricultural rights-of-way, non-agriculture uncultivated areas/soils (12.0 lb ae/A)	Ground	duckweed	0.63	<0.12	0.228	<1.0	1.9
		algae or diatom	0.07	n/a	0.228	3.2	n/a ⁴
pastures and rangeland (8.0 lb ae/A)	Ground	duckweed	0.63	<0.12	0.152	<1.0	1.3
		algae or diatom	0.07	n/a	0.152	2.2	n/a
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways, fencerows, hedgerows, non-agriculture uncultivated areas/soils (1.5 lb ae/A)	Ground	duckweed	0.63	<0.12	0.028	<1.0	<1.0
		algae or diatom	0.07	n/a	0.028	<1.0	n/a
Ornamental Lawns and Turf (1.0 lb ae/A)	Ground	duckweed	0.63	<0.12	0.019	<1.0	<1.0
		algae or diatom	0.07	n/a	0.019	<1.0	n/a
non-agricultural rights-of-ways, fencerows/hedge rows (8.0 lb ae/A)	Aerial	duckweed	0.63	<0.12	0.160	<1.0	1.3
		algae or diatom	0.07	n/a	0.160	2.3	n/a

Table 54: Acute RQs for Aquatic Plants for Triclopyr BEE)¹

Site and Rate of Appl. (lb ae/A)	Appl. Method	Test Species	EC ₅₀ (ppm ae)	EC ₀₅ or NOEC (ppm ae)	EEC (ppm ae)	Acute RQ ²	Endangered Species RQ ³
pastures, rangeland, industrial areas (outdoor), non-agricultural rights-of-ways, fencerow, hedgerows, non-agriculture uncultivated areas/soils (1.5 lb ae/A)	Aerial	duckweed	0.63	<0.12	0.03	<1.0	<1.0
		algae or diatom	0.07	n/a	0.03	<1.0	n/a
DIRECT APPLICATION TO 6 INCHES OF WATER							
forest tree management/ forest pest management (3.0 lb ae/A)	Ground and Aerial	duckweed	0.63	<0.12	2.202	3.5	18.4
		algae or diatom	0.07	n/a	2.202	31.5	n/a
forest tree management/ forest pest management (8.0 lb ae/A)	Ground and Aerial	duckweed	0.63	<0.12	5.872	9.3	48.9
		algae or diatom	0.07	n/a	5.872	83.9	n/a
Forest trees - all or specified (12.0 lb ae/A)	Ground	duckweed	0.63	<0.12	8.808	13.4	73.4
		algae or diatom	0.07	n/a	8.808	125.8	n/a
drainage systems (1.5 lb ae/A)	Aerial	duckweed	0.63	<0.12	1.101	1.7	9.2
		algae or diatom	0.07	n/a	1.101	15.8	n/a
drainage systems (8.0 lb ae/A)	Ground	duckweed	0.63	<0.12	6.606	10.5	55.1
		algae or diatom	0.07	n/a	6.606	94.4	n/a
streams/rivers/ channeled water (12.0 lb ae/A)	Ground	duckweed	0.63	<0.12	8.808	13.4	73.4
		algae or diatom	0.07	n/a	8.808	125.8	n/a

Notes:

¹Factor for conversion of ai to ae is 0.7192 lb ae/A, based upon the ratio of percentages of active ingredients to acid equivalents as specified on product labels. Calculations are based upon a duckweed (*Lemna gibba*) EC₅₀ of 0.88 ppm ai and a non vascular plant (*Navicula pelliculosa*) EC₅₀ of 0.10 ppm ai (equivalent to 0.63 ppm ae and 0.07 ppm ae, respectively)

² The acute RQ is calculated from the EEC/EC₅₀.

³ The Endangered Species RQ is calculated from the EEC/EC₀₅ or NOEC value.

⁴ There are no listed endangered species of algae or diatoms.

Aquatic Plant Assessment

Triclopyr TEA - Aquatic Vascular Plants

The results indicate that for Triclopyr TEA, levels of concern for acute risk are exceeded for vascular aquatic plants from the direct application to water at 12.0 lb ae/A. The LOC for endangered species of aquatic plants is exceeded at 9.0 lb ae/A or higher in a direct application to water scenario.

Triclopyr TEA - Algae and Diatoms

The results indicate that for Triclopyr TEA, levels of concern for acute risk to algae and diatoms are exceeded at application rates of 9.0 lb ae/A or higher from direct application to water scenario.

Triclopyr BEE - Aquatic Vascular Plants

Acute risk and endangered species levels of concern are exceeded for aquatic vascular plants at the rates of 8.0 lb ae/A or higher and at 1.5 lb ae/A or higher when used in a direct application to water scenario.

Triclopyr BEE - Algae and Diatoms

Results indicate that levels of concern for acute risk are exceeded at the rates of 8.0 lb ae/A or higher and at 1.5 lb ae/A or higher when applied directly into water.

(4). Endangered Species

Endangered species LOCs are exceeded for triclopyr TEA for birds, mammals and for aquatic and terrestrial plants. Endangered species LOCs are exceeded for triclopyr BEE for birds, mammals, fish, aquatic invertebrates, estuarine species and aquatic and terrestrial plants.

The Endangered Species Protection Program is expected to become final in the future. Limitations beyond those specified in this RED in the use of triclopyr may be required to protect endangered and threatened species, but these limitations have not been defined and may be

formulation and area specific. EPA anticipates that a 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 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.

b. Environmental Risk Characterization

Triclopyr TEA rapidly dissociates in water to the triclopyr acid/anion and triethanolamine. Triclopyr BEE rapidly hydrolyzes in the environment to the triclopyr acid/anion and butoxyethanol. Both triethanolamine and butoxyethanol are rapidly dissipated by microbial degradation. Triclopyr acid is a weak acid which will dissociate completely to the triclopyr anion at pHs > 5 (dissociation constant pKa 2.93). Therefore, triclopyr anion will be the moiety present in the environment when products containing either triclopyr BEE or triclopyr TEA are used. Triclopyr acid/anion is moderately persistent and is mobile. The predominant degradation pathway for triclopyr in water is photodegradation. The predominant degradation pathway in soil is microbial degradation to the major degradate 3,5,6-trichloro-2-pyridinol (TCP), which is both persistent and mobile.

Triclopyr is moderately persistent, with persistence increasing as it reaches deeper soil levels, where anaerobic conditions predominate; it is also very mobile. However, because triclopyr is not expected to reach high concentrations in ground water, the Agency concludes that it is not a concern in drinking water that is derived from ground water. Triclopyr and TCP do not adsorb to soil and sediment particles, and may be transported in surface runoff waters. Although, triclopyr is not predicted to persist in surface waters, information from two aquatic field dissipation studies conducted on rice indicates that following application of triclopyr, TCP can persist in flood waters. Triclopyr is not currently regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) is not established. Public water supply systems are not required to sample and analyze for triclopyr.

Groundwater Conclusions

The Agency concludes that triclopyr BEE and triclopyr TEA are mobile but not particularly persistent. The multiple potential degradation pathways (hydrolysis, photodegradation, and aerobic soil metabolism) and its rapid degradation significantly decrease the potential for triclopyr to reach deeper soil horizons. The principle degradate, TCP, is relatively mobile and persistent and has the potential to contaminate ground water. If triclopyr or its degradates reach deeper soil levels where anaerobic conditions exist, persistence will increase and it is more likely to reach ground water. If the compounds did reach ground water, they are not likely to reach or exceed OPP's estimate of the HA of 350 ppb for drinking water. The degradate TCP is probably the most mobile of the compounds and the most likely to reach ground water, but it is not expected to reach high concentrations.

Surface Water Conclusions

Information from acceptable and supplemental environmental fate studies indicates triclopyr is non-persistent in surface waters (aquatic field dissipation half-lives of 0.5 and 3.5 days for surface and aerial applications, respectively for Lake Seminole, Georgia). However, information from two aquatic field dissipation studies conducted on rice indicates that following application of triclopyr, TCP can persist in flood waters.

Ecological Toxicity - Characterizing risk:

Birds

Acute Risk

Triclopyr TEA exceeds the LOCs for high acute risk at 12.12 lb ae/A for birds feeding on short grass. The LOC for restricted use is exceeded at the use rates ≥ 6.0 lbs ae/A for birds feeding on short grasses and the use rate of ≥ 9.0 lbs ae/A for birds feeding on broadleaf plants and small insects. The LOC for endangered bird species is exceeded at use rates ≥ 3.185 lbs ae/A for birds feeding on short grasses and at use rates ≥ 6.0 lbs ae/A for bird feeding on long grasses, broadleaf plants, and small insects.

Triclopyr BEE exceeds the LOC for high acute risk for birds feeding on short grasses at the 12.0 lbs ae/A use rate. The LOC for restricted use is exceeded at use rates ≥ 8.0 lbs ae/A on short grasses, long grasses, and broadleaf plants and small insects.

The granular formulation of triclopyr TEA (0.54 lb. a.i./A) does not exceed any level of concern.

Chronic risk

Triclopyr TEA exceeds the chronic risk LOC for fruit and pod food items at the 9.0 and 12.12 lbs ae/A use rates. For the remaining food items (short grasses, long grasses, broadleaf plants and small insects), triclopyr TEA exceeds the LOC for chronic risk at all use rates.

Summary Of Avian Risk

The currently-labeled use rate for triclopyr TEA granular formulation (0.54 lbs ae/A) is not likely to pose a risk to birds.

Acute Risk

Bird species which feed on short grasses are the most susceptible to possible acute impact from the use of triclopyr TEA and BEE at 12.0 lb ae/A. However, since the Kenaga and Hoerger nomograph values are based on zero hour exposure and do not consider any degradative processes, available residues of triclopyr TEA and BEE may be lower than predicted by these values. The foliar persistence and duration of palatability of vegetation treated with triclopyr TEA and BEE is uncertain.

Chronic Risk

There is potential for triclopyr acid to cause reproductive impairment (i.e. chronic effect) to birds when concentrations greater than 100 ppm are reached. Use of maximum residue levels in the avian risk assessment is a first level screen, because it accounts for any uncertainty of laboratory ecotoxicity data, lack of residue fate data on foliage, behavior of bird species in the field, and environmental conditions. This conservative assessment provides safety factors for bird species not accurately represented by the test surrogate species. Although the persistence of triclopyr acid/anion on avian food items is unknown, it is possible that environmental concentrations will remain high enough for sufficient duration to produce chronic effect(s).

Terrestrial Mammals

The Agency determined that all three forms of triclopyr are bioequivalent for testing purposes. (Toxicology Endpoint Selection Document 24 June 1996). Therefore, the same rat LD₅₀ was used to calculate risk quotients (RQ's) for both the BEE and TEA forms of triclopyr in the mammal risk assessment.

Acute risk to mammals

Triclopyr TEA and triclopyr BEE do not exceed any LOC for fruits, pods, and large insects. Triclopyr TEA and triclopyr BEE do not exceed the acute high risk LOC.

Triclopyr TEA and triclopyr BEE exceed the restricted use LOC criteria for mammals feeding on short grasses at use rates ≥ 6.0 lbs ae/A, and on forage and small insects at use rates of ≥ 12.12 lbs ae/A.

Triclopyr TEA and triclopyr BEE exceed the endangered species LOC criteria for mammals feeding on short grasses at the use rate ≥ 3.185 lbs ae/A and for mammals feeding on forage and small insects at use rates ≥ 6.0 lbs ae/A.

Chronic risk to mammals

Results from the 2-generation rat reproduction study indicate that triclopyr TEA and triclopyr BEE exceed the chronic risk LOC for mammalian species at some rates.

Triclopyr TEA and BEE exceed the LOCs for chronic risk to mammals feeding on short grasses at use rates ≥ 1.5 lbs ae/A and on forage or small insects at use rates ≥ 3.185 lbs ae/A.

Neither triclopyr TEA nor triclopyr BEE exceed the chronic LOC for mammals feeding on fruits, pods, and large insects.

Summary Of Mammalian Risk

Mammal species that feed on short grasses are the most susceptible to possible acute impact from the use of triclopyr TEA and BEE above 3.0 lb ae/A; for chronic effects, the rate is at or above 1.5 lb ae/A. However, since the Kenaga and Hoerger nomograph values are based on zero hour exposure and do not consider any degradative processes, residues of triclopyr TEA and BEE may be lower than predicted by these values. The foliar persistence and duration of palatability of vegetation treated with triclopyr TEA and BEE is uncertain.

The acute and chronic risk assessments for mammals are based solely on toxicity data using the laboratory rat. Because other types of mammals consume a greater proportion of their body weight per day, the resultant ingestion of greater quantities of triclopyr may result in greater risk to these mammals.

Although the persistence of triclopyr acid/anion on avian food items is unknown, it is possible that environmental concentrations will remain high enough for sufficient duration to produce chronic effect(s).

Insects

Currently, the Agency has no procedure for assessing risk to nontarget insects. However, because all forms of triclopyr are practically non-toxic to bees, it is not expected that insects will be adversely affected by the use of triclopyr.

Non-Target Aquatic Animals

Triclopyr TEA

Triclopyr TEA exposure does not exceed any level of concern for acute or chronic risk to aquatic (freshwater and estuarine/marine) invertebrates and fish.

Triclopyr BEE

Overall the triclopyr BEE formulation is more toxic to aquatic (freshwater and estuarine/marine) invertebrates and fish, and represents a greater potential acute risk than the TEA formulation. Based on the similarity of acute toxicity endpoints, risk to estuarine/marine aquatic species is assumed to be comparable to that of freshwater species.

Exposures for non-agricultural uses (e.g. forestry, drainage, etc), based on direct application to water, result in high acute risk to fish at use rates greater than 1.5 lbs ae/A and for invertebrates at use rates greater than 8.0 lbs ae/A. In addition, triclopyr BEE may acutely affect endangered fish and mollusks at all use rates, and may affect other aquatic invertebrate species at use rates ≥ 1.5 lbs ae/a.

For agricultural use sites, exposures based on the 8.0 lbs ae/A aerial application may pose acute high risk. Additionally, exposures based on the 1.5 lbs ae/A aerial application may acutely affect endangered fish and mollusks at all use rates and is also a candidate for restricted use. For ground applications, triclopyr poses high risk to fish and mollusks at the 8 lbs ae/A and 12 lbs. a.i./A use rates. At all use rates, ground applications of triclopyr BEE may acutely affect endangered fish and mollusks.

Triclopyr Degradates

The triclopyr degradate, TCP, is more toxic than the TEA or triclopyr acid and is similar to the BEE in acute toxicity to fish.

Summary of Aquatic risk

There are no concerns for acute or chronic risks to aquatic organisms from the use of triclopyr TEA or triclopyr acid. Acute risk to fish and mollusks (including endangered species) is probable from direct application of the triclopyr BEE form to shallow aquatic habitats; however, fate data suggests that exposure will be transitory. Chronic risk from triclopyr BEE is not expected because of its short duration under environmental conditions (e.g. rapid photodegradation and hydrolysis in aquatic systems). The Agency is requiring data to better characterize the environmental fate and toxicity to fish of the triclopyr degradate, TCP.

Non-Target Terrestrial Plants

Triclopyr TEA

Acute risk and endangered plant species' levels of concern from runoff (ground application) are exceeded at ≥ 9.0 lb ae/A (non-target plants inhabiting adjacent acreage) and ≥ 1.5 lb ae/A (non-target plants inhabiting semi-aquatic areas). The 1% drift EEC from ground application exceeds LOCs for non-target terrestrial plants at application rates of ≥ 1.5 lb ae/A and to endangered plant species at rates ≥ 0.375 lb ae/A.

LOCs from runoff (aerial application) are exceeded at application rates ≥ 4.0 lb ae/A to non-target plants and endangered plant species inhabiting adjacent areas and semi-aquatic areas. The 5% spray drift EEC from aerial application exceeds the LOC for non-target and endangered species of plants at application rates ≥ 0.375 lb ae/A or higher.

Triclopyr BEE

Acute risk levels and endangered plant species levels of concern from runoff (ground application) are exceeded at rates of application ≥ 3.0 lb ae/A (non-target plants inhabiting adjacent acreage) and ≥ 1.0 lb ae/A (non-target plants inhabiting semi-aquatic areas). The 1% drift EEC from ground application exceeds LOCs to non-target terrestrial plants at application rates ≥ 1.0 lb ae/A or higher. Endangered plant species inhabiting adjacent areas and semi-aquatic areas may be affected at all application rates of triclopyr BEE.

LOCs from runoff (aerial application) exceeded at application rates ≥ 1.5 lb ae/A for higher to non-target plants inhabiting adjacent areas and semi-aquatic areas. The 5% spray drift EEC from aerial application exceeds the LOC for non-target plants at application rates ≥ 1.5 lb ae/A or higher. Endangered plant species may be affected from aerial application of triclopyr BEE at all application rates.

Summary of Terrestrial Plants Risk

The BEE formulation of triclopyr poses a greater risk to non-target plants than the TEA formulation. Spray drift from aerial application poses a greater risk to non-target plants than runoff from ground application. Endangered plant species may be affected from all uses of triclopyr BEE and TEA.

Spray drift from aerial applications poses a greater acute risk to non-target plants than runoff because foliar uptake of the chemical is more toxic than stem or root uptake. In addition, more plant species will be exposed over a wider area since spray drift affects a greater area than runoff. The spray drift risk quotients exceed the level of concern for risk to non-target terrestrial plants by up to 62 times for triclopyr BEE, as compared with up to 29 times from runoff. Additionally, the spray drift and runoff risk quotients from triclopyr TEA exceed the acute level of concern for non-target terrestrial plants by up to 55 times and 26 times, respectively.

There is a concern for non-target plant species that are protected under various state laws (i.e. cacti in rangelands) and will be exposed from aerial application.

The triclopyr BEE formulation is more toxic to non-target plants from runoff than triclopyr TEA. Based on seedling emergence testing, the BEE formulation is 1000 times more toxic to plants from runoff than the TEA formulation. However, the TEA formulation is more mobile in a runoff scenario than the BEE formulation. Although triclopyr BEE exposure to non-target plants is expected to be less from runoff than the TEA formulation, triclopyr BEE poses a greater risk to non-target plants.

For risk due to spray drift, the triclopyr TEA use on rice at a rate of 0.375 lbs ae/A with one ground application did not exceed the level of concern for acute risk to non-target, non-endangered plants. However, there is an exceedence (LOC=1.0) to endangered species from

spray drift (1%) associated with ground application. In all other registered uses for both triclopyr TEA and triclopyr BEE, the level of concern for acute risk to non-target plants and endangered plant species due to spray drift was exceeded.

The levels of concern for risk to endangered plant species are exceeded for both runoff and spray drift as a result of aerial application of triclopyr BEE. Additionally the levels of concern for risk to endangered plant species are exceeded by 26 times from runoff and 103 times from spray drift from aerial application of triclopyr TEA.

Non-Target Aquatic Plants

Triclopyr TEA

Only direct application of triclopyr TEA at ≥ 9 lbs ae/A to shallow water results in LOC exceedances (up to 1.49 times) to aquatic vascular plants and for algae/diatoms. Endangered species of vascular plants may be affected from triclopyr TEA at rates of ≥ 9 lb ae/A.

Triclopyr BEE

It is expected that there will be significant acute risk to aquatic vascular plants from the use of triclopyr BEE at application rates greater than 1.5 lbs ae/A that are made directly to water. The RQs ranged from 1.3 (at 1.5 lb ae/A) to 10 (at 12 lb ae/A) times.

Algae/diatoms are affected at application rates ≥ 8 lb ae/A from runoff to water and at ≥ 1.5 lb ae/A from direct application to water. The RQs ranged from 1.5 to 2.3 times the LOC for triclopyr BEE runoff into water and from 11 to 88 times of triclopyr BEE being applied directly to water.

Endangered species of aquatic plants may only be affected from runoff into water at ≥ 12 lb ae/A and from all uses involving direct application into water.

Summary of Aquatic Plant Risk:

Aquatic exposure values did not account for rapid hydrolysis that was observed in a forestry study (Thompson et. al. 1995) in which the BEE hydrolyzed to the acid within half a day. Duration of exposure to triclopyr BEE that may result in acute risk is expected to be less than half a day.

Triclopyr BEE is much more toxic to algae/diatoms than to vascular plants. However, due to the type of testing, it is unknown whether triclopyr BEE will result in killing algae (longer time for algae to recover) or that it will have an algastatic effect (algae will recover rapidly after dissipation of herbicide).

There is little risk to aquatic plants from the use of triclopyr TEA. Triclopyr BEE may pose a significant risk to algae/diatoms and vascular plants if applied directly to water. Use sites such as forestry may result in incidental application to water.

Available data indicate that risk from TEA, BEE use can be summarized as follow:

Triclopyr TEA

- There are no risks to fish, aquatic invertebrates, estuarine/marine species, birds or mammals from the currently labeled (0.54 lb ae/A) granular formulation of triclopyr TEA.
- There exists a high potential for acute risk to birds from the use of triclopyr TEA at high application rates.
- There is potential for chronic risk to some birds and mammals from triclopyr TEA, but this conclusion is uncertain due to the lack of data on the rate of dissipation of triclopyr on food items.
- There are no acute or chronic risk to fish, aquatic invertebrates, or estuarine/marine species from the use of triclopyr TEA.
- There is a high potential for acute risk to non-target plants from triclopyr TEA.
- Criteria for restricted use is exceeded for birds and mammals from the use of triclopyr TEA.
- Endangered species of birds, mammals, and plants may be affected by triclopyr TEA.

Triclopyr BEE

- There are no risk to fish, aquatic invertebrates, estuarine/marine species, birds or mammals from the currently labeled (0.54 lb ae/A) granular formulation of triclopyr BEE.
- There is a high potential for acute risk to birds from triclopyr BEE.
- There is a potential for chronic risk to birds and mammals from triclopyr BEE, but this conclusion is uncertain due to the lack of data on the rate of dissipation of triclopyr on food items.

- There is a high potential for transitory acute risk to fish, aquatic invertebrates and estuarine/marine species from triclopyr BEE.
- There are no chronic risk to fish, aquatic invertebrates, or estuarine/marine species from the use of triclopyr BEE.
- There is a high potential for acute risk to non-target plants from triclopyr BEE.
- Criteria for restricted use is exceeded for birds, mammals, fish, aquatic invertebrates, and estuarine/marine species from the use of triclopyr BEE.
- Endangered species of birds, mammals, fish, aquatic invertebrates, estuarine/marine species, and plants may be affected by triclopyr BEE.

Triclopyr Degradates

- The triclopyr degradate 3, 5, 6-trichloro-2-pyridinol (TCP) appears to be persistent in aquatic environments.
- Additional data are required to better characterize the fate and chronic toxicity to fish of TCP.

Water Resources

- There is potential for the major soil degradate of triclopyr, trichloropyridinol (TCP), to leach to groundwater from triclopyr TEA or BEE applications.
- Triclopyr acid is not predicted to persist in surface waters, however, the triclopyr degradate, TCP, may persist.

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 ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing triclopyr as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing triclopyr. Appendix B identifies the generic data requirements that the Agency

reviewed as part of its determination of reregistration eligibility of triclopyr, 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 triclopyr and to determine that triclopyr can be used, with mitigation imposed by this document, without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing triclopyr as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed and a list of additional data required for the technical formulation is contained in Section V of this document.

The Agency made its reregistration eligibility determination based upon the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that all uses of triclopyr 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 triclopyr, if new information comes to the Agency's attention or if the data requirements for registration or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all uses are eligible for reregistration under the conditions specified in this RED.

C. Regulatory Position

To lessen the human health, ecological, water and food quality risks posed by triclopyr, EPA is requiring the following mitigation measures for triclopyr-containing products.

To protect wildlife and non-target plants:

- Reduce the maximum rate of application from the current 12 lbs/ae/A to:
 - 1 lb/ae/A/year on pasture and rangeland and all sites where cattle can be grazed
 - 6 lbs/ae/A for forestry applications
 - 8 lbs/ae/A for all other use sites of triclopyr BEE
 - 9 lbs/ae/A for all other use sites of triclopyr TEA

It should be noted that the reduction to 1 lb/ae/A/year on pasture and rangeland is required because the available residue data do not support applications in excess of that amount to pasture and rangeland. However, this reduction in maximum rate also serves to reduce the calculated risk to the non-target organisms found in and adjacent to those areas. It should also be noted that DowElanco has provided the Agency with a statistical analysis supporting a maximum of 2 lbs/ae/A for the range and pasture use, which the Agency is currently evaluating.

-Require labeling to implement spray drift management practices, based on recommendations of the Spray Drift Task Force.

-Specify appropriate application intervals on all product labels.

To protect water resources:

- In addition to the above mentioned measures, triclopyr labels must also bear the following warning: "This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. "

To protect food quality:

-Limit applications of triclopyr on range and pasture and all sites where cattle can be grazed to 1 lb/ae/A/year.

-Label amendments are required to remove all PHIs for grass forage and to specify a 14-day PHI for grass hay, based on the reassessed tolerance for this commodity.

-Retain the established 3-day preslaughter interval.

-Retain the current restriction against grazing lactating dairy animals until the next growing season.

-Remove all conflicting grazing restrictions/instructions on current triclopyr labels.

Also, in conjunction with the food uses of triclopyr, registrants must develop residue analytical methods to substitute reagents less hazardous than diazomethane and benzene.

To protect homeowners:

- Restrict re-entry to treated areas until sprays have dried and dusts have settled.
- Retain/require label language to avoid eye and skin contact during and after application.

To protect workers:

- Establish REIs and early entry PPE
- Add additional health and safety instructions to labels as specified in Section 5.

The following is a summary of the Agency's regulatory position and rationale for managing risks associated with use of triclopyr. Where labeling revisions are imposed, specific language is set forth in Section V.B.2 of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for triclopyr, 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, as well as the possibility of cumulative effects from triclopyr and other compounds that may have a similar mechanism of toxicity.

The Agency considers that residential exposure to triclopyr from its use on home gardens and lawns is likely to be negligible because no dermal endpoint of concern has been identified, and inhalation exposure is likely to be minimal. Therefore, EPA has considered only acute and chronic exposures from dietary sources and drinking water in its aggregate risk assessment.

In assessing acute aggregate dietary risk EPA has used a maternal NOEL of 30 mg/kg/day from a developmental study in rabbits. Because of the selected endpoint, the sub-population of females 13+ years, is the subgroup of interest. The risk assessment assumed 100% of the crop was treated and that there would be tolerance level residues on all treated crops, as well as an upper bound estimate of triclopyr residues in drinking water--resulting in a significant over estimate of dietary exposure. Notwithstanding the extremely conservative exposure assumptions, the aggregate acute dietary MOE was calculated to be 1250, well within the acceptable range.

The Agency used the same conservative exposure assumptions described above to estimate the chronic aggregate dietary risk from triclopyr residues in food and water. Current

registered uses utilize only approximately 16% of the RfD for the general population. Therefore, the Agency concludes that the aggregate risks of triclopyr for the general population are not of concern.

Because triclopyr shares a common metabolite, TCP, with the insecticide chlorpyrifos, EPA has also considered the potential for aggregate exposure to TCP. Again, using very protective exposure assumptions, for the population sub group of concern, females 13 + years, the Agency calculated an MOE of 600 for acute aggregate dietary risks from TCP. The Agency concludes that the existing uses of triclopyr and chlorpyrifos are unlikely to result in dietary risks of concern from TCP for the general population.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for triclopyr, 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 triclopyr residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from triclopyr 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, triclopyr has a complete database for developmental and reproductive toxicity. Reliable studies cited earlier in this document indicate no special sensitivity of young organisms to triclopyr (see Section IIIb.). Therefore, the Agency has concluded that an uncertainty factor of 100 is adequate to protect infants and children.

EPA estimates that the residues of triclopyr in the diets of infants and children account for approximately 3% of the RfD and residues in drinking water could account for up to an additional 46% of the RfD, using the same conservative exposure assumptions described above for the general population. Thus the aggregate chronic dietary exposure for infants and children could utilize up to approximately 49% of the RfD.

The Agency has also considered the potential for chronic aggregate dietary exposures to TCP and calculated that known, likely sources of TCP could account for 90% of the provisional RfD for TCP for the most highly exposed sub-group, non-nursing infants less than one year old. Thus the Agency concludes that aggregate risks for infants and children resulting from triclopyr uses and the combined sources of the metabolite TCP are not of concern.

The Agency has not yet made a final decision concerning the possible common mechanism of toxicity and the potential for cumulative effects of triclopyr and other compounds. Therefore, for the purposes of the tolerance reassessments in this RED document, EPA has considered the risks of triclopyr and TCP only.

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.

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

Tolerance Reassessment Summary

The Triclopyr Salts and Esters Phase 4 Review (4/25/91, J. Smith) has determined that a clarification of the tolerance expression is warranted to reflect application of the butoxyethyl ester and triethylamine salt of triclopyr. Therefore, the tolerance expression must be revised to "residues of triclopyr ... as a result of the application/use of butoxyethyl ester of triclopyr and triethylamine salt of triclopyr."

The Agency's HED Metabolism Committee has concluded (7/15/96) that the residue to be regulated in grass and rice commodities and milk, poultry and eggs is triclopyr *per se*. The residues to be regulated in meat and meat byproducts are the combined residues of triclopyr and

the metabolite 3,5,6-trichloro-2-pyridinol (TCP). A summary of tolerance reassessments, with respect to the reregistration of triclopyr uses on grasses and rice, is presented below.

Tolerances Listed Under 40 CFR §180.417(a):

The tolerances listed in 40 CFR §180.417(a) are expressed in terms of the combined residues of triclopyr and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine. Sufficient field trial data are available, contingent upon compliance by the registrant in adapting the required label amendments, to ascertain the adequacy of the established tolerances for the following commodities, **as redefined** according to the Agency's metabolism committee conclusions of 7/15/96: grasses, forage; and grasses, forage, hay. See Table 56 below for required revisions to commodity names.

The reassessed tolerances for grass forage and hay are 500 ppm and 200 ppm. These reassessed tolerances are contingent upon compliance by the registrant in adopting the required label amendments (i.e., a maximum single application rate of 1 lb ae/A, a maximum of 1 application/season, removing the PHI/PGI for grass forage, a 14-day PHI for grass hay, and a prohibition on grazing lactating dairy cattle until the next growing season).

Tolerances Listed Under 40 CFR §180.417(b):

The tolerances listed in 40 CFR §180.417(b) are expressed in terms of the combined residues of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol.

Based on the recommended changes in feeding/grazing restrictions and application rates to grasses, adequate data are available to ascertain the adequacy of the established tolerances for the following commodities, **as defined** in 40 CFR §180.417(b): meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep; and liver and kidney of cattle, goats, hogs, horses, and sheep. See table below for recommendations in revisions to commodity names. The tolerance for milk is adequate **as redefined** according to the Agency's metabolism committee conclusions of 7/15/96, i.e., to be expressed in terms of triclopyr *per se*.

The established tolerances for rice grain, rice straw, eggs and poultry commodities were recently established (60 FR 4095, 1/20/95) in conjunction with PP#1F03991. These tolerances are adequate **as redefined** according to the Agency's metabolism committee conclusions of 7/15/96, i.e., to be expressed in terms of triclopyr *per se*.

Table 55: Tolerance Reassessment Summary with Respect to Uses of Triclopyr on Grasses and Rice.¹

Commodity, As Defined	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.417(a) ²:			
Grasses, forage	500	500	Redefine as triclopyr <i>per se</i> . [Grass, forage]
Grasses, forage, hay	500	200	Redefine as triclopyr <i>per se</i> . [Grass, hay]
Tolerances Listed Under 40 CFR §180.417(b) ³:			
Meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep;	0.05	0.05	
Liver and kidney of cattle, goats, hogs, horses, and sheep	0.5	0.5	
Milk	0.01	0.01	Redefine as triclopyr <i>per se</i> .
Rice, grain	0.3	0.3	Redefine as triclopyr <i>per se</i> .
Rice, straw	10.0	10.0	Redefine as triclopyr <i>per se</i> .
Eggs	0.05	0.05	Redefine as triclopyr <i>per se</i> .
Meat, fat, and meat byproducts (except kidney) of poultry	0.1	0.1	Redefine as triclopyr <i>per se</i> .
Fish	0.2	These temporary tolerances, which were established in conjunction with a petition (PP#1F03935) for the registration of triclopyr in aquatic areas, are not addressed in this RED and are not subject to reregistration.	
Shellfish	0.2		
Water, potable	0.5		

¹ Tolerance reassessments are contingent upon label amendments required in this document.

² Currently defined as triclopyr and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine.

³ Currently defined as triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol.

Temporary Tolerances and Pending Tolerance Petitions:

Temporary tolerances have been established for fish and shellfish at 0.2 ppm, and a temporary Allowable Residue Level in Drinking Water (ARLDW) in potable water of 0.5 ppm has been established under PP#6G3306. These temporary tolerances expire in December 1998. Petitions for the registration of triclopyr in aquatic areas (PP#1F03935) and apples (PP#2F4104) are currently pending.

Codex Harmonization

There are no established or proposed Codex MRLs for triclopyr residues. Therefore, there are no issues of compatibility with respect to U.S. tolerances and Codex MRLs.

3. Benefits from Use of Triclopyr

Selective herbicides such as triclopyr are used to control undesirable vegetation, thus encouraging desirable plant species. Selective vegetation control is less disruptive of wildlife habitat than mechanical methods such as mowing, sawing and chopping. Selective vegetation management reduces soil erosion compared to non-selective herbicides or clear cutting. Overgrown or unmanaged vegetation is a fire and safety hazard along roadsides, railroads and utility rights-of-way. Other benefits include reduced cost of road and railway repair and increased visibility.

4. Ecological Risk Mitigation

The triclopyr ecological risk assessment shows that various levels of concern (LOCs) were exceeded for acute/chronic toxicity to plants and animals. Shaded areas in the table below indicate uses that may still exceed LOCs after mitigation measures are adopted.

Table 56: Summary of Potential Ecological Risks

Species	High Acute Risk	Chronic Risk
Birds	<p>TEA (Non granular products)</p> <p>- 12.12 lbs ae/A on short grass</p> <p>BEE (Non granular products)</p> <p>- 12.12 lbs ae/A on short grass</p>	<p>TEA and BEE (Non granular products)</p> <p>9 and 12.12 lbs ae/A</p>
Mammals	High acute risk not exceeded	<p>TEA and BEE (Non granular products)</p> <p>> 1.5 lbs ae/A on short grass</p> <p>>3.185 lbs ae/A on forage and small insects</p>
Insects	Not expected to adversely affect insects	Not expected to adversely affect insects
Aquatic species	<p>BEE</p> <p><u>Non-Ag Uses (forestry, drainage, etc.)-</u></p> <p>>1.5 lbs ae/A for fish</p> <p>>8.0 lbs ae/A for invertebrates</p> <p><u>Ag Uses</u></p> <p>-(aerial application) 8.0 lbs ae/A for fish</p> <p>-(ground application) > 8.0 lbs ae/A for fish and mollusks</p>	Chronic risk not expected

<p>Terrestrial Plants</p>	<p>TEA</p> <p><u>Ground application</u> >9.0 lbs ae/A from runoff from adjacent acreage ≥ 1.5 lbs ae/A for semi-aquatic areas</p> <p><u>Aerial application</u> ≥ 4.0 lbs ae/A for nontarget plants</p> <p>BEE</p> <p><u>Ground application</u> >3.0 lbs ae/A from runoff from adjacent acreage >1.0 lbs ae/A for semi-aquatic areas</p> <p><u>Aerial application</u> ≥ 1.5 lbs ae/A for plants inhabiting adjacent areas and semi aquatic plants</p>	<p>Not accessed for plants</p>
<p>Aquatic Plants</p>	<p>TEA</p> <p>≥ 9.0 lbs ae/A direct application only</p> <p>BEE</p> <p>>1.5 lbs ae/A direct application (vascular plants) ≥ 8.0 lbs ae/A from runoff (algae/diatoms) ≥ 1.5 lbs ae/A from direct application (algae/diatoms)</p>	<p>Not accessed for plants</p>

EPA has worked with DowElanco to define mitigation measures including label improvements to reflect lower maximum application rates and implement spray drift management practices, that will reduce calculated risk to non-target organisms. The highest application rate (12 lbs/ae/A) that was used to calculate RQs will no longer be permitted. The maximum application rate allowed on pasture, rangeland, and all other sites where cattle are grazed will be 1 lb/ae/A per year. (DowElanco has requested a reconsideration of available data to allow 2 lbs/ae/A on pasture and rangeland). Maximum application rate for forestry will be 6 lbs/ae/A. For all other sites, for the BEE formulations the maximum allowed rate will be 8 lbs/ae/A and 9 lbs/ae/A for TEA formulations.

As shown in the table above, after taking into account mitigation measures, some exceedances remain. These include:

- chronic risk to mammals from both the BEE and TEA formulations feeding on short grasses treated at rates in excess of 1.5 lb/ae/A, and on forage and small insects at > 3.185 lbs/ae/A;
- acute risk to fish species from the BEE formulation at rates in excess or 1.5 lbs ae/A applied to forests; and
- acute risk to various classes of non-target plants.

Several factors lessen the Agency's concern regarding these remaining calculated exceedances:

Chronic Risk to Mammals

The residue values (Kenaga & Hoerger) used in EPA's screening assessment are based on 0 hour exposures and do not consider any degradation processes. Whether plants treated with triclopyr remain palatable long after treatment is unknown.

Acute Risk to Fish

Acute risks to fish were calculated assuming direct application to shallow aquatic habitat. Flowing water systems such as forested watershed would result in rapid dissipation of triclopyr. Current registered labels, with the exception of rice, do not allow direct application to water.

Acute Risk to Plants

Because triclopyr is an herbicide, EPA expects calculated risk quotients to exceed levels of concern for some non-target plants. In order to minimize off-site movement of triclopyr, EPA is requiring that spray drift management practices be implemented via triclopyr labeling.

In making a reregistration decision the Agency weighs the ecological risk against the benefits derived from using a chemical. The risk reduction measures required in this RED, namely reductions in application rates and requirements for spray drift management are consistent with those imposed for other chemicals with similar risks. Because of this risk mitigation, coupled with the benefits of vegetation management from using triclopyr, the Agency does not believe the remaining ecological risk to be unreasonable.

5. Ground Water

EPA's pesticides in Ground Water Database reports sampling for triclopyr in Maine, Texas, Virginia, and Vermont. A total of 379 wells were sampled and 5 wells were found to contain triclopyr residues. The major degradate of triclopyr, TCP, is both mobile and persistent. EPA is requiring a label advisory warning users that under certain conditions, use of this chemical may result in groundwater contamination. Refer to section V.B.2 for specific language.

6. 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.

At this time some of the registered uses of triclopyr are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are outside the scope of the WPS include use:

- # on pastures or rangelands,
- # or in or around animal premises,
- # on plants grown for other than commercial or research purposes, such as residential lawns
- # on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS).
- # in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

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 (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers

of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

WPS and NonWPS Uses: EPA's evaluation of the dermal and inhalation toxicity of triclopyr indicates that significant toxicity from either route of exposure is unlikely. As a result of this evaluation, the Agency has determined that risks to handlers, for both WPS and non-WPS uses, do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all triclopyr end-use products. Handler PPE requirements, both WPS and non-WPS, for triclopyr are to be based solely on the acute toxicity of individual end-use products.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for triclopyr end-use products that are intended primarily for homeowner use. Any PPE for homeowners will be based on the acute toxicity of the specific end use product.

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.

During the reregistration process, EPA determined that the restricted-entry interval for all occupational-use products that contain triclopyr TEA and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 48 hours. The basis for this decision is that triclopyr TEA is categorized as toxicity category I (severe) for eye irritation potential and also is classified as a skin 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. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.
2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since both triclopyr TEA and BEE are classified as category IV for skin irritation potential and III for acute dermal toxicity, and EPA has determined that no regulatory action must be taken due to the acute effects or other adverse effects of triclopyr, the PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS. Since triclopyr TEA is classified as category I 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 triclopyr end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of triclopyr TEA (classified as toxicity category I for eye irritation potential and is a skin sensitizer), it is establishing entry restrictions for all nonWPS occupational uses of triclopyr TEA 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.

Homeowner-Use Products

Since EPA has concerns about post-application exposures to persons after homeowner applications of triclopyr TEA (classified as toxicity category I for eye irritation potential and is a skin sensitizer), it is establishing entry restrictions for all homeowner uses of triclopyr TEA 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.

EPA recognizes the apparent discrepancy between establishing a 48 hour reentry interval for triclopyr TEA uses that are covered by the WPS and setting a seemingly lesser standard for non-WPS uses, including homeowner products, of not allowing entry "until sprays have dried" or "dusts have settled." The Agency believes that this distinction is justified because of fundamental differences in the frequency and duration of the exposures involved. WPS uses are generally agricultural row and field crops where workers, such as harvesters and maintenance workers, are not only likely to reenter the treated area, but also likely to come into sustained contact with treated crops. In contrast, for non-WPS triclopyr uses, such as pasture and rangeland and rights-of-way, reentry is likely to be less frequent and sustained contact with treated plants is less likely to occur. In the case of triclopyr use by homeowners, reentry is likely, however the amount of residue that a homeowner would be exposed to would be much less (due to lower percent ai in homeowner products and lower application rates) than an agricultural worker, and the duration of exposure would be shorter.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing triclopyr. For the specific labeling statements, refer to Section V of this document.

7. 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.

8. Spray Drift Management

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, whose membership consists 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 BY 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 triclopyr for the above eligible uses has been reviewed and determined to be substantially complete. The Agency is requiring additional confirmatory data to better characterize the fate and chronic toxicity to fish of triclopyr, specifically its 3,5,6-trichloro-2-pyridinol (TCP) degradate, in the aquatic environment. A fish early life stage study (guideline 72-4) using rainbow trout, coho or chum salmon is required for TCP because aquatic concentrations of TCP may be greater than 1% of the LC₅₀ (1.5 ppm) for rainbow trout (the most sensitive species). A one year duration aerobic metabolism study (guideline 162-4) is also required. Previous aerobic aquatic metabolism studies have not fully characterized the degradation of TCP. The Agency encourages registrants to conduct the new aerobic metabolism study using natural waters and sediment from native habitat for the fish species selected for the early life stage test.

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 following statement under Directions for Use:

- (a) "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 the support of such use(s).
- (b) "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 the support of such use(s).

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix D, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies.

2. Labeling Requirements for End-Use Products

The following amendments are required to all labels that contain range and pasture sites, including rights of way, fence rows, or any area where grazing or harvesting is allowed.

- (1) specify a maximum single application rate of 1 lb. ae/A and only one application per growing season;
- (2) remove all preharvest and pregrazing intervals for grass forage except for the existing restriction against grazing lactating dairy cattle until the next growing season;
- (3) specify a 14 day PHI for grass hay; and
- (4) retain the existing pre-slaughter interval of 3 days.

Labels for both triclopyr BEE and TEA formulations that contain forestry applications must specify a maximum of 6 lbs/ae/year for that site.

For all other uses, triclopyr BEE labels must specify a maximum of 8 lbs/ae/A/year, and triclopyr TEA labels must specify a maximum of 9 lbs/ae/A/year.

To protect water resources:

- In addition to the above mentioned measures, triclopyr labels must also bear the following warning:

"This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. "

For all uses except rice, labels must specify:

"Do not apply directly to water."

Occupational/Residential Labeling

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain triclopyr, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain triclopyr, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use (WPS and nonWPS) and Products Intended Primarily for Homeowner Use

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is not establishing active-ingredient-based minimum (baseline) PPE or engineering control requirements for triclopyr end-use products.

Determining PPE Requirements for End-use Product Labels

Any necessary PPE for each triclopyr end-use product will be established on the basis of the end-use product's acute toxicity category.

Placement in Labeling

For occupational-use products, the personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

For homeowner-use products, the personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions

For **sole-active-ingredient** end-use products that contain triclopyr the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain triclopyr the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 48-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all triclopyr TEA end-use products.

A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all triclopyr BEE end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves,
- shoes plus socks, and
- protective eyewear.

Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of triclopyr end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:

"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions:

The Agency is establishing the following entry restrictions for all homeowner uses of triclopyr end-use products:

For liquid applications:

"Do not allow people or pets to enter the treated area until sprays have dried."

For dry applications:

"Do not allow people or pets to enter the treated area until dusts have settled."

Placement in labeling:

Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing triclopyr that are intended primarily for occupational use.

Application Restrictions

"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."

Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

1. Registrants: place the following user-safety requirement on the labeling only if coveralls are required for pesticide handlers on the end-use product label:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrants: place the following user-safety requirement on the labeling always:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are given, use detergent and hot water. Keep and wash PPE separately from other laundry."

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."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

Products Intended Primarily for Home Use

Application Restrictions

"Avoid contact with eyes, skin, or clothing during and after application."

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

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."

Registrants: place the following user-safety recommendation on the labeling only if gloves and/or protective eyewear are required for homeowner users:

- # "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural rice patties.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they shall be observed.

The applicator should be familiar with and take into account the information covered in the [Aerial Drift Reduction Advisory Information](#).

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

! Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

! Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

! Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

! Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

! Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke

generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

D. 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 triclopyr 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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 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 Triclopyr Acid (116001)

REQUIREMENT	USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>		
71-1	Avian Acute Oral Toxicity-Duck	BCDFJK 40346401
71-2A	Avian Dietary - Duck	BCDFJK 00031249
71-2B	Avian Dietary- Quail	BCDFJK 00049638 (supplemental), 40346403
71-4A	Avian Reproduction - Quail	BCDFJK 00031251
71-4B	Avian Reproduction - Duck	BCDFJK 00031250
141-1	Honey Bee Acute Contact	BCDJK 40356602
<u>TOXICOLOGY**</u>		
81-1	Acute Oral Toxicity - Rat	ALL 00031940
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL 00056009
82-1A	90-Day Feeding - Rodent	BD 00150378
82-1B	90-Day Feeding - Non-Rodent	BD 00071794 (supplemental)
83-1B	Chronic Feeding Toxicity - Non- Rodent	BD 41200301 (supplemental), 00071793
83-2A	Oncogenicity - Rat	BD 40107701
83-2B	Oncogenicity - Mouse	BD 40356601
83-4	2-Generation Reproduction - Rat	BD 43545701
84-2A	Gene Mutation (Ames Test)	ALL 00031939, 00057085
84-2B	Structural Chromosomal Aberration	ALL 00057086, 00028996, 00057087

Data Supporting Guideline Requirements for the Reregistration of Triclopyr Acid (116001)

REQUIREMENT	USE PATTERN	CITATION(S)
84-4 Other Genotoxic Effects	ALL	00038408, 40055702
85-1 General Metabolism	BD	41353001
85-2 Dermal Penetration	BCDFJK	00153805 (supplemental), 00153807 (supplemental)
<u>ENVIRONMENTAL FATE</u>		
161-2 Photodegradation - Water	BCDFJ	41732201, 42411804
161-3 Photodegradation - Soil	BJ	44329901 (in review)
162-1 Aerobic Soil Metabolism	BCJK	40346304
162-3 Anaerobic Aquatic Metabolism	DF	00151967
162-4 Aerobic Aquatic Metabolism	DF	40479101 (additional data are required for the TCP metabolite)
163-1 Leaching/Adsorption/ Desorption	ALL	40749801, 42493901(TCP)
165-1 Confined Rotational Crop	BD	40356607, 41219108

**NOTE: Toxicology studies conducted with triclopyr have been performed using either the free acid, the triethylamine salt (TEA), or the butoxyethyl ester (BEE) form. The issue of bioequivalency for the purpose of testing the three chemical forms of triclopyr was addressed by the registrant conducting special studies with the TEA and BEE forms. These studies which include data on comparative disposition, plasma half-life, tissue distribution, hydrolytic cleavage under physiological and environmental conditions (MRID # 43394101, 42444701, and 42437901) were found to adequately address the issue of bioequivalency. In addition, subchronic toxicity studies conducted with each form supported the pharmacokinetic data in demonstrating bioequivalence. Therefore, with the exception of the acute toxicity database (as noted in each of the three separate bibliographies) toxicology studies conducted with any one form of triclopyr have been used to support the toxicology database as a whole.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Triclopyr Triethylamine TEA (116002)

REQUIREMENT			USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>				
61-2A	Start. Mat. & Mnfg.	Process	ALL	40564901, 42090401
61-2 B	Formation of Impurities		ALL	40564901, 42090401
62-1	Preliminary Analysis		ALL	42650401 (supplemental)
63-2	Color		ALL	42650402
63-3	Physical State		ALL	42650402
63-4	Odor		ALL	42650402
63-5	Melting Point		ALL	42650402
63-7	Density		ALL	42650402
63-8	Solubility		ALL	40440702, 41019703, 42090403
63-9	Vapor Pressure		ALL	41219104, 42090403
63-10	Dissociation Constant		ALL	41219106, 42090403
63-11	Octanol/Water Partition		ALL	41219101, 42090403
63-12	pH		ALL	42650402
63-13	Stability		ALL	42650402
<u>ECOLOGICAL EFFECTS</u>				
71-1	Acute Avian Oral - Quail/Duck		BCDFJK	40346501
71-2A	Avian Dietary - Quail		BCDFJK	40346503

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Triethylamine TEA
(116002)**

REQUIREMENT	USE PATTERN	CITATION(S)
71-2B Avian Dietary - Duck	BCDFJK	40346502
72-1A Fish Toxicity Bluegill	BCDFJK	00151956, 42090407
72-1B Fish Toxicity Rainbow Trout	BCDFJK	00151956, 42090408
72-2 Invertebrate Toxicity	BCDFJK	00151959, 42090409
72-3A Estuarine/Marine Toxicity - Fish	BCDFJ	42646101
72-3B Estuarine/Marine Toxicity Fish-TEP	BCDFJ	41633703
72-3C Estuarine/Marine Toxicity Mollusk - TEP	BCDFJ	42646101, 0062623 (supplemental)
72-3D Estuarine/Marine Toxicity Shrimp - TEP	BCDFJ	42646102, 0062623 (supplemental)
72-4A Early Life Stage Fish	BCDFJ	00151958, 42090410(additional data are required for TCP metabolite)
72-4B Life Cycle Invertebrate	BCDFJ	00151959, 42090411
123-1A Seed Germination/Seedling Emergence	CFJ	43129801
123-1B Vegetative Vigor	CFJ	43129801
123-2 Aquatic Plant Growth	CFJ	41736303(supplemental), 41736302, 41633706, 41633705, 41633707, 41633708, 41633709
141-1 Honey Bee Acute Contact	BCDJK	40356602
<u>TOXICOLOGY**</u>		
81-2 Acute Dermal Toxicity - Rabbit/Rat	ALL	41443302

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Triethylamine TEA
(116002)**

REQUIREMENT	USE PATTERN	CITATION(S)
81-3	Acute Inhalation Toxicity - Rat	ALL 41443303
81-4	Primary Eye Irritation - Rabbit	ALL 41443304
81-5	Primary Dermal Irritation - Rabbit	ALL 41443305
81-6	Dermal Sensitization - Guinea Pig	ALL 41443306
82-1	90-Day Feeding - Rodent	BD 00150378
83-1A	Chronic Feeding Toxicity - Rodent	BD 40107701
83-1B	Chronic Feeding Toxicity - Non-Rodent	BD 41200301, 00071793
83-2A	Oncogenicity - Rat	BD 40107701
83-2B	Oncogenicity - Mouse	BD 40356601
83-3A	Developmental Toxicity - Rat	BD 43217602
83-3B	Developmental Toxicity - Rabbit	BD 43217603
83-4	2-Generation Reproduction - Rat	BD 43545701
<u>ENVIRONMENTAL FATE</u>		
160-5	Chemical Identity	ALL 40564901
161-1	Hydrolysis	ALL 41879601
162-1	Aerobic Soil Metabolism	BCJK 43837501
162-3	Anaerobic Aquatic Metabolism	DF 43837502
162-4	Aerobic Aquatic Metabolism	DF 43837503(additional data are required for TCP metabolite)

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Triethylamine TEA
(116002)**

REQUIREMENT	USE PATTERN	CITATION(S)
164-2 Aquatic Field Dissipation	DF	43955901, 41714304 (supplemental), 42821301
201-1 Droplet Size Spectrum		
202-1 Drift Field Evaluation		
<u>RESIDUE CHEMISTRY</u>		
171-4A Nature of Residue - Plants	BD	PP#1F2508, 00072443,40356607, 42726701, 43122102
171-4B Nature of Residue - Livestock	BD	00071805, 00127280, 40356606, 40356606, 42339002
171-4C Residue Analytical Method - Plants	BD	00071802, 00071803, 43122102,
171-4D Residue Analytical Method - Animal	BD	00071810, 00071811, 00071812, 00071813, 00071814, 42775001, 42784301
171-4E Storage Stability	BD	42630101
171-4J Magnitude of Residues - Meat/Milk/Poultry/Egg	BD	00071806, 00071808
171-4K Crop Field Trials -Grass forage	BD	PP#1F2508,00134173, 41961001, 42090416, 42090424
-Grass hay		PP#1F2508, 00134173, 41961001, 42090416, 42090424,

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Triethylamine TEA
(116002)**

REQUIREMENT

USE PATTERN

CITATION(S)

**NOTE: Toxicology studies conducted with triclopyr have been performed using either the free acid, the triethylamine salt (TEA), or the butoxyethyl ester (BEE) form. The issue of bioequivalency for the purpose of testing the three chemical forms of triclopyr was addressed by the registrant conducting special studies with the TEA and BEE forms. These studies which include data on comparative disposition, plasma half-life, tissue distribution, hydrolytic cleavage under physiological and environmental conditions (MRID # 43394101, 42444701, and 42437901) were found to adequately address the issue of bioequivalency. In addition, subchronic toxicity studies conducted with each form supported the pharmacokinetic data in demonstrating bioequivalence. Therefore, with the exception of the acute toxicity database (as noted in each of the three separate bibliographies) toxicology studies conducted with any one form of triclopyr have been used to support the toxicology database as a whole.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Triclopyr Butoxyethyl ester--BEE (116004)

REQUIREMENT	USE PATTERN	CITATION(S)	
<u>PRODUCT CHEMISTRY</u>			
61-1	Chemical Identity	ALL	40557001
61-2	Start. Mat. & Mnfg. Process	ALL	40557001, 42090417
61-3	Formation of Impurities	ALL	40557001, 42090419
62-1	Preliminary Analysis	ALL	40557002, 42131802
62-2	Certification of limits	ALL	40557002
62-3	Analytical Method	ALL	42090418, 40557002
63-2	Color	ALL	40557003
63-3	Physical State	ALL	40557003
63-4	Odor	ALL	40557003
63-5	Melting Point	ALL	n/a
63-6	Boiling Point	ALL	40557003
63-7	Density	ALL	40557003, 42090419
63-8	Solubility	ALL	41734303, 41019702
63-9	Vapor Pressure	ALL	40473601, 42443402
63-10	Dissociation Constant	ALL	n/a
63-11	Octanol/Water Partition	ALL	42090420
63-13	Stability	ALL	41633702

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Butoxyethyl ester--BEE
(116004)**

REQUIREMENT		USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>			
71-1A	Acute Avian Oral - Quail/Duck	BCDFJK	41902002
71-1B	Acute Avian Oral - Quail/Duck TEP	BCDFJK	41902003
71-2A	Avian Dietary - Quail	BCDFJK	00134180, 41905501
71-2B	Avian Dietary - Duck	BCDFJK	00134179, 41905502
72-1A	Fish Toxicity Bluegill	BCDFJK	42917901, 41736304(supplemental), 00151963(supplemental), 00151965(supplementary)
72-1B	Fish Toxicity Bluegill - TEP	BCDFJK	41971604(supplemental), 43442601
72-1C	Fish Toxicity Rainbow Trout	BCDFJK	42884501
72-1D	Fish Toxicity Rainbow Trout- TEP	BCDFJK	41971603(supplemental), 43442602
72-2A	Invertebrate Toxicity	BCDFJK	00151963 (supplemental), 00151965
72-3A	Estuarine/Marine Toxicity - Fish	BCDFJ	42053901
72-3B	Estuarine/Marine Toxicity - Mollusk	BCDFJ	41971602
72-3C	Estuarine/Marine Toxicity - Shrimp	BCDFJ	41971601
72-3D	Estuarine/Marine Toxicity Fish- TEP	BCDFJ	41969901

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Butoxyethyl ester--BEE
(116004)**

REQUIREMENT	USE PATTERN	CITATION(S)
72-3E	Estuarine/Marine Toxicity Mollusk - TEP	BCDFJ 41969903
72-3F	Estuarine/Marine Toxicity Shrimp - TEP	BCDFJ 41969902
72-4A	Early Life Stage Fish	BCDFJ 43230201 (additional data are required for TCP metabolite)
72-6	Aquatic Organism Accumulation	BCDFJK 42090421
122-1A	Seed Germination/Seedling Emergence	CFJ 42908301, 41734301
123-1A	Seed Germination/Seedling Emergence	CFJ 43650001
123-1B	Vegetative Vigor	CFJ 43650001
123-2	Aquatic Plant Growth	CFJ 41633704, 42090422, 42719101, 42721101, 42721102, 42721103
141-1	Honey Bee Acute Contact	BCDJK 41219109
<u>TOXICOLOGY**</u>		
81-1	Acute Oral Toxicity - Rat	ALL 40557004
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL 40557005
81-3	Acute Inhalation Toxicity - Rat	ALL 40557006
81-4	Primary Eye Irritation - Rabbit	ALL 40557007
81-5	Primary Dermal Irritation - Rabbit	ALL 40557008
81-6	Dermal Sensitization - Guinea Pig	ALL 40557009

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Butoxyethyl ester--BEE
(116004)**

REQUIREMENT	USE PATTERN	CITATION(S)
82-1A	90-Day Feeding - Rodent	BD 00150378
82-2	21-Day Dermal - Rabbit	BCDFKJ 42212701
83-1A	Chronic Feeding Toxicity - Rodent	BD
83-2A	Oncogenicity - Rat	BD 40107701
83-2B	Oncogenicity - Mouse	BD 40356601
83-3A	Developmental Toxicity - Rat	BD 43675801, 41688301
83-3B	Developmental Toxicity - Rabbit	BD 43217601
83-4	2-Generation Reproduction - Rat	BD 43545701
84-2A	Gene Mutation (Ames Test)	ALL 41732202
84-2B	Structural Chromosomal Aberration	ALL 41747101
84-4	Other Genotoxic Effects	ALL 41747102
<u>ENVIRONMENTAL FATE</u>		
161-1	Hydrolysis	ALL 00134174
161-2	Photodegradation - Water	BCDFJ 43007601
162-1	Aerobic Soil Metabolism	BCJK 43799101
162-3	Anaerobic Aquatic Metabolism	DF 00151967, 43799103
162-4	Aerobic Aquatic Metabolism	DF 43799106 (additional data are required for TCP metabolite)
164-1	Terrestrial Field Dissipation	BCK 42730601, 43033401, 44039301

**Data Supporting Guideline Requirements for the Reregistration of Triclopyr Butoxyethyl ester--BEE
(116004)**

REQUIREMENT	USE PATTERN	CITATION(S)
164-3 Forest Field Dissipation	J	44039301, 41445001, 44039302, 43011601 (supplemental)
165-1 Confined Rotational Crop	BD	41219108, 40356607
201-1 Droplet Size Spectrum		Spray Drift Task Force
202-1 Drift Field Evaluation		Spray Drift Task Force

**NOTE: Toxicology studies conducted with triclopyr have been performed using either the free acid, the triethylamine salt (TEA), or the butoxyethyl ester (BEE) form. The issue of bioequivalency for the purpose of testing the three chemical forms of triclopyr was addressed by the registrant conducting special studies with the TEA and BEE forms. These studies which include data on comparative disposition, plasma half-life, tissue distribution, hydrolytic cleavage under physiological and environmental conditions (MRID # 43394101, 42444701, and 42437901) were found to adequately address the issue of bioequivalency. In addition, subchronic toxicity studies conducted with each form supported the pharmacokinetic data in demonstrating bioequivalence. Therefore, with the exception of the acute toxicity database (as noted in each of the three separate bibliographies) toxicology studies conducted with any one form of triclopyr have been used to support the toxicology database as a whole.

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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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 Registrant'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: 703-487-4650).

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 8570-34 and 8570-35, Certification with Respect to Citation of Data and Data Matrix.

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, Citation of Data and Data Matrix Forms

TRICLOPYR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Triclopyr.

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 Triclopyr . 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, Citation of Data and Data Matrix Forms in replying to this 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 are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 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 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 CP Moran at (703) 308-8590.

All responses to this Notice for the Product Specific data requirements should be submitted to:

CP Moran
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: Triclopyr

TRICLOPYR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Triclopyr.

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 Triclopyr. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) a list of registrants receiving this DCI (Attachment 5), and (6) the Cost Share, Citation of Data and Data Matrix Forms in replying to this 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 are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on are needed. These data are needed to fully complete the reregistration of all eligible 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 Dean Monos at (703) 308-8074.

All responses to this Notice for the generic data requirements should be submitted to:

Dean Monos, Chemical Review Manager
Reregistration Branch III
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Triclopyr

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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

- Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be 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 cancelled 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 Ingredient or Pure 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 completed "Certification With Respect To Citation of Data" and "Data Matrix" forms.

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

TRB'S BATCHING OF PRODUCTS CONTAINING TRICLOPYR AS THE ACTIVE INGREDIENT 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 the active ingredients 3,5,6-Trichloro-2-pyridinyloxyacetic acid (triclopyr), the triethylamine salt of triclopyr and triclopyr, butoxyethyl ester, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding 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. Registrants have the option of participating with all or some other registrants of products in their product's batch, to deal 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 or 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 or she may do so provided that the data base is complete and valid by today's standards (see the attached acceptance criteria), 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. Registrants may not support their product using data conducted on a product from a different batch. TRB must approve any new or canceled formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch. 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 or 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 or 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 or 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 or her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredients 3,5,6-Trichloro-2-pyridinyloxyacetic acid (triclopyr), the triethylamine salt of triclopyr and triclopyr, butoxyethyl ester.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	62719-40	triclopyr, butoxyethyl ester ... 61.6%	liquid
	62719-70	triclopyr, butoxyethyl ester ... 61.6%	liquid
	62719-251	triclopyr, butoxyethyl ester ... 61.6%	liquid
	62719-258	triclopyr, butoxyethyl ester ... 61.6%	liquid
	OK91000900	triclopyr, butoxyethyl ester ... 61.6%	liquid
2	62719-67	triclopyr, butoxyethyl ester ... 16.5% 2,4-D butoxyethyl ester ... 34.4%	liquid
	62719-260	triclopyr, butoxyethyl ester ... 16.5% 2,4-D butoxyethyl ester ... 34.4%	liquid
3	62719-176	triclopyr, butoxyethyl ester ... 16.7%	liquid
	62719-177	triclopyr, butoxyethyl ester ... 16.7%	liquid
4 ¹	239-2515 ²	triclopyr, triethylamine salt ... 0.70%	liquid/ aerosol
	239-2587	triclopyr, triethylamine salt ... 0.70%	liquid

	802-596	triclopyr, triethylamine salt	... 0.75%	liquid
5	62719-262	triclopyr, triethylamine salt clopyralid	... 0.50% ... 0.18%	solid
	62719-263	triclopyr, triethylamine salt clopyralid	... 0.50% ... 0.18%	solid
6	239-2491	triclopyr, triethylamine salt	... 8%	liquid
	802-594	triclopyr, triethylamine salt	... 8%	liquid
7	62719-37	triclopyr, triethylamine salt	...44.4%	liquid
	62719-53	triclopyr, triethylamine salt	...44.4%	liquid
	62719-215	triclopyr, triethylamine salt	...44.4%	liquid
	62719-230	triclopyr, triethylamine salt	...44.4%	liquid
	62719-257	triclopyr, triethylamine salt	...44.4%	liquid
8	228-313	triclopyr, triethylamine salt 3,6-dichloro-2-pyridinecarboxylic acid 2,4-Dichlorophenoxyacetic acid, triisopropanolamine salt	... 5.59% ... 1.30% ... 50.7%	liquid
	228-321	triclopyr, triethylamine salt 3,6-dichloro-2-pyridinecarboxylic acid 2,4-Dichlorophenoxyacetic acid, triisopropanolamine salt	... 3.80% ... 1.30% ... 50.7%	liquid
	62719-217	triclopyr, triethylamine salt 3,6-dichloro-2-pyridinecarboxylic acid 2,4-Dichlorophenoxyacetic acid, triisopropanolamine salt	... 3.80% ... 1.30% ... 50.7%	liquid

9	228-316	triclopyr, triethylamine salt ... 15.2%	liquid	2,4-Dichlorophenoxyacetic acid, dimethylamine salt ... 34.2%
	62719-75	triclopyr, triethylamine salt ... 15.2%		2,4-Dichlorophenoxyacetic acid, dimethylamine salt ... 34.2%
10	62719-92	triclopyr, triethylamine salt ... 33.0%	liquid	clopyralid ... 12.1%
	62719-232	triclopyr, triethylamine salt ... 33.0%		clopyralid ... 12.1%

¹Products in batch 4 may cite data conducted on products in batch 6.

²Due to the formulation of reg. no. 239-2515, this product may not share a primary eye irritation study with the other products in batch #4.

Table 2 lists the products in the “No Batch” group. These products can not be batched because they were not considered to be similar to other the products in terms of acute toxicity. The registrant of this product is responsible for meeting the acute toxicity data requirements for it individually. These products may not cite acute toxicity/ irritation data derived from any other products in this RED. The registrant may cite pre-existing data conducted on their individual product (or data cited in this RED for the technical product) if it exists and it meets current Agency standards.

Table 2.

Registration Number	Percent Active Ingredient	Product Type
228-317	triclopyr butoxyethyl ester ... 16.50%	liquid
	isooctyl (2-ethylhexyl) ester of 2-methyl-4-chlorophenoxyacetic acid ... 56.14%	
	dicamba ... 3.60%	

499-409	triclopyr, triethylamine salt ... 0.076% 2,4-dichlorophenoxyacetic acid, dimethylamine salt ... 0.171%	liquid
538-180	triclopyr, butoxyethyl ester ... 1.15%	solid
17545-8	triclopyr ... 61.6%	solid
62719-87	triclopyr, butoxyethyl ester ... 96%	solid
62719-91	triclopyr, butoxyethyl ester ... 35.3%	liquid
62719-246	triclopyr, triethylamine salt ... 1.70% clopypalid, triethylamine salt ... 0.57%	solid/stick
62719-248	triclopyr, triethylamine salt ... 2.0% 2,4-D, dimethylamine salt ... 4.5%	solid/stick

Attachment 5 List of All Registrants Sent This Data Call-In (insert) Notice

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.
- l. 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 all 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.



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)

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 % by Weight
b. % by Weight

14. Certified Limits % by Weight
a. Upper Limit
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



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 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)



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
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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																																																																																												

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 that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDS, or contact Dean Monos at (703)-308-8074.

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 Triclopyr.

The following documents are part of the Administrative Record for 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