United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-021
March 2001

Reregistration Eligibility Decision for Triallate

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-00-019 March 2001

R.E.D. FACTS

Triallate

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2695, triallate.

Use Profile

Triallate is a pre-emergent herbicide federally registered, but restricted to use in CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY on barley, lentils, peas (dried and succulent), triticale, wheat, and canary grass. The Agency has found that all currently registered uses of triallate, except canary grass, are eligible for reregistration, provided specified changes are made to the label. Canary grass is not being supported by the registrant for reregistration and the tolerance has been revoked. In addition, since completion of the RED, a tolerance has recently been established for a new use of triallate on sugar beets.

On average, about 2.3 million pounds of triallate are applied annually on 2.1 million acres. Depending on the crop, triallate formulations may be applied before or after planting, either by ground or aerial equipment. Application is typically made either in the fall or in the spring, before targeted weed species germinate.

Regulatory History

Triallate was first registered as a herbicide in the U.S. in 1961. Because triallate is a List B chemical, no Registration Standard was prepared. A Data Call-In (DCI) was issued in 1991 requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. In 1993 and 1994, two additional DCIs were issued requiring the submission of a female mouse oncogenicity study at higher dose levels and a developmental neurotoxicity study.

Human Health Assessment

Toxicity

Triallate is a herbicide in the class of thiocarbamates, which includes pebulate, molinate, EPTC, butylate, vernolate, and cycloate. As with other chemicals in this class, neurotoxicity is the major toxic effect; however, other toxic effects, including carcinogenicity were also observed in toxicology studies for this compound.

Toxicity categories, which range from I (most toxic) to IV (least toxic), show that triallate has a low order of acute oral (Toxicity Category III); dermal (Toxicity Category IV); and inhalation (Toxicity Category IV) toxicity. In primary irritation studies, triallate produces slight irritation to the eye (Toxicity Category III) and skin (Toxicity Category IV), and is a skin sensitizer.

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats.

Cumulative Risk

In accordance with the FQPA, the Agency is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share a common mechanism of toxicity. In contrast to other carbamates, the Agency has a less fully developed understanding of whether the thiocarbamates share a common mechanism of toxicity with other cholinesterase-inhibiting or carcinogenic chemicals. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides).

Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

Dietary Risks

Overall acute and chronic dietary (food only) risks associated with triallate use on all registered use sites, including the proposed use of triallate on sugar beets, are not of concern to the Agency. Acute and chronic drinking water concentrations were also estimated to evaluate the contribution of drinking water to dietary risk. These drinking water estimates are based on ground and surface water computer models that predict concentrations for both parent triallate and the metabolite TCPSA. Aggregating both food and drinking water acute and chronic (non-cancer) risks, the dietary exposures are not of concern to the Agency.

Triallate is classified as a Group C chemical (possible human carcinogen). Based on a linear low-dose (Q_1*) approach for human cancer risk characterization, the cancer dietary risk is 7.1×10^{-8}, which is less than EPA's target of 1×10^{-6} (1 in 1 million) and, therefore, is not of concern to the Agency.

Although chronic (cancer) dietary (food only) risk is not of concern to the Agency, aggregating the cancer dietary risk (food) with model estimated drinking water concentrations is of concern. To address this, the registrant initiated a surface water monitoring program to measure parent triallate and metabolite TCPSA in high use areas with vulnerable soil conditions.

Tolerances

Tolerances [refer to 40 CFR 180.314 (c)] or maximum residue limits are summarized below:

- Revoke 1 tolerance (lentils hay), since it is no longer considered a significant livestock feed item.
- Add 3 new tolerances (barley hay; wheat forage; wheat hay), due to changes to OPPTS GLN 860.1000.
- The tolerance for peas will apply to lentils.
- All other tolerances are to be increased, except barley grain, which will remain the same.

Worker Risks

There are potential occupational exposures to pesticide handlers and to workers when applying triallate. For mixers/loaders, applicators, and flaggers, risks for all exposure scenarios are not of concern with either personal protective equipment (PPE) (i.e., gloves and dust/mist filtering respirators) or engineering controls (enclosed cockpits and trucks). The addition of some of these protective measures are necessary to reduce cancer risk to handlers.

Significant exposure to triallate during harvesting, or any other late season activity, is not likely since triallate is applied pre-emergence. Therefore, post-application exposure is not expected, provided that the current 12-hour restricted-entry interval (REI) is observed.

Environmental Assessment

Ecological Risks

The use of triallate is not likely to pose significant risk to birds, fish, large mammals, reptiles or nontarget insects. Levels of concern are slightly exceeded for endangered small mammals; however, this risk is dependent upon ingestion of large amounts of contaminated insects or seed in the diet. Levels of concern for acute risk, based on water modeling results, are slightly exceeded for endangered aquatic invertebrates. However, because the habitat of endangered aquatic organisms where triallate is registered are not likely to be exposed to the high modeled concentrations of triallate, effects to endangered aquatic invertebrates are not expected. Additionally, levels of concern for acute risk are exceeded for terrestrial and semiaquatic plants. Although risks to plants are greater than the level of concern, the overall ecological risk associated with the use of triallate is low; therefore, no additional mitigation measures to reduce estimated ecological risks are necessary.

Risk Mitigation

In order to support a RED for triallate, some risk mitigation measures are necessary and must be implemented. To address aggregate cancer dietary risk concerns (food and water), the registrant initiated a surface water monitoring program to measure parent triallate and metabolite TCPSA in high use areas with vulnerable soil conditions. A final report of this study is expected in late 2002. Interim results indicate that surface drinking water concentrations are not of concern to the Agency.

There are also potential occupational exposures to pesticide handlers and to workers when applying triallate. For mixers/loaders, applicators, and flaggers, risks for all exposure scenarios are mitigated with either personal protective equipment (PPE) (i.e., chemical resistant gloves and dust/mist filtering respirators) or engineering controls (i.e., enclosed cockpits and trucks).

Additional Data Required

EPA is requiring the following additional generic studies for triallate to confirm its regulatory assessments and conclusions: discussion of formation of impurities; stability to normal and elevated temperatures, metals, and metal ions; pH; UV/Visible absorption; partition coefficient; crop field trials (wheat hay); processed food/feed (barley); field accumulation in rotational crops; aquatic invertebrate life-cycle (21 day); aquatic plant growth; and surface drinking water monitoring.

The Agency also is requiring product-specific data, including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All triallate end-use products must comply with EPA's current pesticide product labeling requirements, with the risk mitigation measures discussed above, and uses no longer eligible for reregistration should be excluded. For a comprehensive list of labeling requirements, please see the triallate RED document.

Regulatory Conclusion

The Agency has found that all currently registered uses of triallate, except canary grass, are eligible for reregistration, provided specified changes are made to the label. The use of eligible triallate products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to triallate will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for triallate during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs or http://www.epa.gov/pesticides/.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419; telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the triallate RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161; telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the triallate RED, or reregistration of individual products containing triallate, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460; telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is http://ace.orst.edu/info/nptn/ .

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessment for the thiocarbamate pesticide triallate. Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of triallate. The EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of triallate, and its associated human health and environmental risks. The Agency's decision on the individual chemical triallate which was approved on August 4, 2000, can be found in the attached document entitled, "Reregistration Eligibility Decision for Triallate."

A Notice of Availability for this Reregistration Eligibility Decision (RED) for Triallate is published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Agency's web page www.epa.gov/pesticides and in the Public Docket.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA)**,** the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. In cooperation with the U.S. Department of Agriculture, the Agency held a teleconference on March 20, 2000, where the results of the revised human health and environmental effects risk assessments were presented to interested stakeholders. Information discussed during the call, such as triallate usage and occupational practices, are reflected in this RED. Also, a close-out conference call was conducted on July 19, 2000 with many of the same participants from the March 20 conference call, to discuss the risk management decisions and resultant changes to the triallate labels.

Please note that the triallate risk assessment and the attached RED concern only this particular thiocarbamate. While current data are limited, the thiocarbamates, including triallate, appear to be comparatively weak cholinesterase inhibitors, and the individual chemicals are generally regulated based

on other dissimilar toxic endpoints from each other and thus, the thiocarbamates do not appear to exhibit a common mechanism of action within the group of chemicals. At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether or not triallate shares a common mechanism of toxicity with other cholinesterase-inhibiting or possible human carcinogen chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting or human carcinogen chemicals.

This document contains a generic and a product-specific Data Call-In (DCI) that outline further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover. Additionally, the first set of required responses to both DCIs are due 90 days from the receipt of the DCI letter. The second set of required responses to the product-specific DCI are due eight months from the date of this letter.

End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document. If you have questions on this document or the label changes necessary for reregistration, please contact the Special Review and Reregistration Division representative, Dirk Helder at (703) 305-4610. For questions about product reregistration and/or the Product Data Call-In that accompanies this document, please contact Barbara Briscoe at (703) 308-8177.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Triallate

List B
Case 2695

Table of Contents

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
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
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment

Glossary of Terms and Abbreviations

NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid (Triallate Metabolite)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of triallate, including the consideration of risk to infants and children for any potential dietary, drinking water, dermal or oral exposures. The Agency made its reregistration eligibility determination based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that all currently registered uses of triallate, except for canary grass, are eligible for reregistration, provided specified changes are made to the label. Canary grass is not being supported by the registrant for reregistration and tolerances have been revoked.

Use Summary

Triallate is a pre-emergent herbicide federally registered, but restricted to use in CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY on barley, lentils, peas (dried and succulent), triticale, wheat, and canary grass (seed crop only). In addition, a tolerance petition for sugar beets is currently pending. On average, about 2.3 million pounds of triallate are applied annually on 2.1 million acres. Depending on the crop, triallate formulations may be applied before or after planting, either by ground or aerial equipment. Application is typically made either in the fall or in the spring, before targeted weed species germinate.

Dietary Risks

Triallate is a herbicide in the class of thiocarbamates, which includes pebulate, molinate, EPTC, butylate, vernolate, and cycloate. As with other chemicals in this class, neurotoxicity is the major toxic effect; however, other toxic effects, including carcinogenicity were also observed in toxicology studies for this compound.

Overall acute and chronic dietary (food only) risks associated with triallate use on all registered use sites, including the proposed use of triallate on sugar beets, are not of concern to the Agency. The Agency based its dietary exposure assessment on a refined Tier 3-Monte Carlo probabilistic analysis with anticipated residues and percent of crop treated data. Acute and chronic drinking water concentrations were also estimated to evaluate the contribution of drinking water to dietary risk. These drinking water estimates are based on ground and surface water computer models that predict concentrations for both parent triallate and the metabolite TCPSA. Aggregating both food and drinking water acute and chronic (non-cancer) risks, the dietary exposures are not of concern to the Agency.

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats. The Agency utilized a low-dose (Q_1*) approach to characterize human cancer risk. Although chronic (cancer) dietary (food only) risk is not of concern to the Agency, aggregating the cancer dietary risk (food) with model estimated drinking water concentrations is of concern. To address this, the registrant initiated a surface water monitoring

program to measure parent triallate and metabolite TCPSA in high use areas with vulnerable soil conditions. A final report of this study is expected in late 2002.

Worker Risks

There are potential occupational exposures to pesticide handlers and to workers when applying triallate. For mixers/loaders, applicators, and flaggers, risks for all exposure scenarios are mitigated with either personal protective equipment (PPE) (i.e., gloves and dust/mist filtering respirators) or engineering controls (enclosed cockpits and trucks). The addition of some of these protective measures are necessary to reduce cancer risk to handlers.

Significant exposure to triallate during harvesting, or any other late season activity, is not likely since triallate is applied pre-emergence. Therefore, post-application exposure is not expected, provided that the current 12-hour restricted-entry interval (REI) is observed.

Ecological Risks

The use of triallate is not likely to pose significant risk to birds, fish, large mammals, reptiles or nontarget insects. Levels of concern are slightly exceeded for endangered small mammals; however, this risk is dependent upon ingestion of large amounts of contaminated insects or seed in the diet. Levels of concern for acute risk, based on water modeling results, are slightly exceeded for endangered aquatic invertebrates. However, because the habitat of endangered aquatic organisms where triallate is registered are not likely to be exposed to the high modeled concentrations of triallate, effects to endangered aquatic invertebrates are not expected. Additionally, levels of concern for acute risk are exceeded for terrestrial and semiaquatic plants. Although risks to plants are greater than the level of concern, the overall ecological risk associated with the use of triallate is low; therefore, no additional mitigation measures to reduce estimated ecological risks are necessary.

Cumulative Risk

In accordance with the Food Quality Protection Act (FQPA), the Agency is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share a common mechanism of toxicity. In contrast to other carbamates, the Agency has a less fully developed understanding of whether the thiocarbamates share a common mechanism of toxicity with other cholinesterase-inhibiting or carcinogenic chemicals. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides). Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

More detailed information can be found in the technical supporting documents for triallate referenced in this reregistration eligibility decision document. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

Triallate Reregistration Eligibility Decision Team

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I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

The Food Quality Protection Act requires that the Agency consider the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency is examining whether and to what extent some or all organophosphorous and carbamate pesticides may share acetylcholinesterase inhibition as a common mechanism of toxicity. In contrast to other carbamates, the Agency has a less fully developed understanding of whether or not the thiocarbamates share acetylcholinesterase inhibition as a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. While current data are limited, the thiocarbamates appear to be comparatively weak cholinesterase inhibitors and are generally regulated based on other dissimilar toxic endpoints. At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether or not triallate, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting or possible human carcinogen chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting or human carcinogen chemicals.

Similarly, the Agency is examining whether and to what extent some or all pesticides that may be human carcinogens may also share a common mechanism of toxicity. Current information on the common mechanism of toxicity for possible or probable human carcinogens is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other human carcinogen chemicals.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of triallate, including the consideration of risk to infants and children for any potential dietary,

drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. In an effort to simplify the RED, the information presented herein is summarized. More detailed information can be found in the technical supporting documents for triallate referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket. This document consists of six sections. Section I is the introduction. Section II provides a profile of the use and usage of triallate, and its regulatory history. Section III gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement risk mitigation measures outlined in Section IV. Finally, the Appendices list all related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

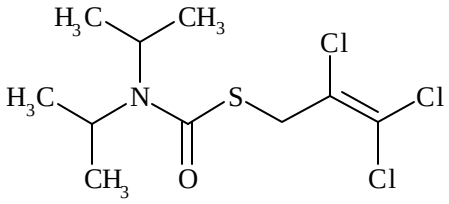
A. Regulatory History

Triallate has been registered in the United States since 1961 for use as a herbicide. A Data Call-In (DCI) was issued in 1991 for triallate requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. Because triallate is a List B chemical, no Registration Standard was prepared. However, in 1993 and 1994, two additional DCIs were issued requiring the submission of a female mouse oncogenicity study at higher dose levels and a developmental neurotoxicity study, respectively. Also, the Agricultural Data Call-In (AGDCI) was issued in 1995, requiring foliar residue dissipation data on products that are foliarly applied and transfer coefficients to develop restricted entry intervals for workers. In response, Monsanto modified its product label (Registration No. 524-307) to restrict use to a pre-emergent or pre-plant soil application to remove it from the scope of the AGDCI. On March 24, 1998, following review and approval of the changed product label, the Agency waived the guideline requirements of the AGDCI for triallate products. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data which were submitted in response to the DCIs.

The Agency is currently reviewing a petition to establish tolerances for triallate use on sugar beets. The decision of whether or not to grant tolerances for sugar beet use is outside the scope of this RED, and will be made separately by the Agency. However, to assist in the decision-making process on whether or not to grant tolerances for triallate use on sugar beets, the dietary assessment in this RED, including the calculations of the Drinking Water Levels of Comparison (DWLOCs), includes the proposed use of triallate on sugar beets.

Also, in an effort to promote transparency of the reregistration process and public understanding of and participation in regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA), has modified the reregistration process. This modified process provides opportunities for stakeholders to ask questions about and provide input to the risk assessment and risk mitigation strategies, via conference calls and other formats. Consistent with this process, a conference call was conducted on March 20, 2000 with EPA, USDA, the registrant, and other stakeholders (i.e., growers, commodity groups, land grant universities, and others) to discuss the basis of the calculated risks of triallate, and the Agency's resultant risk concerns. Information discussed during the call, such as triallate usage and occupational practices, are reflected in this RED. Also, a close-out conference call was conducted on July 19, 2000 with many of the same participants from the March 20 conference call, to discuss the risk management decisions and resultant changes to the triallate labels.

B. Chemical Identification



Triallate technical is an amber to dark brown solid with a melting point of 29-30 °C, specific gravity of 1.2600-1.2624 at 35 °C, octanol/water partition coefficient (log K_{ow}) of 4.54, and vapor pressure of 1.1 x 10^{-4} mm Hg at 25 °C. Triallate is slightly soluble in water (4 ppm at 25 °C), and is soluble in methylene chloride, n-octanol, and toluene at >200 g/100 mL.

- **Common Name:** Triallate
- **Chemical Name:** S-2,3,3-trichloroallyl diisopropylthiocarbamate
- **Chemical Family:** Thiocarbamate
- **CAS Registry Number:** 2303-17-5
- **OPP Chemical Code:** 078802
- **Empirical Formula:** $C_{10}H_{16}Cl_3NOS$
- **Trade Name:** Far-Go®, Buckle®, and Avadex BW®
- **Basic Manufacturer:** Monsanto Company

C. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of triallate eligible for reregistration is contained in Appendix A.

Type of Pesticide
Triallate is a pre-emergent selective herbicide for general use.

Use Sites
Triallate is federally registered, but restricted to use in Colorado, Idaho, Kansas, Minnesota, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming on barley, lentils, peas (dried and succulent), triticale, and wheat. The only non-food/non-feed use is canary grass (seed crop only); however, canary grass is not being supported by the registrant for reregistration and tolerances have been revoked. A tolerance petition for sugar beets is currently pending. There are no existing or proposed residential uses for triallate products.

Target Pests
Wild oat, bromegrass, Japanese brome, cheat, downy brome, yellow foxtail, pigeongrass, green foxtail, annual ryegrass

Formulation Types Registered
Triallate is sold in the United States under the trade names Far-Go®, Buckle®, and Avadex BW®. The 10% granular (G) for Far-Go® and Buckle®, and the 4 lb/gal emulsifiable concentrate (EC) for Far-Go® are the only triallate formulations registered for food/feed uses. Although Avadex BW® is registered in the United States, it is currently only sold in Canada. Moreover, the Buckle® granular formulation contains 10% triallate and 3% trifluralin.

Method and Rates of Application
Triallate may be applied by groundboom, tractor-drawn spreader, fixed-wing aircraft, and soil incorporation equipment.

Depending on the crop, triallate formulations may be applied, either by ground or aerial equipment, at application rates of 1.0-1.5 lb ai/acre; either before or after planting; as a surface broadcast (no-till) or incorporated in the soil. A very small percentage of the granular triallate formulation (<1 % of total triallate products produced) are aerially applied.

Timing of Application
Application is typically made either in the fall (70%) or in the spring (30%) before targeted weed species germinate. Typically, the products are immediately incorporated into the soil to minimize volatilization. However, surface application of the granular formulation is also allowed with delayed incorporation or without incorporation in no-till systems, which helps prevent soil erosion in some cases. The EC formulated products require immediate soil incorporation for all applications.

D. Estimated Usage of Pesticide

Table 1 below summarizes the best available estimates for the pesticide uses of triallate. 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. Triallate Usage Summary

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated (000)		Lbs ai Applied (000)		Average Application Rate			States of Most Usage (% of total ai used on this site)
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ A/yr	# appl /yr	lb ai/A /app	
Barley	7,505	653	1,000	9	13	710	1,088	1.1	1.0	1.1	MT, ID, ND, WA 81%
CRPA	34,308	3	7	0	0	7	14	2.0	1.0	2.0	ND 97%
Lots, Farmsteads, etc.	24,815	11	63	0	0	11	63	1.0	1.0	1.0	GA 100%
Peas (dry) and lentils	249	33	75	13	30	41	94	1.3	1.0	1.3	ID, WA 89%
Peas (green)	386	16	47	4	12	16	47	1.0	1.0	1.0	WA, OR 96%
Summer Fallow	29,040	73	175	0	1	84	196	1.2	1.0	1.1	WA, MT 91%
Wheat (spring)	20,799	1,155	1,753	6	8	1,110	1,684	1.0	1.0	1.0	ND, MT, MN 90%
Wheat (winter)	45,854	200	283	0	1	270	541	1.3	1.1	1.2	MT, WA 84%
Totals		2,144				2,249					

CRPA = Conservation Reserve Program Acres

COLUMN HEADINGS

Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily. Wtd Avg % of crop treated used for chronic (cancer and non-cancer) dietary risk assessment.

Est Max=Estimated maximum, which is estimated from available data. Est Max % of crop treated used for acute dietary risk assessment.

Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1996.

Calculations of the above numbers may not appear to agree because they are displayed as rounded:

- to the nearest 1000 for acres treated or lb. ai (Therefore 0 = < 500)
- to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

SOURCES

EPA data (1987-1996), USDA/NASS (1990-1996), California (1993-1995)

III. Summary of Triallate Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for the thiocarbamate pesticide triallate, as presented fully in the documents: *Triallate-HED Reregistration Eligibility Document, April 18, 2000*, and *Reregistration Eligibility Document for Triallate Environmental Fate and Effects Chapter, September 30, 1999*. Since the completion of the Environmental Fate and Effects Risk Assessment, the Agency made changes in its assessment of surface water concentrations of triallate and its metabolite TCPSA. Specifically, the Agency has included the use of the Index Reservoir (IR) and Percent Crop Area (PCA) in the Tier II PRZM-EXAMS surface water model simulations. These changes are described in the Agency's December 22, 1999 and March 28, 2000 memoranda from the Environmental Fate and Effects Division.

The purpose of this decision document is to summarize the key features and findings of this risk assessment in order to help the reader better understand the conclusions reached in the assessment. While the risk assessments and related addenda are not included in this document, they are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

A. Human Health Risk Assessment

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports a reregistration eligibility determination for all currently registered uses. Triallate has a low order of **acute oral toxicity and is classified as a Toxicity Category III**, based on test results that indicate the LD_{50} (males) = 3612 mg/kg; LD_{50} (females) = 3455 mg/kg; and LD_{50} (combined) = 3382 mg/kg (MRID No. 44660701). The Agency has determined that only triallate and its metabolite 2,3,3-trichloroprop-2-ene sulfonic acid (TCPSA) should be regulated and assessed for dietary exposure in plant commodities. The Agency decided to regulate on the TCPSA metabolite because it is present at more than 10% of the total radioactive residue (TRR) in the plant metabolism studies, and in the absence of toxicological data for this metabolite, the same toxicity as the parent compound was assumed.

A brief overview of the toxicity studies used for the dietary risk assessment is outlined in Table 2 in this document. Further details on the toxicity of triallate can be found in the *Hazard Characterization* section of the April 18, 2000 Human Health Risk Assessment.

Acute Dietary

For the general population, the No Observed Adverse Effect Level (NOAEL) of 60 mg/kg/day was established based on decreased mean body weight, altered motor activity, and changes in functional

observation battery (FOB) in the rat acute neurotoxicity study at the Lowest Observed Adverse Effect Level (LOAEL) of 300 mg/kg/day. Because of the neurotoxic characteristics of triallate (altered motor activity observed in both sexes 7 hours after treatment at the mid- and high-doses that persisted up to 14 days in high-dose females), this endpoint is considered appropriate for assessing risk in the general population.

For the females 13-50 years population subgroup, the NOAEL of 5 mg/kg/day was established based on increased skeletal malformations/variations in the rabbit developmental toxicity study at the LOAEL of 15 mg/kg/day. The skeletal malformations are presumed to occur after a single exposure (dose), and thus, are appropriate for this (acute) risk assessment. In addition, skeletal malformations (malaligned sternebrae) were also seen in rat fetuses following *in utero* exposure to triallate.

Chronic (Non-Cancer) Dietary

The NOAEL of 2.5 mg/kg/day was established based on decreased survival in males and females, decreased mean body weights in males, and increased adrenal weights in males in the 2-year chronic toxicity/carcinogenicity study in rats at the LOAEL of 12.5 mg/kg/day. Although a 2-year chronic toxicity study in dogs was conducted, the dose and endpoint selection is based on the rat study, because the systemic toxicity observed is more suitable for deriving the reference dose (RfD). In the 2-year study with dogs, the NOAEL was 1.275 mg/kg/day and the LOAEL was 4.25 mg/kg/day based on increased hemosiderin deposition, serum alkaline phosphatase and liver weight observed in female dogs. The Agency concluded that the dog study is not suitable for deriving the RfD, because: 1) hemosiderin deposition is a non-specific finding and cannot be correlated to other pathological findings; 2) the alkaline phosphatase levels observed in female dogs were all within biologically normal ranges; 3) alkaline phosphatase is a non-specific enzyme and is not indicative of liver pathology or biliraistais unless these increases are four times higher than normal and/or accompanied with increases in liver specific enzymes; 4) the increases in liver weights were not corroborated with histopathological lesions in the liver, and 5) these endpoints are not suitable for regulatory purposes.

Chronic (Cancer) Dietary

Triallate is classified as a Group C chemical - possible human carcinogen. This classification is based on the following factors: (i) hepatocellular carcinomas found in male mice at minimally adequate doses, with a positive trend and a borderline significant increase in females at inadequate doses; (ii) the increased incidence in male rats of renal tubular cell adenoma (a rare tumor type) above historical control levels was considered biologically significant, although no absolute pair-wise statistical significance was found; (iii) triallate is considered a mutagen because of positive genotoxicity results in *Salmonella typhimurium*, mouse lymphoma cells and Chinese hamster cells; and (iv) triallate is structurally related to several carcinogenic analogs, such as sulfallate, Telone II, and dichlorvos.

b. FQPA Safety Factor

The FQPA safety factor was retained for triallate because, there is quantitative evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits; developmental effects (decreased fetal body weight and increased incidence of malaligned sternebrae) were observed in the absence of maternal toxicity. However, the FQPA safety factor was **reduced to 3x** because:

- the toxicology data base is complete;
- increased susceptibility was observed in only one species (rabbits);
- there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity study in rats, the two-generation reproduction study in rats, or the developmental neurotoxicity study in rats;
- there was no evidence of abnormalities to the fetal nervous system in the developmental neurotoxicity study in rats; and
- adequate data are available or conservative modeling assumptions are used to assess dietary food and drinking water exposure (the only components of an aggregate exposure assessment needed for this pesticide).

The FQPA safety factor for triallate is **only applicable to the females 13 -50** population subgroup because the effects of concern (observed in the prenatal developmental toxicity study in rabbits) occur *in utero* and not during post-natal exposure. Moreover, the FQPA safety factor for triallate is only applicable to acute dietary risk assessment, because the effects of concern were observed only during *in utero* exposure and are presumed to occur after a single (acute) exposure.

c. Hazard Determination

The Population Adjusted Dose (PAD) is a relatively new term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA safety factor (SF). Where the FQPA SF has been removed (equivalent to 1x), the acute or chronic RfD is identical to the acute or chronic PAD. In the case of triallate, the FQPA SF has been removed (equivalent to a factor of 1x), except for the acute dietary risk assessment for the females 13-50 years population subgroup. For this subgroup, the acute PAD is adjusted to account for the 3x FQPA SF. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

Acute PAD

An acute RfD of 0.60 mg/kg/day was derived for the *general population* (including adult males, infants and children), based on the NOAEL of 60 mg/kg/day in the acute neurotoxicity study and an uncertainty factor (UF) of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The FQPA SF was removed (equivalent to a factor of 1x) for this population. Consequently, the acute PAD is identical to the acute RfD at 0.60 mg/kg/day for the general population.

An acute RfD of 0.05 mg/kg/day was derived for the *females 13-50 years* subpopulation group, based on the NOAEL of 5 mg/kg/day in the developmental toxicity study in rats and an UF of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The 3x FQPA SF was retained since the *in utero* endpoint is appropriate for this population subgroup (females 13-50 years). Thus, the acute PAD is 0.017 mg/kg/day.

Chronic (Non-Cancer) PAD

A chronic (non-cancer) RfD of 0.025 mg/kg/day, based on a NOAEL of 2.5 mg/kg/day in the 2-year chronic toxicity/carcinogenicity study in rats and an UF of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The FQPA SF was removed (equivalent to a factor of 1x) for chronic exposures. Consequently, the chronic PAD is identical to the chronic RfD at 0.025 mg/kg/day.

Chronic (Cancer)

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats. A linear low-dose (Q_1*) approach was used to characterize human health risk. The unit risk, Q_1* based on the hepatocellular carcinomas in male mice, is 7.17×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

The Agency considered the female mouse study to be inadequate, because the prior dosing was judged to be too low. The registrant has been given the option to repeat this study or to have the cancer risk assessment based on the low-dose extrapolation model (Q_1*) based on the male mice liver tumor. If the registrant chooses to repeat the study, the decision on cancer risk assessment will be deferred until completion and evaluation of the new study. The Agency is confident that the low-dose extrapolation model (Q_1*), based on the effects in the male mice, is a conservative enough approach to adequately characterize triallate human health cancer risk. At this time, the registrant has chosen not to repeat this study. Therefore, in the absence of any additional relevant data, the Q_1* based on the induction of liver tumors in the male mouse was used to assess cancer risk.

The doses, toxicity endpoints selected, and supporting studies for various dietary exposure scenarios are summarized in Table 2.

Table 2. Summary of Triallate Dietary Toxicity Endpoints

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study (MRID No.)
Acute Dietary (Females 13-50 years)	NOAEL=5 UF=100 FQPA SF=3	Increased skeletal malformations/variations.	Developmental- Rabbit (43315001)
	Acute RfD = 0.05 mg/kg/day Acute PAD=0.017 mg/kg/day		
Acute Dietary (General Population)	NOAEL=60 UF=100 FQPA SF=1	Decreased mean body weight; altered motor activity; and changes in functional observation battery (FOB).	Acute Neurotoxicity-Rat (42908101)
	Acute RfD=0.60 mg/kg Acute PAD=0.60 mg/kg/day		
Chronic (non cancer) Dietary	NOAEL=2.5 UF= 100 FQPA SF=1	Decreased survival (%+&), decreased mean body weights (%) and increased adrenal weights (%).	Chronic Toxicity/ Carcinogenicity-Rat (40384701)
	Chronic RfD = 0.025 mg/kg/day Chronic PAD=0.025 mg/kg/day		
Chronic (cancer) Dietary	**Group C - "Possible human carcinogen" - $Q_1^* = 7.17 \times 10^{-2}$ (mg/kg/day)$^{-1}$** in human equivalents [converted from animals to humans by use of the (mg/kg body weight)^{¾} cross species scaling factor).		

d. Exposure Assumptions

The dietary (food) exposure analysis is a refined Tier 3 approach based on the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

For all dietary analyses, anticipated residues (ARs) and percent of crop treated data were used. Since wheat, barley, and dry peas are considered blended commodities, the ARs for chronic and acute analyses are the same. For the purposes of this assessment, residue field trial data were used for the chronic and acute AR calculations. USDA Pesticide Data Program (PDP) monitoring data were available for wheat; however, these data were not used for the AR calculation for wheat, because PDP does not analyze for the TCPSA metabolite. All of the samples analyzed by PDP reported non-detectable residues of parent triallate. Field trial samples were analyzed for both triallate and the TCPSA metabolite, and there were measurable residues in these. FDA monitoring data for peas are also available. However, these data were not used in the AR calculation for peas, because very few samples were analyzed, and analyses determined the parent compound only. All of the samples showed non-detectable residues. Available field trial data for peas also analyzed the TCPSA metabolite, resulting in measurable residues. For more information on the parameters and assumptions used for assessing dietary risks, see the *Dietary Exposure* section of the April 18, 2000 Human Health Risk Assessment.

As noted above, the Agency is currently reviewing a petition to establish tolerances for triallate use on sugar beets. While the decision on whether or not to grant tolerances for sugar beet use will be made separately from this RED, to assist in that decision making process, the dietary assessment in this RED includes the proposed use of triallate on sugar beets. Field trials on sugar beets were provided as part of the petition, and were used to assess the contribution of triallate use on sugar beets in the dietary exposure analysis.

e. Dietary (Food) Risk Assessment

Acute Dietary Risk

Acute dietary risk is calculated considering what is eaten in one day (in this instance, the full range of consumption values as well as the range of residue values in food). A risk estimate that is less than 100% of the acute Population Adjusted Dose (PAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's level of concern. The acute PAD is the reference dose (RfD) adjusted for the FQPA safety factor.

A probabilistic (Monte Carlo) acute dietary analysis was conducted for triallate. This analysis is highly refined (Tier 3), and represents a realistic estimate of possible acute dietary exposure using the available residue data. The assessment is based on all uses supported through reregistration and the proposed use of triallate on sugar beets. The results of the acute analysis at the 99.9th percentile are presented in Table 3.

Table 3. Acute Dietary Risk (Food Only)

Population Subgroup	Exposure (mg/kg/day)	% aPAD
U.S. Population	0.000268	<1
Females (13+, nursing)	0.000305	1.8
Children (1-6 years)	0.000650	<1
All infants (< 1 year)	0.000736	<1

As indicated in Table 3, the risk estimates are significantly below the Agency's level of concern (<100% of the acute PAD) for acute dietary exposure for all population subgroups at the 99.9th percentile. For more information on acute dietary risk assessment, see the *Dietary Exposure and Risk Analysis* section of the April 18, 2000 Human Health Risk Assessment.

Chronic (Non-Cancer) Dietary Risk

Chronic (non-cancer) dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and

no adverse health effects would be expected) does not exceed the Agency's level of concern. The results of the analysis, based on the uses supported through reregistration and the proposed use of triallate on sugar beets, are summarized in Table 4.

Table 4. Chronic (Non-cancer) Dietary Risk (Food Only)

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000001	<1 %
Females (13+, nursing)	0.000002	<1 %
Children (1-6 years)	0.000003	<1 %
Non-nursing infants (<1 year)	0.000003	<1 %

As indicated in Table 4, the chronic (non-cancer) dietary risk (food) does not exceed the Agency's level of concern (<100% of the chronic PAD) for the general U.S. population and all subgroups. For more information on chronic dietary risk assessment, see the *Dietary Exposure and Risk Analysis* section of the April 18, 2000 Human Health Risk Assessment.

Chronic (Cancer) Dietary Risk

Chronic (cancer) dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is combined with a linear low-dose approach (Q_1*) to determine the lifetime (cancer) risk estimate.

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats. A linear low-dose (Q_1*) approach was used to characterize human health risk. The unit risk, Q_1* based on the hepatocellular carcinomas in male mice, is 7.17×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents. The method to calculate cancer dietary risk for triallate is provided below Table 5.

Table 5. Cancer Dietary Risk

Subgroup	Exposure (mg/kg/day)	Lifetime Risk Estimate[1]
U.S. Population	0.000001	7.1×10^{-8}

[1]

$$Lifetime\ Risk\ Estimate = 70\text{-}year\ Lifetime\ Exposure\ (mg/kg/day) \times Q_1^*$$
$$= (0.000001\ mg/kg/day) \times (7.17 \times 10^{-2}\ (mg/kg/day)^{-1})$$

The Agency generally considers 1×10^{-6} (1 in 1 million) or less as negligible risk for cancer dietary exposure. The results of this analysis indicate that the cancer dietary (food) risk of 7.1×10^{-8}, associated with the uses supported through reregistration and the proposed use of triallate on sugar

beets, is below the Agency's level of concern for food alone. For more information on chronic (cancer) dietary risk assessment, see the *Dietary Exposure and Risk Analysis* section of the April 18, 2000 Human Health Risk Assessment.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether or not modeled or monitoring estimated environmental concentrations (EECs) exceed this level. EECs that are above the corresponding DWLOC exceed the Agency's level of concern. Modeling is generally considered to be an unrefined assessment and provides high-end estimates.

The drinking water assessment for triallate was conducted on parent triallate and its metabolite TCPSA. TCPSA was included in the water assessment because it is included in the tolerance expression for triallate. While monitoring data from surface and ground water sources are available on parent triallate, none are available on the metabolite TCPSA. Given the uncertainties in TCPSA fate and transport, and that pesticides with similar properties (high mobility and moderate persistence) are found in drinking water, the Agency has based its drinking water assessment on the model estimates. Since the triallate uses on spring and winter wheat are expected to yield the highest EECs in surface and ground waters, these crop scenarios were used to predict triallate and TCPSA concentrations in ground and surface waters. Additionally, all drinking water model estimates are based on the maximum application rate of 1.5 lbs ai/acre.

Surface Water

Surface drinking water concentrations were estimated using the PRZM/EXAMS (Tier II) computer model with the Index Reservoir and Percent Crop Area. The Index Reservoir was developed from a real watershed in western Illinois, and is used as a standard watershed that is combined with variables representing characteristics of local soils, weather, and cropping practices to represent a vulnerable watershed that could support a drinking water supply. Tier II PRZM-EXAMS modeling predicts that the maximum total triallate residue (triallate + TCPSA) concentration in surface water is not likely to exceed 9.45 ppb for peak (acute) concentration and 1.26 ppb for 36-year annual mean (chronic: cancer and non-cancer) concentrations.

In comparison, non-targeted surface water monitoring data from the USGS National Water Quality Assessment (NAWQA) program indicate that chronic concentrations of triallate (parent only) in laboratory filtered surface waters from high use triallate areas are substantially lower than PRZM-EXAMS predictions. The maximum time-weighted annual mean concentration of triallate (parent only) in surface water is 0.077 ppb. Surface water data from Canadian monitoring studies on unfiltered

surface waters show a similar pattern. There are no surface water monitoring data for TCPSA to assess runoff potential from actual triallate use.

Ground Water

Ground drinking water concentrations were estimated using the SCI-GROW (Tier I) computer model. Model simulations indicate that the maximum total triallate residue (triallate + TCPSA) concentrations are not likely to exceed 0.21 ppb. Triallate is not reported as an analyte in the EPA Pesticides in Ground Water Database, and there were no reported ground water detections of triallate in the STORET database. Recent data from the non-targeted USGS NAWQA program indicate that there have been five detections of triallate in shallow ground water. The detected concentrations ranged between 0.001- 0.002 ppb. However, it should be noted that none of these detections were in aquifers that are considered to be major suppliers of drinking water, nor do they reflect any treatment of drinking water sources. Additionally, the reported NAWQA detections for parent triallate are approximately an order of magnitude lower than the SCI-GROW model prediction (0.02 ppb). Environmental fate data for triallate suggest that triallate is not expected to move into ground water because of moderately high sorption affinity to soil (low mobility) and low to moderate persistence. In contrast, TCPSA exhibits fate properties of pesticides (high mobility and moderate persistence) found in ground water. There are, however, no ground water monitoring data for TCPSA to assess leaching potential under actual use conditions.

The results of both surface and ground water model estimates and their comparison with the DWLOCs are summarized in Table 6. For more information on drinking water risks and the calculations of the DWLOCs, see the *Water Exposure* section of the April 18, 2000 Human Health Risk Assessment, the *Water Resource Assessment* of the September 30, 1999 Environmental Fate and Effects Risk Assessment, and the Agency's December 22, 1999 and March 28, 2000 memoranda amending the Tier II PRZM-EXAMS surface water model simulations.

Table 6. Drinking Water DWLOC and EEC Comparisons (Triallate + TCPSA)

Population Subgroup	DWLOCs (ppb)			EECs (ppb)		
	Acute	Chronic		Ground Water	Surface Water	
		Non-Cancer	Cancer		Acute	Chronic (Non-Cancer/Cancer)
U.S. General Population	21,000	875	0.45	0.21	4.23 (2" incorporation)	0.57 (2" incorporation)
Children (1-6 years)	6,000	250			9.45 (no incorporation)	1.26 (no incorporation)
Females (13+ nursing)	500	750				

For **acute risk**, potential (peak) concentrations of triallate + TCPSA in either ground water (0.21 ppb) or surface water for no incorporation (9.45 ppb) result in exposure that is below the Agency's level of

concern for females 13+ nursing (acute DWLOC = 500 ppb), the population subgroup with the highest risk estimate.

For **chronic (non-cancer) risk**, potential (average) concentrations of triallate + TCPSA in either ground water (0.21 ppb) or surface water for no incorporation (1.26 ppb) results in exposure that is below the Agency's level of concern for children 1-6 years old (chronic non-cancer DWLOC = 250 ppb), the most exposed population subgroup.

For **chronic (cancer) risk**, potential (average) concentrations of triallate + TCPSA in ground water (0.21 ppb) result in exposure that is below the Agency's level of concern (cancer DWLOC = 0.45 ppb). However, potential concentrations in surface water (0.57 ppb for 2" incorporation and 1.26 ppb for no incorporation) result in exposure that exceeds the Agency's level of concern for the U.S. population (0.45 ppb). It is important to note that triallate products are typically immediately incorporated into the soil to minimize loss by volatilization, especially for products formulated as ECs, which require incorporation.

As discussed above, there were no surface water monitoring data for TCPSA to assess runoff potential from actual triallate use. To address the uncertainties of the fate properties of TCPSA, and total parent and metabolite concentrations in drinking water, the registrant initiated a three year surface drinking water monitoring study in June 1999 to measure triallate and TCPSA concentrations. The study is designed to measure raw and finished triallate and TCPSA residue levels at five surface drinking water collection locations. The locations where measurements are to be taken were selected based on a variety of factors, including high triallate use; small watersheds with a high percentage of land planted to wheat; higher rainfall; and vulnerable soil conditions. Interim results of the surface water monitoring data were provided to the Agency on February 16 and May 22, 2000. The preliminary results indicate that the higher concentrations of triallate and TCPSA appear during the spring runoff, and especially in smaller watersheds with higher rainfall. Furthermore, the results to date indicate that all raw and finished measurements of peak and mean exposure to total parent triallate and TCPSA at all five sites are below the cancer DWLOC (0.45 ppb). Additional monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002.

3. Aggregate Risk

Aggregate risk looks at the combined risk from dietary exposure through both food and drinking water, as well as from exposures from non-occupational sources (e.g., residential uses). Generally, all risks from these exposures must be less than 100% of the acute PAD and chronic PAD (both *non-cancer* and *cancer*). For triallate, the aggregate risks are limited to dietary (food and water) exposure, because there are no residential uses.

Acute Dietary
Considering both the acute dietary (food) risk estimates and the surface and ground water estimated concentrations (drinking water) for triallate, the exposure is less than 100% of the acute PAD, and therefore, is not of concern.

Chronic (Non-Cancer) Dietary
Considering both the chronic (*non-cancer*) dietary (food) risk estimates and the surface and ground water estimated concentrations (drinking water) for triallate, the exposure is less than 100% of the chronic PAD, and therefore, is not of concern.

Chronic (Cancer) Dietary
The Agency generally considers 1×10^{-6} (1 in 1 million) or less as negligible risk for cancer. The results of this analysis indicate that the cancer dietary (food) risk estimate of 7.1×10^{-8} associated with the uses supported through reregistration and the proposed use on sugar beets is not of concern. The cancer DWLOC is 0.45 ppb. The Tier II (PRZM-EXAMS) estimated average concentration of triallate + TCPSA in surface water is 0.566 ppb (mean annual with 2" incorporation) and 1.26 ppb (mean annual with no incorporation). Concentrations in ground water are not expected to be higher than 0.21 ppb. The 36-year annual mean estimated concentrations in surface water exceed the DWLOCs for triallate + TCPSA in drinking water as a contribution to cancer aggregate exposure. However, the drinking water component is based on model predictions, which are generally conservative in estimating chemical concentrations in drinking water. To address this concern, the registrant initiated a three-year surface drinking water monitoring study in June 1999 to measure raw and finished triallate + TCPSA concentrations at five surface drinking water collection locations. Interim results of the surface water monitoring study indicated that peak and mean exposure to total parent triallate and TCPSA at all five sites are below the cancer DWLOC (0.45 ppb). Additional monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of triallate include individual farmers or growers and professional applicators who mix, load, and/or apply pesticides. Dermal and inhalation risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from an animal study. For triallate, MOEs greater than 100 are not of concern. The Agency also conducted an assessment of the cancer risk associated with triallate following exposures to occupational handlers. Cancer risks to workers of 1×10^{-6} (1 in 1 million) and less are considered to be negligible. For more information on the assumptions and calculations of potential risks to workers, see the *Occupational Exposure* section of the April 18, 2000 Human Health Risk Assessment.

a. Occupational Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete. Triallate has a low order of acute toxicity via dermal and inhalation routes, and produces slight irritation to the eyes and skin. Although triallate was not a skin sensitizer in the Buehler dermal sensitization assay, but was shown to be a sensitizer in the guinea pig maximization sensitization test, the Agency considers both test methods to be acceptable for assessing the potential to cause or elicit skin sensitization reactions. Because a positive response is observed in one of the sensitization tests, triallate is determined to be a skin sensitizer. The following is the acute toxicity profile for occupational exposure:

Table 7: Acute Toxicity Profile

Route of Exposure	MRID No.	Results	Toxicity Category
Dermal	42192001	LD_{50} > 5000 mg/kg	IV
Inhalation	00121856	LC_{50} > 5.3 mg/L	IV
Eye Irritation	44591801	Slight eye irritant	III
Dermal Irritation	44581601	Slight dermal irritant	IV
Dermal Sensitizer	44308301	Dermal Sensitizer	NA

For more occupational toxicity information used to assess risks to workers, see the *Hazard Characterization* section of the April 18, 2000 Human Health Risk Assessment.

Dermal Endpoint

For the short- and intermediate-term dermal endpoint, an oral NOAEL of 5 mg/kg/day was selected based on increased skeletal malformations/variations in the rabbit developmental toxicity study at the LOAEL of 15 mg/kg/day. A 21-day dermal toxicity study in rats with a systemic toxicity NOAEL of 500 mg/kg/day and a LOAEL of 3000 mg/kg/day is available. However, the Agency selected the developmental NOAEL from an oral study based on the following factors: 1) skeletal malformations were seen following *in utero* exposure in two species, rats and rabbits; 2) concern for the differences in the endpoints seen following oral administration in the developmental toxicity study (skeletal malformations) and dermal administration in the 21-day dermal toxicity study (body weight loss) in the same species (rats); 3) developmental effects were not evaluated in the dermal toxicity study (i.e., the consequence of these effects can not be ascertained for the dermal route of exposure); and 4) concern for exposure to pregnant workers.

A dermal absorption factor of 1% was estimated based on the results of the oral developmental toxicity study (LOAEL= 30 mg/kg/day) in rats, and a 21-day dermal toxicity study (LOAEL= 3000 mg/kg/day) in rats. While it is not appropriate to use the 21-day dermal study as a critical study for the risk assessment (see above), it is appropriate for use to extrapolate a dermal absorption factor, because

the oral and dermal studies in the same species (rat) demonstrated the same toxic effect (decreases in body weight gain), thus indicating dermal absorption.

Inhalation Endpoint

For the short- and intermediate-term inhalation endpoint, an oral NOAEL of 5 mg/kg/day was selected based on increased skeletal malformations/variations in the same rabbit developmental toxicity study that was selected for the dermal endpoint. A 7-week subchronic inhalation toxicity study in rats was conducted, but is not appropriate for regulatory purposes because the study is classified as supplementary due to technical difficulties (the animals may not have been uniformly exposed to the test material).

Cancer Endpoint

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats. A linear low-dose (Q_1*) approach was used to characterize human health risk. The unit risk, Q_1* based on the hepatocellular carcinomas in male mice, is 7.17×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

An overview of the toxicity studies used for the occupational risk assessment is outlined in Table 8. For more occupational toxicity information used to assess risks to workers, see the *Hazard Characterization* section of the April 18, 2000 Human Health Risk Assessment.

Table 8. Summary of Triallate Occupational Toxicity Endpoints

Exposure Scenario	Dose (mg/kg/day)	Absorption Factor*	Endpoint	Study (MRID No.)
Short- and Intermediate-Term (Dermal)	Oral NOAEL=5	1%	Increased skeletal malformations/variations.	Developmental-Rabbit (43315001)
Short- and Intermediate-Term (Inhalation)	Oral NOAEL=5	100%	Increased skeletal malformations/variations.	Developmental-Rabbit (43315001)
Long-Term (Dermal and Inhalation)	A dose and endpoint was not selected because of the current use pattern (maximum application rate of 1.5 lb ai/A per year), and limited handler and re-entry worker activities. Since long-term dermal and inhalation exposure (continuous exposure of greater than 180 days) is not anticipated, this risk assessment is not required.			
Chronic (cancer) Dietary	**Group C - "Possible human carcinogen" - Q_1* = 7.17×10^{-2} $(mg/kg/day)^{-1}$** in human equivalents [converted from animals to humans by use of the $(mg/kg\ body\ weight)^{3/4}$ cross species scaling factor.			

* Since an oral NOAEL was selected, a dermal absorption factor of 1% and an inhalation absorption factor of 100% (default value) are used.

b. Occupational Exposure

Chemical-specific exposure data were not available for triallate, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values used by the Agency, and the PHED unit exposure values are the best available estimates of exposure.

Anticipated use patterns, application methods, and range of application rates were derived from current labeling. The daily amount treated is based on standard assumptions. Triallate can be applied with a groundboom, tractor-drawn spreader, or a fixed-wing aircraft, and at a rate of 1.0 to 1.5 pounds active ingredient/acre (ai/A) for liquid formulations, and 1.25 to 1.5 pounds ai/A for granules.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach (going from minimal to maximum levels of protection) to obtain an appropriate MOE. The lowest tier is represented by the baseline exposure scenario (i.e., single layer clothing, socks, and shoes), followed by, if required (MOEs are less than 100), increasing levels of risk mitigation [i.e., personal protective equipment (PPE) and engineering controls (EC)]. The current labels for triallate require handlers to wear long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, and protective eyewear for liquid end-use products; and long-sleeved shirt and long pants, and shoes plus socks for granular end-use products. The levels of protection that formed the basis for calculations of triallate exposure from handler activities are outlined in Table 10.

Based on the handlers activity pattern, the duration of exposure is only short-term (1-7 days) and intermediate-term (1 week to 6 months) for occupational handlers (this is based on the fact that there are different planting periods for the registered crops for triallate). Based on the current use pattern (maximum application rate of 1.5 lb ai/A per year) and handler activities, long-term (chronic) exposure is not anticipated nor expected; therefore, a long-term (chronic) exposure risk assessment is not required.

Handler Exposure

There are potential occupational exposures to pesticide handlers and to other workers when applying triallate. Occupational handlers and workers are potentially exposed via dermal and inhalation routes. The occupational dermal and inhalation risk estimates for triallate handler scenarios (mixers/loaders/applicators) are not of concern with use of minimum personal protective equipment (PPE) (single layer clothing with gloves) for mixers/loaders of liquid products; baseline protection (single layer clothing) for loaders of granular products, applicators using ground equipment, and flaggers; and engineering controls (enclosed cockpits) for aerial applicators.

The inhalation risk expected from triallate exposure is minimal, because of the low acute toxicity (LC_{50} > 5.3 mg/L, Toxicity Category IV), moderate vapor pressure (1.1×10^{-4} mm Hg at 25 °C for the technical grade), and low unit exposure values estimated by daily inhalation doses with baseline levels of personal protection. However, occupational inhalation daily dose values were still calculated and presented for this risk assessment.

EPA conducted an assessment of the cancer risk associated with triallate following exposures to occupational handlers. The cancer risks, for the handler (dermal plus inhalation) exposures, are based on the assumption that a private farmer applies triallate products 15 days a year and a commercial applicator applies triallate products 30 days a year. The calculated cancer risks for all scenarios at baseline protection (i.e., single-layer clothing) and with personal protective equipment (PPE) (i.e., single-layer clothing with gloves for mixers/loaders, and double-layer clothing for ground applicators) are greater than 1×10^{-6}. With the addition of engineering controls (i.e., closed mixing/loading systems, enclosed cabs and cockpits), over half of the scenarios are either near or below 1×10^{-6}.

Mixer/Loader/Applicator Risk

A description of the occupational mixer/loader/applicator scenarios and resulting risks are summarized in Tables 9 and 10. For more information on the occupational risks, see the *Risk Calculations, Occupational Exposure* section of the April 18, 2000 Human Health Risk Assessment.

Table 9. Mixer/Loader/Applicator Scenario Summary

Scenario No.	Description	Product Form	Application Method	Rate (lbs ai/A)	Acres Treated
1(a)	Mixer/Loader	Liquid	Groundboom	1.5	80
1(b)	Mixer/Loader	Liquid	Aerial		350
2(a)	Mixer/Loader	Granules	Aerial		350
2(b)	Mixer/Loader	Granules	Tractor Drawn/Mechanical Spreader		80
3(a)	Applicator	Liquid	Groundboom		80
3(b)	Applicator	Liquid	Aerial		350
4(a)	Applicator	Granules	Tractor Drawn Spreader		80
4(b)	Applicator	Granules	Aerial		350
5	Flagger	Liquid	Aerial		350
6	Flagger	Granules	Aerial		350

Table 10. Mixer/Loader/Applicator Risk Summary

Scenario No.	Baseline	PPE	Engineering Controls	Dermal MOEs[a]			Inhalation MOEs[a]			Cancer Risk[b]		
				Baseline	PPE	Eng C	Baseline	PPE	Eng C	Baseline	PPE	Eng C
1(a)	SLC[c]	SLC[c] with gloves[d]	Closed mixing and loading	86	11000	NR	2100	NR	NR	1.5E-4	7.2E-6	8.5E-7
1(b)				20	2500		480			6.7E-4	3.8E-5	3.7E-6
2(a)				6800	NR		340			3.9E-5	3.8E-5	7.9E-7
2(b)				29000			1500			9.0E-6	8.8E-6	1.8E-7
3(a)	SLC[c]	SLC[c] with coveralls	Closed cab tractor	18000			3400			4.5E-6	4.3E-6	4.7E-7
3(b)	See Engineering Controls		Enclosed cockpit	NA		11000	NA		8300	NA		2.6E-6
4(a)	SLC[c]	SLC[c] with coveralls	Closed cab tractor	25000	NR		2100	NR		6.6E-6	6.3E-6	1.2E-6
4(b)	See Engineering Controls		Enclosed cockpit	NA		33000	NA		450	NA		7.6E-7
5	SLC[c]	NR	Enclosed cab	5000	NR		1700	NR		1.0E-5	NA	7.8E-6
6				19000			3800			4.0E-6		3.3E-6

[a] Dermal and Inhalation MOEs represents both short and intermediate-term exposure because the NOAELs are the same. Target MOE$100.

[b] Cancer risk figures represent exposure to commercial applicators (30 days exposure/year). Risk to private applicators are half of commercial applicators.

[c] SLC (Single Layer Clothing): includes long sleeve shirt, long pants, shoes and socks for dermal exposure; **no respirator** for inhalation exposure; and open cab tractor for ground applicators.

[d] Gloves: 90% protection factor for chemical-resistant gloves.

NR: Not required, since less protective measures have MOEs>100.

NA: Data either not available (aerial applicators) or no measurable effect (flaggers).

Liquid end-use product labels require long-sleeved shirt and long pants; shoes plus socks; chemical-resistant gloves; and protective eyewear.

Granular end-use product labels require long-sleeved shirt and long pants; shoes plus socks.

Harvester Exposure and Risk

Finally, exposure to workers through entry into agricultural fields treated with triallate was also considered. For workers entering a treated site, restricted entry intervals (REIs) are generally calculated to determine the minimum length of time required before workers or others are allowed to enter after treatment. However, for triallate, the Agency believes that the potential for post-application worker exposure is low, provided the currently required 12 hour REI is observed. The low potential for exposure is due to the timing of applications. Triallate is applied to the soil and/or soil incorporated pre-emergence for wheat, barley, peas, and lentils. This is well before the plants are mature, which likely mitigates the potential for post-application exposure due to contact with treated foliage. Significant exposure to triallate during harvesting, or any other late season activity, is not likely since triallate is applied pre-emergent. Therefore, a post-application exposure assessment is not required.

Incident Reports

Based on reports from the OPP Incident Data System, Poison Control Centers, California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network, there were relatively few incidents of illness due to triallate exposure. Of the incidents where exposure was reported, the medical outcome was either minor or no symptoms had developed. Moreover, on the list of the top 200 chemicals for which the National Pesticide Telecommunications Network received calls from 1984-1991, triallate was not reported to be involved in human incidents.

B. Environmental Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. More detailed information on the environmental and ecological risks associated with the use of triallate may be found in the *Reregistration Eligibility Document for Triallate Environmental Fate and Effects Chapter, September 30, 1999*. The complete environmental fate and effects risk assessment is not included in this document, but is available on the Agency's web page at www.epa.gov/pesticides, and in the Public Docket.

1. Fate and Transport

Triallate is stable to chemical degradation processes including hydrolysis, aqueous photolysis, and photolysis on soil. The presence of environmental photosensitizers could contribute to triallate photodegradation in natural waters. The major route of triallate degradation is aerobic soil metabolism, with a large percentage of the chemical completely degrading to carbon dioxide ($t_{1/2}$ = 18-98 days). In a recently submitted study, triallate degraded aerobically with calculated half lives of 37 days in clay loam at 20°C; 57 to 60 days in a sandy loam at 20°C; 58 days in silty clay loam at 20°C; and 98 days in sandy loam 1 at 10°C. The rate of metabolism of triallate in sandy loam soil was influenced by the temperature of the test system. Triallate metabolizes much more slowly under anaerobic conditions; 21% of the applied radioactivity was recovered as parent triallate after 30 days aerobic and 60 days anaerobic incubation.

Open literature data indicate that triallate volatilization is a route of dissipation under actual use conditions. In a USGS review, triallate volatilization accounted for 15% of applied triallate for incorporated triallate, and 74% of applied triallate for unincorporated triallate. In another study, 21% of applied triallate volatilized over a 24-day period after application of granular triallate.

The batch equilibrium data indicate that triallate is not expected to be mobile. Soil column leaching studies appear to confirm triallate's lack of mobility in soil. In an aged column leaching study, 7% of the applied radioactivity was found in the leachate. In a recently submitted study, 17.5 % of the applied C^{14}-activity in the leachate was identified as the metabolite TCPSA. Triallate volatilized with a flux of 3.6×10^{-3} µg/cm^2/hr from sand treated at a rate of 1.5 lb ai/acre. Under these conditions, half of the applied triallate would dissipate as vapor in 30 days. Virtually all of the volatilized material was parent. Because of triallate volatility under typical use conditions, particularly with the liquid (EC) formulations, the label instructions indicate that triallate must be incorporated into the soil immediately after spraying.

Field dissipation studies with a granular formulation suggest that triallate dissipated with half-lives of 20-190 days in six U.S. locations (ID 60 days, SD 20 days, MT 30 days, ND 50 days, KS 85 days, and WA 190 days).

Triallate accumulated in fish with bioconcentration factors (BCFs) of 700x in edible fish tissues, 2700x in viscera, and 1600x in whole fish. However, depuration was >90% within 14 days after ending exposure; therefore, triallate is unlikely to significantly bioconcentrate up the food chain.

Limited environmental fate data for the metabolite TCPSA is available. The submitted fate data for TCPSA were derived from structural activity relationships and from a limited number of preliminary laboratory studies. The available data indicate that the metabolite TCPSA is more mobile than the parent triallate (K_{oc}=35 ml/g) and is moderately persistent in soil ($t_{1/2}$ = 66 days).

For more environmental fate and transport information on triallate, see the *Environmental Fate Assessment* section of the September 30, 1999 Environmental Fate and Effects Risk Assessment.

2. Water Resources

Because water monitoring data for the TCPSA metabolite are not available, the Agency has relied on computer simulation models to assess risks to aquatic organisms. The Agency used the Tier II PRZM/EXAMS model to estimate triallate concentrations in surface water bodies. These estimated environmental concentrations (EECs) are used to calculate exposure and risk to aquatic organisms. The surface water model EECs were conducted for parent triallate only, because limited environmental fate and toxicity data are available on the metabolite TCPSA. Also, the PRZM/EXAMS estimates for potential exposure to aquatic organisms do not include the Index Reservoir (IR) and Percent Crop Area (PCA) refinements that are part of the human drinking water assessment. The IR was developed from a real watershed in western Illinois to be used as a standard watershed to estimate surface

drinking water concentrations, and is not appropriate for use to estimate pesticide concentrations in water bodies available to aquatic organisms. Since triallate is used mainly on small grains (spring wheat and winter wheat), it is expected that triallate use on these grains is the highest source contribution of triallate loading into surface and ground waters. Therefore, winter wheat and spring wheat scenarios were used as the scenarios for aquatic exposure assessments. Depending upon the application rate and whether or not the pesticide was incorporated, the Tier II model predicted peak (acute) concentrations that ranged from 2.01 ppb to 5.50 ppb, and the 60-day average (chronic) concentrations ranged from 0.72 ppb to 2.49 ppb.

For more information on estimated triallate concentrations in surface water to assess risks to aquatic organisms, see the *Water Resource Assessment* and *Risk to Nontarget Freshwater or Estuarine Aquatic Organisms* of the September 30, 1999 Environmental Fate and Effects Risk Assessment. Also, see the *Dietary Risk from Drinking Water* section of this RED for a discussion of human drinking water concentrations and risk.

3. Ecological Risks

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various species. The higher the RQ, the greater the concern. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. For more information on the ecological risks posed by the use of triallate, see the *Ecological Effects Hazard Assessment* and *Ecological Risk Assessment* sections of the September 30, 1999 Environmental Fate and Effects Risk Assessment.

Overall, the ecological risks from triallate use are low. The use of triallate is not likely to pose significant risk to birds, fish, large mammals, reptiles or nontarget insects. Levels of concern (LOCs) are slightly exceeded for endangered small mammals (RQs < 0.15); however, this risk is dependent on ingestion of high amounts of contaminated insects or seed in the diet. Because triallate products are typically immediately incorporated into the soil following application, this potential risk may be reduced.

The likelihood of acute high risk to invertebrates is not predicted from runoff from incorporated or unincorporated uses of triallate. However, based on Tier II water modeling results from wheat use with delayed or no incorporation, LOCs are slightly exceeded for acute risk to endangered aquatic invertebrates (RQs # 0.16). However, the only endangered aquatic invertebrate in the counties where triallate is registered and potentially used is the Higgins eye pearly mussel, which occurs in large rivers such as the Mississippi. This habitat is not likely to receive high exposure modeled concentrations of triallate due to the dilution factors associated with large river systems; therefore, triallate is not expected to have an effect on endangered aquatic invertebrates.

Nevertheless, there are a number of uncertainties which may increase the risk factors to aquatic organisms. First, the major use areas of triallate include many areas which have wetland and pothole habitats. For example, 7% of the total land area of the Red River Basin is covered by wetlands. Modeled water residues are for deeper water bodies; thus, shallow water contamination of potholes, marshes or other similar aquatic habitats might more closely approach chronic toxicity thresholds. Prairie potholes also often serve as important feeding areas for overwintering or migrating waterfowl which benefit from high temporal populations of aquatic invertebrates. Small grain and edible bean crops commonly surround small prairie pothole areas.

Triallate exceeds acute risk, restricted use, and endangered species levels of concern for terrestrial (RQs = 1.0 to 1.5) and semiaquatic plants (RQs = 5 to 15). Acute risk to aquatic plants will be assessed upon receipt of aquatic plant studies as required under Guideline 123-2.

No ecological incidents have been reported from triallate use.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not 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 triallate 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 triallate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of triallate.

These data were sufficient to allow the Agency to determine that triallate can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing triallate as the active ingredient are eligible for reregistration, provided specified changes are made to the label. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency made its reregistration eligibility determination based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that all currently registered uses of triallate, except canary grass, are eligible for reregistration, provided specified changes are made to the label. Canary grass is not being supported by the registrant for reregistration and tolerances have been revoked. However, the Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the

reregistration of triallate. The Agency may also require the submission of additional data (1) to support the registration of products containing triallate, (2) if the data requirements for registration change, or (3) if the guidelines for generating such data change.

It is important to note that the decision that all currently registered uses of triallate, except for canary grass, are eligible for reregistration, provided specified changes are made to the label, does not include the petition to establish tolerances for triallate use on sugar beets. As stated earlier, the decision on whether or not to grant tolerances for sugar beet use will be made separately from this RED.

B. Regulatory Position

1. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for triallate, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices and scenarios, and the environmental behavior of triallate. Since there are no residential or lawn uses of triallate, no dermal or inhalation exposure is expected in and around the home. Therefore, EPA has considered only acute, chronic (non-cancer), and chronic (cancer) exposures from dietary (food and drinking water) sources in its aggregate risk assessment.

In assessing acute aggregate dietary risk, the Agency has used a NOAEL of 60 mg/kg/day in an acute neurotoxicity study in rats for the U.S. general population, and a NOAEL of 5 mg/kg/day from a developmental toxicity in rabbits for the females (13-50 years) population subgroup. A highly refined (Tier 3) probabilistic (Monte Carlo) analysis, for acute dietary exposure to the residues of triallate on registered crops and proposed use on sugar beets, was performed by the Agency. For all dietary analyses, anticipated residues and percent crop treated information were used. The results of this analysis indicate that the acute dietary (food) exposure for the U.S. population and all population subgroups at the 99.9^{th} percentile are significantly below the Agency's level of concern (<2% aPAD) (see Table 3). To determine the contribution of drinking water to acute dietary exposure, an acute DWLOC was calculated to be 21,000 ppb for the U.S. general population. The surface and ground water estimated environmental concentrations (9.45 ppb and 0.21 ppb, respectively) are significantly below the acute DWLOC (see Table 6); therefore, acute dietary exposure from both food and water are below the Agency's level of concern.

The Agency also conducted a Tier 3 analysis for chronic (non-cancer) dietary (food) exposure to triallate on registered crops and the proposed use on sugar beets. A NOAEL of 2.5 mg/kg/day was established from a 2-year chronic toxicity/carcinogenicity study in rats. Based on the results of this analysis, the chronic dietary (food) risk estimates associated with triallate use patterns are significantly below the level of concern for the U.S. population and all relevant subgroups (<1% cPAD) (see Table

4). The DWLOC calculated to assess the drinking water contribution to chronic dietary exposure is 875 ppb for the U.S. general population. The surface and ground water estimated environmental concentrations (1.26 ppb and 0.21 ppb, respectively) are significantly below the chronic DWLOC (see Table 6); therefore, chronic (non-cancer) dietary exposure from both food and water are below the Agency's level of concern.

For cancer dietary risk assessment, the Agency has estimated the cancer dietary (food) risk to be 7.1×10^{-8} for uses supported through reregistration and the proposed use of triallate on sugar beets (see Table 5). Because the Agency generally considers 1×10^{-6} or less to be negligible for dietary cancer risk, the risk of cancer from dietary exposure to triallate is below the Agency's level of concern. The DWLOC calculated to assess the drinking water contribution to cancer dietary exposure is 0.45 ppb. While ground water estimated environmental concentrations (0.21 ppb) are below the cancer DWLOC, the total triallate residue concentrations in surface water following spring application to wheat (1.26 ppb for non-incorporation) exceed the cancer DWLOC (see Table 6). Given the generally conservative nature of the drinking water screening models; indications from available monitoring data for parent triallate that suggest that the risk of drinking water exposure is less than that predicted by model simulations; and the initiation of a surface water monitoring program by the registrant to measure actual concentrations of triallate and its metabolite TCPSA from vulnerable drinking water sources, no additional mitigation measures are deemed necessary at this time to protect the U.S. general population.

2. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for triallate, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, 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 triallate residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from triallate residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. For triallate, the FQPA safety factor of 10 was **reduced to 3**. The FQPA safety factor of 3 is only applicable to the females (13-50 years) population subgroup, because the effects of concern (observed in the prenatal developmental toxicity study in rabbits) occur *in utero* and not during post-natal exposure. Moreover, the FQPA safety factor for triallate is only applicable to the acute dietary risk assessment, since the effects of concern were observed only during *in utero* exposure. The FQPA safety factor does not apply to occupational exposure, and no registered residential uses exist at this time.

EPA estimates that for registered uses of triallate and its proposed use on sugar beets, the residues of triallate in the diets of infants and children account for less than 1% of both the acute and chronic (non-cancer) PAD (see Table 3 and 4). Additionally, the residues in drinking water are significantly below the acute DWLOC (6000 ppb) and chronic DWLOC (250 ppb) for the children (1-6 years) population subgroup (see Table 6). The Agency, therefore, concludes that acute and chronic (non-cancer) aggregate risks for infants and children resulting from triallate uses are not of concern.

3. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, triallate may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

4. Cumulative Risks

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 is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share acetylcholinesterase inhibition as a common mechanism of toxicity. In contrast to the methyl and N-methyl carbamates, the Agency has a less fully developed understanding of whether or not the thiocarbamates share acetylcholinesterase inhibition as a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. While current data are limited, the thiocarbamates appear to be comparatively weak cholinesterase inhibitors and are generally regulated based on other toxic endpoints. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides) [see the August 31, 1999, EPA Memorandum entitled September 1999

Meeting of the FIFRA Science Advisory Panel: Working Documents for the Session: "Proposed Guidance for Conducing Cumulative Hazard Assessments for Pesticides that Have a Common Mechanism of Toxicity" and "The Carbamate Pesticides and the Grouping of Carbamate with the Organophosphorous Pesticides"].

In September 1999, the Agency presented a paper (cited above) on the common mechanism of toxicity of the carbamate pesticides to the Science Advisory Panel (SAP). In that presentation, the Agency noted that although various classes of compounds may inhibit acetylcholinesterase, the potency, reversibility, and related factors may influence whether or not related pesticides should be included in a cumulative risk assessment.

Similarly, the Agency is examining whether and to what extent some or all pesticides that may be human carcinogens may also share a common mechanism of toxicity. Current information on the common mechanism of toxicity for possible or probable human carcinogens is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other human carcinogen chemicals.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether or not triallate, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting or possible human carcinogen chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting or human carcinogen chemicals.

C. Tolerance Reassessment Summary

The established tolerances [40 CFR §180.314, (a)] for residues of triallate in/on plant commodities are currently expressed in terms of triallate *per se* (parent only). The triallate tolerance expression will be revised in order to reflect the Agency's determination that triallate and its TCPSA metabolite should be regulated and assessed for dietary exposure in plant commodities. The Agency decided to regulate on the TCPSA metabolite because it is present at more than 10% of the total radioactive residue (TRR) in the plant metabolism studies. Tolerances are to be expressed as triallate for the combined residues of the herbicide triallate (S-2,3,3-trichloroallyl diisopropylthiocarbamate) and its metabolite TCPSA (2,3,3-trichloroprop-2-ene sulfonic acid) in or on the following commodities: barley, peas, and wheat. No tolerances have been established for animal or processed food/feed commodities. A total of nine tolerances will be reassessed as part of this RED.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1 (OPPTS GLN 860.1000), triallate tolerances for certain commodities which have been removed from Table 1

(OPPTS GLN 860.1000) need to be revoked, and some commodity definitions must be corrected. A summary of triallate tolerance reassessments is presented in Table 11.

Tolerances Listed Under 40 CFR §180.314 (a)
All tolerances listed under 40 CFR §180.314 (a) will be moved to §180.314 (c) with the revised tolerance expression to specify regional registration of triallate, and §180.314 (a) *General* will be reserved. Uses of the registered granular (G) and emulsifiable concentrate (EC) formulations of triallate, when applied according to label directions, are permitted only in the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.

Sufficient data have been submitted to reassess the established tolerances for the following plant commodities, **as defined**: barley, grain; barley, straw; peas; peas, forage; peas, hay; wheat, grain; and wheat, straw. The available data from field trials reflecting the maximum registered use patterns suggest that the combined residues of triallate and its TCPSA metabolite will exceed the currently established tolerance level of 0.05 ppm for most of the above commodities.

The established tolerances for the following commodities, **as defined**, will be revoked: lentils; and lentils, hay. Lentils are classified as peas in accordance with 40 CFR §180.1(h), and adequate data are available for peas.

New Tolerances to be Established Under 40 CFR §180.314 (c)
As a result of changes in Table 1 (OPPTS GLN 860.1000), field residue data and tolerances are required for barley hay, wheat forage, and wheat hay. The required data for wheat hay may be translated to barley hay, because the registered uses of triallate on barley and wheat are identical. Adequate data are available for wheat forage to initiate establishment of a tolerance, and these data are the basis for tolerance establishment.

The available wheat processing data indicate that the combined residues of triallate and TCPSA did not concentrate in flour but concentrated in bran (2.5x) and shorts (2.0x). These fractions were processed from whole wheat grain bearing nondetectable residues of triallate (<0.01 ppm) and detectable residues of TCPSA (0.03 ppm) following treatment at 1.7x the maximum registered rate. The highest average field trial (HAFT) (combined residues) of wheat grain from trials reflecting 1x treatment is <0.02 ppm. Based on this HAFT and the observed concentration factors, the maximum expected combined residues are <0.05 ppm for bran (2.5 x <0.02) and <0.04 ppm for shorts (2.0 x <0.02 ppm). These maximum expected residues are equal or less than the reassessed tolerance of 0.05 ppm for wheat grain. Therefore, tolerances for the combined residues of triallate and TCPSA in wheat bran and shorts are not needed.

The reregistration requirements for limited/extensive field rotational crop studies have not been fulfilled. Depending on the outcome of these required studies, rotational crop tolerances may be required.

The expected dietary burdens of triallate to beef/dairy cattle and poultry animals were recalculated following tolerance reassessment of livestock feed items. There is no reasonable expectation of finite residues (Category 3 of 40 CFR §180.6); therefore, tolerances are not required for milk, eggs, and animal tissues.

Pending Active Tolerance Petition

PP#8F2128: Monsanto has proposed the establishment of regional tolerances for the combined residues of triallate and its TCPSA metabolite in/on sugar beet roots at 0.1 ppm, sugar beet foliage at 0.5 ppm, and dried sugar beet pulp at 0.2 ppm. The decision of whether to establish the proposed tolerances for sugar beets will be made separately from this RED.

Table 11. Tolerance Reassessment Summary for Triallate

Commodity	Established Tolerance [1] (ppm)	Reassessed Tolerance [2] (ppm)	Comments [*Correct Commodity Definition*]
Tolerance Listed Under 40 CFR §180.314 (c)			
Barley, grain	0.05 (N)	0.05	The available data, reflecting the maximum registered use pattern, indicate that residues of triallate and its TCPSA metabolite were <0.01 ppm each in/on barley grain.
Barley, straw	0.05 (N)	0.3	The available data, reflecting the maximum registered use patterns, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.26 ppm in/on barley straw. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Lentils	0.05 (N)	Transferred to Peas	Since a tolerance for peas is established, the tolerance for lentils should be revoked. According to 40 CFR §180.1(h), the established tolerance for peas will apply to lentils. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Lentils, hay	0.05 (N)	Revoke	Lentil forage and hay are no longer considered significant livestock feed items and have been removed from Table 1 (OPPTS GLN 860.1000). Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Peas [*Pea, succulent*]	0.05 (N)	0.2	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.12 ppm in/on the seed and pods of succulent peas and <0.02 ppm in/on the seed and pods of dried peas. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Peas [*Pea, dry*]	0.05 (N)	0.2	
Peas, forage [*Pea, field, vines*]	0.05 (N)	0.5	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.39 ppm in/on the vines of succulent peas and 0.27 ppm in/on the vines of dried peas. Remove the "(N)" (negligible residues) designation to conform to Agency practice.

Commodity	Established Tolerance [1] (ppm)	Reassessed Tolerance [2] (ppm)	Comments [*Correct Commodity Definition*]
Peas, hay [*Pea, field, hay*]	0.05 (N)	1.0	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.73 ppm in/on the straw of succulent peas and 0.36 ppm in/on the straw of dried peas. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Wheat, grain	0.05 (N)	0.05	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.04 ppm in/on wheat grain. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
Wheat, straw	0.05 (N)	1.0	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.94 ppm in/on wheat straw. Remove the "(N)" (negligible residues) designation to conform to Agency practice.
New Tolerances Needed Under 40 CFR §180.314 (c)			
Barley, hay	--	TBD [3]	The requested data for wheat hay will be translated to barley hay.
Wheat, forage	--	0.5	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.42 ppm in/on wheat forage.
Wheat, hay	--	TBD [3]	Additional data are needed.
Tolerances to be Established Under 40 CFR §180.314 (c) Pending Petition			
Sugar Beet, root	--	0.1	Petition PP#8F2128 pending. No additional data are needed.
Sugar Beet, top	--	0.5	
Sugar Beet, pulp	--	0.2	

[1] The established tolerance is expressed in terms of triallate *per se.*

[2] The reassessed tolerance is expressed in terms of the combined residues of triallate and its TCPSA metabolite.

[3] TBD = To be determined. Establishment of tolerance(s) cannot be made at this time because additional data are required.

Codex Harmonization

No maximum residue limits for triallate have been established by Codex for any agricultural commodities. Therefore, there are no issues regarding compatibility with respect to U.S. tolerances.

Residue Analytical Methods

Plants: The current PAM Vol. II method is a GC/ECD method (designated as Method A) which is used for analysis of residues of triallate *per se* in/on lentils, peas, and grain and straw of barley and wheat (Pesticide Reg. Sec. 180.314). PAM Vol. II reports the sensitivity of the method (LOQ) as 0.02 ppm.

In conjunction with an ongoing petition (PP#8F2128) for the regional registration of triallate on sugar beets, the registrant has proposed a GC/ECD method (designated as Method RES-099-96, Version No. 2) for tolerance enforcement purposes. The method determines residues of triallate and its TCPSA metabolite. Because this method has been subjected to a successful independent laboratory validation and has also been validated in an Agency study at Beltsville, MD, the Agency concludes that Monsanto's GC/ECD method (designated as Method RES-099-96, Version No. 2) is adequate for data gathering and enforcement purposes. This method has recently been submitted and forwarded to FDA for evaluation and inclusion in PAM Volume II.

Animals: An enforcement method for determination of residues of triallate and its TCPSA metabolite is not required because tolerances for eggs, milk, and animal tissues have not been established and are not required for reregistration purposes.

D. Human Health Risk Mitigation

1. Dietary Mitigation

A dietary exposure analysis from food using the Dietary Exposure Evaluation Model (DEEM™) was completed for a refined Tier 3 approach for acute, chronic (non-cancer), and chronic (cancer) dietary exposure. The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For all analyses, anticipated residues and percent of crop treated data were used.

The drinking water assessment for triallate was conducted on parent triallate and its metabolite TCPSA. Although monitoring data from surface and ground water sources are available on parent triallate, none are available on the metabolite TCPSA. Given the uncertainties in TCPSA fate and transport, and that pesticides with similar properties (high mobility and moderate persistence) are found in drinking water, the Agency has based its drinking water assessment on the model estimates.

Acute Dietary (Food)
The percent acute population adjusted doses (PADs) are significantly below the Agency's level of concern at the 99.9th percentile of exposure for the females 13+ subgroup (<2% aPAD) and for the general population (<1% aPAD) (see Table 3). Therefore, no mitigation measures are necessary at this time to address acute dietary risk from food.

Chronic (Non-cancer) Dietary (Food)
Chronic dietary risk from food is also well below the Agency's level of concern. All chronic (non-cancer) %PADs for all subgroups were less than 1% (see Table 4). Therefore, no mitigation measures are necessary at this time to address chronic dietary risk from food.

Cancer Dietary (Food)
The Agency generally considers 1 x 10^{-6} (1 in 1 million) or less to be negligible risk for cancer. The results of this analysis indicate that the cancer dietary risk of 7.1 x 10^{-8}, associated with the uses supported through reregistration of triallate and its proposed use on sugar beets, is below the Agency's level of concern (see Table 5). Therefore, no mitigation measures are necessary at this time to address cancer dietary risk from food.

Drinking Water
As explained earlier in this document, model estimates (EECs) of potential drinking water exposure from ground water sources do not exceed the acute or chronic (non-cancer and cancer) DWLOC values, and therefore, are below the Agency's level of concern. Similarly, potential drinking water exposure from surface water sources do not exceed the acute or chronic (non-cancer) DWLOC values, and also do not pose a concern to the Agency. However, potential exposure from surface drinking water sources does exceed the Agency's level of concern for chronic (cancer) dietary risk (see Table 6).

As discussed, the Agency's primary concern with potential contamination of drinking water through surface run-off is from spring application of triallate to wheat fields that is not incorporated into the soil. Because no monitoring data of the metabolite TCPSA are currently available, the Agency has relied on model predictions of both parent triallate and TCPSA to evaluate the level of pesticide concentrations in drinking water. Based on Tier II PRZM/EXAMS modeling predictions using the Index Reservoir (IR) and Percent Crop Area (PCA), and at the maximum application rate (1.5 lbs ai/acre), the surface water estimated concentrations of cumulative triallate residues slightly exceed the cancer DWLOC (see Table 6).

Surface Water Monitoring Study
To address this concern, the registrant initiated a surface drinking water monitoring program in June 1999 to measure triallate and TCPSA concentrations. It is a three-year program designed to measure actual raw and finished triallate and TCPSA residue levels at five select surface drinking water collection locations. The locations where measurements are to be taken were selected based on a variety of factors, including high triallate use; small watersheds with a high percentage of land planted to wheat; higher rainfall; and vulnerable soil conditions. The five sites selected are: Peck, ID; Lewiston, ID; Cut Bank, MT; Chester, MT; and Minot, ND. Other sites may be added as more confirmatory data may be needed or new use sites added.

Interim results of the surface water monitoring data were provided to the Agency on February 16 and May 22, 2000. The preliminary results indicate that the higher concentrations of triallate and TCPSA appear during the spring runoff, and especially in smaller watersheds with higher rainfall. However, the results to date indicate that all raw and finished measurements of peak and mean exposure to total parent triallate and TCPSA at all five sites are below the cancer DWLOC (0.45 ppb). Additional monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002.

Tier II PRZM-EXAMS modeling with the IR and PCA is intended for use as a screening estimate to evaluate pesticide residue concentrations in surface drinking water sources. That is, the model estimates are generally expected to be higher than most actual residue values measured in areas where a particular crop is grown. While surface water modeling estimates for pesticide residues are not always more conservative than monitoring measurements, it is expected that monitoring data from the surface water monitoring program already underway will continue to indicate that actual concentrations of total triallate and TCPSA in surface drinking water sources are below the cancer DWLOC. This expectation is based, in part, on USGS NAWQA and Canadian monitoring studies, which indicate that chronic concentrations of triallate (parent only) in filtered surface waters from high use triallate areas are substantially lower than PRZM-EXAMS predictions.

Although environmental fate data suggest that parent triallate is not expected to move into ground water, in contrast, TCPSA exhibits fate properties (high mobility and moderate persistence) of pesticides commonly found in ground and surface waters. Therefore, all triallate product labels should be amended to incorporate the following advisory:

Ground Water Label Advisory
"Triallate has a degradation product with properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Surface Water Label Advisory
"Under some conditions, the triallate degradate TCPSA may have a high potential for runoff into surface water (primarily via dissolution in runoff water). These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain surface water."

Pending review of the final report of the surface drinking water monitoring study for triallate and TCPSA, no mitigation measures to address drinking water concerns, beyond the ground and surface water label advisory, are warranted at this time.

2. Occupational Risk Mitigation

a. Handler Exposure

Dermal and Inhalation
There are potential occupational exposures to pesticide handlers and to workers when applying triallate. Occupational handlers and workers are potentially exposed via dermal and inhalation routes. The occupational dermal and inhalation risk estimates for triallate handler scenarios

(mixers/loaders/applicators) are not of concern with use of minimum personal protective equipment (PPE) (single layer clothing with gloves) for mixers/loaders of liquid products; baseline level of protection (single layer clothing) for loaders of granular products, applicators using ground equipment, and flaggers (see Tables 9 and 10). These same levels of protective clothing are currently required on triallate product labels for the given scenarios.

To calculate occupational exposure, the Pesticide Handler Exposure Database (PHED) was used, because there is no chemical-specific data which reflects the actual use patterns of triallate. For aerial applicators, the PHED provides estimated exposures for **enclosed** fixed-wing aircraft only; therefore, the calculated dermal and inhalation exposure and risks for aerial applicators are based on engineering controls (i.e., enclosed cockpits). During a March 20, 2000 conference call with EPA, USDA, the registrant, and other stakeholders (i.e., growers, commodity groups, land grant universities, and others) to discuss the basis of the calculated risks of triallate, it was determined that there are very few aerial applicators of triallate products, and that those that do aerially apply triallate already utilize engineering controls in the form of enclosed cockpits. Based on this information, the Agency believes that the impact and burden for aerial applicators to be in enclosed cockpits will be negligible. For these reasons, the Agency has determined that enclosed cockpits for aerial applicators are necessary on triallate product labels.

Cancer

By policy, EPA considers non-dietary (including occupational) cancer risks of 1×10^{-6} (1 in 1 million) and less to be negligible. Based on the Agency's experience, risks typically outweigh benefits for risks greater than 1×10^{-4}. For risks between 1×10^{-4} and 1×10^{-6}, the Agency generally examines occupational risks to determine whether or not the benefits of use outweigh the risks, and will seek ways to mitigate unacceptable risks. This policy allows for the consideration of a wide range of factors in making a risk management decision for occupational risks. These factors may include: risk to individuals, number of people exposed, weight of scientific evidence regarding carcinogenicity, lower risk alternatives, and benefits associated with the pesticide under review. EPA will seek to reduce the individual risks to the greatest extent feasible, preferably to 1×10^{-6} or less. The goal is to ensure that there is a adequate level of protection from exposure to pesticide for workers. Through the reregistration process and taking benefits into account, additive protective clothing or equipment or changes in application methods may be necessary.

EPA conducted an assessment of the carcinogenic risk associated with triallate following exposures to occupational handlers. The calculated cancer risks for all scenarios at baseline protection (i.e., single-layer clothing) and with personal protective equipment (PPE) (i.e., single-layer clothing with gloves for mixers/loaders, and double-layer clothing for applicators using ground equipment) are greater than 1×10^{-6}. With the addition of engineering controls (i.e., closed mixing/loading systems, enclosed cabs and cockpits) most scenarios are either near or below 1×10^{-6} (see Tables 9 and 10).

Consistent with EPA's policy to reduce individual cancer risks to the greatest extent feasible, preferably to 1 x 10^{-6} or less, the following additional personal protective equipment (PPE) is necessary for triallate handlers: chemical-resistant gloves for mixers/loaders of liquid end-use products; a dust/mist filtering respirator for loaders of granular end-use products; and flaggers to be in enclosed truck cabs. The Agency views these additional protective clothing and equipment as feasible and effective in reducing cancer risks to triallate handlers. Furthermore, these measures are industry standards for similar formulations, and in some cases already being utilized by individual growers. Although the cancer risks with these additional protective measures are still above 1 x 10^{-6}, additional PPE or the benefits of the use of the pesticide compared with the cost of further protective measures, such as engineering controls (i.e., closed mixing and loading systems and enclosed tractor cabs), are viewed to outweigh the limited estimated further risk reductions.

To summarize, the following protective measures are necessary to mitigate risks to handlers and other workers with triallate end-use products:

Liquid end-use products

Mixers, loaders, applicators*, flaggers*, and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

In addition, mixers, loaders, and equipment cleaners and handlers exposed to the concentrate must wear chemical-resistant gloves.

Granular end-use products

Loaders, applicators*, flaggers* and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

In addition, loaders must wear:

- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N, R, P, or HE filter. (Note that if a product contains oil or has instructions that would allow concurrent application with an oil-containing material, registrants must remove the "N" in the respirator statement.)

* See engineering controls below for additional requirements.

Engineering Controls

- Aerial applicators must be in an enclosed cockpit.
- Flaggers must be in an enclosed cab.

Since completing the occupational risk assessment for triallate handlers, the Agency revised its policy on the standard values for the number of acres that can be treated in a single day by various types of agricultural equipment. When assessing exposure scenarios that include high acre crops, such as wheat, the standard acres aerially treated has been increased from 350 to 1200 acres per day. The policy also provides for modification of this value when more detailed information regarding the geographical/cultural characteristics of the crop is available. Based on various sources, including information from the registrant, aerially treating 1200 acres of wheat fields with triallate is considered a high end value. Typically, aerial applicators treat approximately 500 acres of wheat with triallate in a day, due to wind restrictions. Applicators are generally only able to apply early and/or late in the day when the wind conditions are acceptable. Even using 1200 acres, the dermal and inhalation MOEs for handlers, based on the added levels of protection for some scenarios (i.e., gloves for mixers/loaders of liquid products; dust/mist filtering respirator for loaders of granular products; enclosed cockpits for aerial applicators; and enclosed truck cabs for flaggers) are still above the target MOE of 100. Therefore, no additional levels of protection other than those listed above are necessary.

The revised policy also notes that the use of high end acres treated per day values (i.e., 1200 acres per day for aerial application to wheat and other field crops) may not be appropriate for intermediate-term, long-term or cancer exposures, depending on the use pattern of the chemical being assessment. When there are risks of concern for these exposure durations, such as cancer risk concerns for triallate, chemical specific use information should be obtained. Based on the Agency's understanding of triallate use practices and additional information from the registrant, for commercial aerial applicators that are likely to apply to as much as 1200 acres in a day, it is expected that they will apply for approximately 6 to 10 days per year. For aerial applicators that may apply the typical amount of 500 acres per day, it is estimated that they will apply for approximately 10 to 20 days per year. As noted earlier, the triallate occupational cancer risk assessment is based on commercial applicators being exposed for 30 days per year (and private applicators are assumed to be exposed for 15 days per year) and applying to 350 acres per day. This additional use practice information appears to indicate that the total exposure per year to commercial aerial applicators is comparable for high end and typical acreage applications, and is consistent with the cancer risk estimates provided in Table 10. Therefore, the triallate occupational risk assessment accurately assesses cancer risks to aerial applicators of triallate, and no additional levels of protection other than those listed above are necessary.

b. Post-Application Exposure

For triallate, the Agency believes that the potential for post-application worker exposure is low, given the currently required 12 hour restricted entry interval (REI). The potential for exposure is low because of the timing of applications. Triallate is applied to the soil and/or soil incorporated pre-emergence for wheat, barley, peas, and lentils. This is well before the plants are mature, which likely mitigates the potential for post-application exposure due to contact with treated foliage. Significant exposure to triallate during harvesting, or any other late season activity, is not likely since triallate is applied pre-

emergent. Therefore, no further mitigation measures, beyond the current 12 hour REI, to protect harvesters are necessary.

E. Environmental Risk Mitigation

Overall, the ecological risk from triallate use is low. The use of triallate is not likely to pose significant risk to birds, fish, large mammals, reptiles or nontarget insects. However, levels of concern (LOCs) are slightly exceeded for endangered small mammals (RQs < 0.15); however, this risk is dependent on ingestion of high amounts of contaminated insects or seed in the diet. Because triallate products are typically incorporated into the soil after application, and is required for the EC formulation products, the potential risk is expected to be lower. Based on Tier II water modeling results from wheat use, LOCs are slightly exceeded for acute risk to endangered aquatic invertebrates (RQ < 0.16). However, because the only endangered aquatic invertebrate in the counties where triallate is registered and potentially used occurs in large rivers, such as the Mississippi, it is not expected that they will be exposed to the high modeled concentrations of triallate, due to the dilution factors with a large river system. Therefore, it is determined that triallate will have no effect on endangered aquatic invertebrates. Triallate also exceeds acute high risk, restricted use, and endangered species triggers for terrestrial (RQs < 1.5) and semiaquatic plants (RQs < 15). Acute risk to aquatic plants will be determined upon receipt of aquatic plant studies as required under Guideline 123-2.

Although risks to plants are greater than the LOC, the overall ecological risk associated with the use of triallate is low; therefore, no additional mitigation measures to reduce estimated ecological risks are necessary.

F. Other Labeling

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing triallate. For the specific labeling statements, refer to Section V of this document.

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to changes as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may alter from the interim process, will be described in a future Federal Register notice. The

Agency is not requiring 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.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in Section V of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language for products that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method: "Do not allow this product to drift."

V. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV and V, which include, among other things, submission of the following:

For products containing triallate, registrants need to submit the following items for each product within eight months of the date of the product-specific DCI:

(1) an application for reregistration (EPA Form 8570-1, filled in, with a description on the application, such as, "Responding to Reregistration Eligibility Decision" document);

(2) five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

(3) responses to the generic and/or product specific DCIs as instructed in the enclosed DCIs;

(4) two copies of the Confidential Statement of Formula (CSF); and

(5) a certification with respect to data compensation requirements. Note that the first set of required responses for the product-specific DCI is due 90 days from the receipt of the DCI. The second set of required responses is due eight months from the date of the DCI. For questions about product reregistration and/or the product-specific DCI, please contact Barbara Briscoe at (703) 308-8177.

For the generic DCI, the following items are due:

(1) DCI response form, due 90 days from the receipt of the DCI;

(2) Registrant response form, due 90 days from the receipt of the DCI;

(3) the actual generic data in response to the DCI.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of triallate for the eligible uses has been reviewed and determined to be substantially complete. The following confirmatory data are required:

Table 12: Generic Data Requirements

Guideline Test Name	New Guideline No.	Old Guideline No.
Discussion of formation of impurities	OPPTS 830.1670	61-2(b)
Stability to normal and elevated temperatures, metals, and metal ions	OPPTS 830.6313	63-13
pH	OPPTS 830.7000	63-12
UV/Visible Absorption	OPPTS 830.7050	NA
Partition coefficient (*n*-octanol/water), shake flask method	OPPTS 830.7550	63-11
Crop field trials (wheat hay)	OPPTS 860.1500	171-4(k)
Processed food/feed (barley)	OPPTS 860.1520	171-4(l)
Field accumulation in rotational crops	OPPTS 860.1900	165-2
Aquatic invertebrate life-cycle (21 days) study	NA	72-4(b)
Aquatic plant growth studies	NA	123-2
Surface drinking water monitoring study	OPPTS 835.7200	NA

Chemistry Studies

Pertinent product chemistry data requirements remain unfulfilled for the Monsanto 94% T/TGAI concerning discussion of formation of impurities, stability, pH, UV/visible absorption, and octanol/water partition coefficient (OPPTS 830.1670, 830.6313, 830.7000, 830.7050, and 830.7550). The registrant must submit the data required in the attached data summary tables for the 94% T/TGAI, and either certify that the suppliers of beginning materials and the manufacturing process for the triallate technical product have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

No additional data are required for wheat straw. Although a tolerance has not been established for wheat forage, adequate data are available for this wheat raw agricultural commodity (RAC). Wheat hay has now been included in Table 1 (OPPTS GLN 860.1000) as a significant livestock feed item. Therefore, data depicting residues of triallate and its TCPSA metabolite in/on the hay of spring and

winter wheat harvested following a single pre-emergence soil application of representative G and EC formulations at 1.5 lb ai/A are required. Separate (or side-by-side) field trials should be conducted for each registered formulation. The trials must be conducted in the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY where regional registration is currently permitted. Wheat hay samples should be analyzed within the storage intervals for which residues have been demonstrated to be stable under frozen storage conditions. The registrant is required to propose tolerances for wheat hay when acceptable data have been submitted and evaluated.

No additional data are required for barley straw. Barley hay has now been included in Table 1 (OPPTS GLN 860.1000) as a significant livestock feed item. The requested wheat hay data may be translated to barley hay since the registered uses of triallate on barley and wheat are identical. The registrant is required to propose a tolerance for barley hay when acceptable wheat hay data have been received and evaluated.

A barley processing study utilizing an exaggerated application rate (or a rate equivalent to the maximum theoretical concentration factor) is required. If the exaggerated field trial should result in non-quantifiable residues of triallate and its TCPSA metabolite in/on the RAC (barley grain), then the harvested RAC samples need not be processed, and tolerances for barley processed commodities will not be required. However, if the exaggerated rate should produce quantifiable residues in/on the RAC, then the harvested RAC samples should be processed into pearled barley, flour, and bran according to method(s) simulating commercial practices. Each processed fraction should be analyzed for triallate residues of concern.

Because triallate and TCPSA were detected in rotational crop commodities, the registrant is required to conduct limited field rotational crop studies. The limited field trials are to be conducted on representative crops of the root and tuber vegetables, leafy vegetables, and small grains at two sites per crop for a total of six trials. The six trials are to be conducted on crops which the registrant intends to have as rotational crops on the product labels. Samples are to be analyzed for residues of triallate and TCPSA. If these limited field trials indicate that quantifiable triallate residues of concern will occur, then extensive field rotational crop trials and rotational crop tolerances will be required. The need for rotational crop restrictions will be determined following submission and evaluation of the required field rotational crop studies.

Environmental Fate and Ecological Effects

Triallate ecotoxicity data are not sufficient in certain areas. An adequate battery of aquatic plant tests (all 5 studies) is required to be conducted for this chemical. The registrant has attempted to provide some limited aquatic plant data (one species), however this does not fulfill this data requirement. Chronic testing of aquatic invertebrates is only partially acceptable as no determination of potential effects to growth can be made. Presently, no exposure to estuarine habitats and organisms has been considered due to triallate's exclusive use in the north central region of the United States. Future use petitions involving crops which may expose estuarine organisms should be accompanied by acute and chronic testing of estuarine fish and invertebrates (Guidelines 72-3 and 72-4).

To address concerns regarding triallate concentrations in surface drinking water collection locations, the registrant is required to conduct a surface drinking water monitoring study that measures raw and finished triallate and TCPSA concentrations. The locations where measurements are to be taken shall be based on factors that include high triallate use; small watersheds with a high percentage of land planted to wheat; higher rainfall; and vulnerable soil conditions. Interim results of the surface water monitoring data were provided to the Agency on February 16 and May 22, 2000. The preliminary results indicate that the higher concentrations of triallate and TCPSA appear during the spring runoff, and especially in smaller watersheds with higher rainfall. However, the results to date indicate that all raw and finished measurements of peak and mean exposure to total parent triallate and TCPSA at all five sites are below the cancer DWLOC (0.45 ppb). Additional monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002.

The Agency has evaluated the need for confirmatory environmental fate data for TCPSA. Because the supplemental environmental fate data indicate it is highly mobile and moderately persistent in soil and aquatic environments, the Agency believes that repeating the aerobic soil metabolism and adsorption/desorption studies will not provide data that will alter the current environmental fate assessment of TCPSA. Therefore, the Agency believes that confirmatory fate data for TCPSA are not needed at this time.

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling must bear the labeling contained in the table at the end of this section, including the deletion of triallate use on canary grass.

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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 13 at the end of this section.

C. Labeling Changes Summary Table

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
The use on canary grass is not being supported for reregistration by the registrant.	Delete the use on canary grass.	
End Use Products Intended for Occupational Use (all uses within the scope of WPS)		
Handler PPE requirements for emulsifiable concentrate (EC) formulations that are established by the RED and based on the active ingredient. [a]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [*registrant inserts correct material*]. If you want more options, follow the instructions for category *[registrant insert A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." [a] "Mixers, loaders, applicators*, flaggers*, and other handlers must wear: C Long-sleeved shirt and long pants C Shoes plus socks In addition, mixers, loaders, equipment cleaners, and other handlers exposed to the concentrate must wear chemical-resistant gloves. * See engineering controls below for additional requirements"	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
Handler PPE requirements for granular (G) formulations that are established by the RED and based on the active ingredient. [a]	"Personal Protective Equipment (PPE)" "Loaders, applicators*, flaggers*, and other handlers must wear: C Long-sleeved shirt and long pants C Shoes plus socks In addition, loaders must wear: C A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N, R, P, or HE filter" [b] "* See engineering controls below for additional requirements"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	"Engineering Controls" "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides [40 CFR 170.240(d)(6)]." "Flaggers must be in an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides for dermal protection and in addition to wearing the required PPE specified above, have immediately available for use in case they must leave the cab: coveralls, chemical-resistant gloves, and chemical-resistant footwear."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
Environmental Hazards	"Environmental Hazards" "Do not apply directly to water, or to areas where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." *Ground Water Advisory* "Triallate has a degradation product with properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination." *Surface Water Advisory* "Under some conditions, the triallate degradate TCPSA may have a high potential for runoff into surface water (primarily via dissolution in runoff water). These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain surface water."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval For WPS products as required by Supplement Three of PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours." "Do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete following application."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice 93-7.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:" • "coveralls • chemical-resistant gloves, such as or made out of any waterproof material • shoes plus socks"	
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." "Do not allow this product to drift."	Place in the Direction for Use directly above the Agricultural Use Box.

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
Spray Drift language that must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outermost nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"CONTROLLING DROPLET SIZE"** " ! Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. ! Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. ! Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. ! Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. ! Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE AND HUMIDITY**" "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE INVERSIONS**" "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use

Table 13. Summary of Labeling Changes for Triallate		
Description	**Amended Labeling Language**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use
Other Use/Application Restrictions.	"Application is limited to one per growing season and must not exceed 1.5 pounds of active ingredient per acre."	Directions for Use under General Precautions and restrictions and/or Applications Instructions

[a] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

[b] Note that if a product contain oil or has instructions that would allow concurrent application with an oil-containing material, registrants must remove the "N" in the respirator statement.

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 triallate 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 label requirements and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

Appendix A. Table of Use Patterns Eligible for Reregistration

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max Single Application Rate (lb ai/A)	Max No. of Applications/ Season	Max Seasonal Rate (lb ai/A)	Preharvest Interval (Days)	Use Limitations
Barley						
Fall or spring Pre-emergence soil incorporated Ground/Aerial	**10% G** [524-291] [524-292] [524-375] **4 lb/gal EC** [524-145]	1.5	1	1.5	Not Required (NR)	Use limited to the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.
Lentils						
Spring Pre-emergence soil incorporated Ground/Aerial	**10% G** [524-292] **4 lb/gal EC** [524-145]	1.5	1	1.5	NR	Use limited to the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.
Peas (Including Green, Field, Chickpeas, and Garbanzo Beans)						
Spring Pre-emergence soil incorporated Ground/Aerial	**10% G** [524-292] [524-375] **4 lb/gal EC** [524-145]	1.5	1	1.5	NR	Use limited to the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.
Triticale						
Spring Pre-emergence soil incorporated Ground/Aerial	**10% G** [524-292] **4 lb/gal EC** [524-145]	1.5	1	1.5	NR	Use limited to the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.
Wheat						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max Single Application Rate (lb ai/A)	Max No. of Applications/ Season	Max Seasonal Rate (lb ai/A)	Preharvest Interval (Days)	Use Limitations
Fall or spring Pre-emergence soil incorporated Ground/Aerial	**10% G** [524-291] [524-292] [524-375] **4 lb/gal EC** [524-145]	1.5	1	1.5	NR	Use limited to the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case covered by this RED. It contains generic data requirements that apply in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1, 2, & 3). The data requirements are listed in the order of Old Guideline Number and appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 4). 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 5). If the Agency has acceptable data in its files, this column list the identify 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. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Old Guideline Number	New Guideline Number	Requirement	Use Pattern	Citation(s)
PRODUCT CHEMISTRY				
(61-2b)	830.1670	Discussion of formation of impurities	A, B	Data Gap
(63-11)	830.7550	Partition coefficient (n-octanol/water), shake flask method	A, B	Data Gap
(63-12)	830.7000	pH	A, B	Data Gap
(63-13)	830.6313	Stability to normal and elevated temperatures, metals, and metal ions	A, B	Data Gap
none	830.7050	UV/Visible Absorption	A, B	Data Gap
ECOLOGICAL EFFECTS				
(71-1)	850.2100	Avian acute oral toxicity - bobwhite quail	A, B	ACC244201 / MRID 3035
(71-2)	850.2200	Avian dietary toxicity test	A, B	40730602, 40730603
(71-4)	850.2300	Avian reproduction test	A, B	44700701
(72-1)	850.1075	Fish acute toxicity test - bluegill	A, B	ACC 241961 / MRID 29471, ACC 245191 / MRID 76892
(72-1)	850.1075	Fish acute toxicity test - rainbow trout	A, B	ACC 245191 / MRID 76891
(72-2)	850.1010	Aquatic invertebrate acute toxicity, freshwater - daphnia magna (21 day study)	A, B	41896601
(72-2)	850.1010	Aquatic invertebrate acute toxicity, freshwater - daphnia magna	A, B	41895601, ACC 241961 / MRID 29470
(72-4)	850.1400	Fish early-life stage toxicity test - rainbow trout	A, B	44660901
(72-4b)	none	Aquatic invertebrate life-cycle (21 day) study	A, B	Data Gap
(123-1)	850.4250	Vegetative vigor	A, B	42471701
(123-1a)	850.4225	Seedling emergence	A, B	42471801
(123-2)	none	Aquatic plant growth studies	A, B	Data Gap
(141-1)	850.3020	Honey bee acute contact toxicity	A, B	42304301
(141-2)	850.3030	Honey bee toxicity of residues on foliage	A, B	44700801
TOXICOLOGY				
(81-1)	870.1100	Mammalian acute oral - rat	A, B	00109746, 44660701

Old Guideline Number	New Guideline Number	Requirement	Use Pattern	Citation(s)
(81-2)	870.1200	Acute dermal - rabbit	A, B	42192001
(81-3)	870.1300	Acute inhalation - rat	A, B	00121856
(81-4)	870.2400	Primary eye irritation - rabbit	A, B	44591801
(81-5)	870.2500	Primary dermal irritation - rabbit	A, B	44581601
(81-6)	870.2600	Dermal sensitization - guinea pig Buehler Test	A, B	00132879
(81-7)	870.6100	Acute delayed neurotoxicity - hen	A, B	00132874, 40072104
(81-7)	870.6100	Mammalian acute oral - rat (1 day dietary-neurotoxicity)	A, B	42908101
(81-8)	870.6200	Acute neurotoxicity - rat	A, B	42908101
(82-1)	870.3100	90-Day feeding - rat	A, B	00115639, 44767501
(82-2)	870.3200	21-Day dermal - rat	A, B	41487001
(82-4)	none	Subchronic inhalation (6 hr/day 5 days/week for 7 weeks) - rat	A, B	40072105, 00132878
(82-7)	870.6200	Subchronic neurotoxicity - rat	A, B	44694501, 43021601
(83-1)	870.4100	Chronic toxicity - dogs	A, B	00029455, 40730604
(83-1a)	870.4100	Mammalian chronic dietary - rat	A, B	40384701, 44767501
(83-2)	870.4200	Chronic toxicity/ carcinogenicity - rat	A, B	40384701, 41116901
(83-2)	870.4200	Chronic toxicity/ carcinogenicity - mice	A, B	00132859
(83-2)	870.4200	Chronic toxicity/ carcinogenicity - hamster	A, B	00151790, 00159797
(83-3)	870.3700	Developmental toxicity - rat	A, B	00114260, 41706906
(83-3)	870.3700	Developmental toxicity - rabbit	A, B	00114261, 43315001
(83-4)	870.3800	2-Generation reproduction study - rat	A, B	00144308, 00132880
(83-6)	870.6300	Developmental neurotoxicity - rat	A, B	44710501
(84-2)	870.5395	Cytogenetics / *In vivo* mouse micronucleus assay	A, B	44591701
(84-2)	870.5300	Gene mutation / *In vitro* mammalian cell assay in mouse lymphoma cells	A, B	00083644, 41091007
(84-2)	870.5385	Cytogenetics / *In vivo* hamster micronucleus assay	A, B	00114263

Old Guideline Number	New Guideline Number	Requirement	Use Pattern	Citation(s)
(84-2)	870.5100	Gene mutation in *Salmonella typhimurium*	A, B	00088624
(84-2)	870.5550	Other mutagenic mechanisms / *In vivo* / *In vitro* unscheduled DNA synthesis in primary rat hepatocytes	A, B	44701001
(84-2)	870.5550	Other mutagenic mechanisms / *In vitro* unscheduled DNA synthesis in primary rat hepatocytes	A, B	40730601
(84-2)	870.5900	Other mutagenic mechanisms / *In vitro* sister chromatid exchange in Chinese hamster ovary cells	A, B	00121859
(85-1)	870.7485	General metabolism - rat	A, B	00138159
(85-1)	870.7485	General metabolism - rat	A, B	40072106
ENVIRONMENTAL FATE				
(161-1)	835.2120	Hydrolysis study	A, B	00144567
(161-2)	835.2240	Photodegradation in water	A, B	00144567, 41541301
(161-3)	835.2410	Photodegradation on soil	A, B	00144567, 41892301
(162-1)	835.4100	Aerobic soil metabolism	A, B	00144567, 92187028, 44611302, 44715601
(162-2)	835.4200	Anaerobic soil metabolism	A, B	00144567, 92187054, 44611302
(163-1)	835.1230	Leaching and adsorption /desorption studies	A, B	00144567, 44611302
(163-2)	835.1410	Laboratory volatility from soil	A, B	42651101
(163-3)	835.8100	Field volatility	A, B	Majewski and Capel, 1995
(164-1)	835.6100	Terrestrial field dissipation	A, B	00145426
(165-2)	860.1900	Field accumulation in rotational crops	A, B	Data Gap
(165-4)	850.1730	Laboratory studies of pesticide accumulation in fish	A, B	41497601, 43021201
none	835.7200	Surface drinking water monitoring study	A, B	Data Gap
RESIDUE CHEMISTRY				
(171-4k)	860.1500	Crop field trials (wheat hay)	A, B	Data Gap
(171-4l)	860.1520	Processed food/feed (barley)	A, B	Data Gap

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

GUIDE TO APPENDIX D

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.

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.

MRID #	CITATION
29455	Drescher, W.; Mastalski, K.; Fletcher, D.; et al. (1979) Status Report to Monsanto Company: Two-Year Chronic Oral Toxicity Study with Triallate Technical in Beagle Dogs: IBT No. 8580-10581. (Unpublished study including letters dated Nov 21, 1979 and Feb 12, 1980 from M.G. Robl to F.C. Meyer, Mar 4, 1980 from B.Y. Cockrell to Myron S. Weinberg and Mar 10, 1980 from M.S. Weinberg to George Levinskas, report nos. MSL-0458 and MSL-0986, undated method and addendum, received Mar 17, 1980 under 524-124; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:242057-A)
83644	Brusick, D.J. (1977) Mutagenicity Evaluation of CP 23426 in the Mouse Lymphoma Assay: LBI Project No. 2684. Final rept. (Unpublished study received Mar 30, 1978 under 524-124; prepared by Litton Bionetics, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:233353-B)
88624	Brusick, D.J. (1977) Mutagenicity Evaluation of CP 23426: LBI Project No. 2683. Final rept. (Unpublished study received Mar 30, 1978 under 524-124; prepared by Litton Bionetics, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:233353-C)
109746	Auletta, C.; Rinehart, W. (1979) Acute Oral Toxicity study in Rats: [Triallate]: Project No. 4919-77. (Unpublished study received Oct 16, 1979 under 524-145; prepared by Bio/dynamics, Inc., submitted by Monsanto Co., Washington, DC; CDL:241271-J)
114260	Alvarez, L.; Kier, L.; Folk, R. (1982) Triallate--a Teratology Study in the Rat: Study No. 800320/ML 80-493. Final rept. (Unpublished study received Sep 8, 1982 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:248293-A)
114261	Schardein, J.; Laughlin, K.; Blair, M.; et al. (1982) Teratology Study in Rabbits (IR-80-087): 401-146. (Unpublished study received Sep 8, 1982 under 524-124; prepared by International Research and Development Corp., submitted by Monsanto Co., Washington, DC; CDL:248293-B)
114263	Blazak, W. (1982) An Evaluation of the Mutagenic Potential of Triallate Employing the in vivo Cytogenetics Assay in Syrian Golden Hamsters: SRI Project LSC-2537-1; Monsanto Study No. SI-80-478/ML-80-142. Final rept. (Unpublished study received Sep 8, 1982 under 524-124; prepared by SRI International, submitted by Monsanto Co., Washington, DC; CDL:248294-B)
115639	Stout, L.; Thake, D.; Folk, R. (1982) Three Month Feeding Study of Triallate Technical in Male and Female Sprague-Dawley Rats: Report No. MSL-2458. Final

rept. (Unpublished study received Oct 5, 1982 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:248539-A)

121856 Velasquez, D.; Roloff, M.; Folk, R. (1982) Acute Toxicity of Triallate Administered by Inhalation to Sprague-Dawley Male and Female Rats: Job/Project No. ML-81-318/81031. Final rept. (Unpublished study received Dec 22, 1982 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:071283-F)

121859 Loveday, K.; Donahue, B. (1982) In vitro Sister Chromatid Exchange Assay in Chinese Hamster Ovary Cells Treated with Triallate Technical: Project No. 10842; Project No. BA-81-299. (Unpublished study received Dec 22, 1982 under 524-124; prepared by Bioassay Systems Corp., submitted by Monsanto Co., Washington, DC; CDL:071284-B)

132859 Stout, L.; Ruecker, F.; Thake, D.; et al. (1983) Two Year Study of Triallate Administered in Feed to Mice: Report No. MSL-3196. Final rept. (Unpublished study received Nov 30, 1983 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:251837-A; 25 1838; 251839)

132874 Abou-Donia, M. (1983) Effect of a Single Oral Dose of Triallate on Hens: Project No. DU-81-266. Final rept. (Unpublished study received Nov 30, 1983 under 524-124; prepared by Duke Univ. Medical Center, Dept. of Pharmacology, submitted by Monsanto Co., Washington, DC; CDL:251840-B)

132878 Velasquez, D.; Thake, D.; Roloff, M.; et al. (1983) Seven-week Toxicity Study of Triallate Administered to Male and Female Sprague-Dawley Rats by Inhalation: Report No. MSL-3192. Final rept. (Unpublished study received Nov 30, 1983 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:251840-F)

132879 Auletta, C.; Loder, C.; Daly, I.; et al. (1983) A Dermal Sensitization Study in Guinea Pigs: [Triallate]: Bio/dynamics Project No. 4265-83; Monsanto Reference No. BD-83-020. (Unpublished study received Nov 30, 1983 under 524-124; prepared by Bio/dynamics, Inc., submitted by Monsanto Co., Washington, DC; CDL: 251840-G)

132880 Kier, L.; Alvarez, L.; Ribelin, W.; et al. (1983) Triallate Technical: A Two Generation Reproduction Study in the Rat: Study No. 820123. Interim rept. (Unpublished study received Nov 30, 1983 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:251841-B)

MRID #	CITATION
138159	Suba, L. (1983) Rat Metabolism Data: [Triallate]: Special Report MSL-3286. (Unpublished study received Jan 13, 1984 under 524-124; submitted by Monsanto Co., Washington, DC; CDL:252186-A; 252187; 252188)
144308	Kier, L.: Ribelin, W. (1984) Triallate Technical: A Two Generation Reproduction Study in the Rat: Final Report: Report No. MSL-3651. Unpublished study prepared by Monsanto Co. 1254 p.
144567	Sutherland, M.; Banduhn, M.; Purdum, W. (1985) The Environmental Chemistry Studies of Triallate, N,N-Di-(1-methylethyl)-S-(2,3,3-trichloro-2-propenyl) thiocarbamate: Report No. MSL-3527. Unpublished study prepared by Monsanto Co. 116 p.
145426	Klein, A.; Lauer, R.; Horner, L.; et al. (1985) Dissipation of Triallate and the Major Metabolite of Triallate from Field Treated Soils after Treatment with Far-Go Ec or Avadex BW Herbicides: Project No. 7112. Unpublished study prepared by Monsanto Co. and Analytical Biochemistry Laboratories. 148 p.
151790	Adams. R. (1984) Lifetime Chronic/Oncogenicity Study of Triallate Technical Administered Orally to Syrian Golden Hamsters: Final Report: C-253 (BR-81-245). Unpublished study prepared by Bio-Research Consultants, Inc. 913 p.
159797	Groya, F., comp. (1986) Addendum to the Chronic Toxicity/Oncogenicity Feeding Study in Hamsters: R.D. No. 679: Special Report MSL-5695. Unpublished study prepared by Monsanto Agricultural Co. 96 p.
40072104	Abou-Donia, M. (1986) Effect of a Single Oral Dose of Triallate on Hens: ?Additional Information Relating to the Previously submitted Study: Study No. DU-81-266. Unpublished study prepared by Duke Univ. Medical Center--Durham, North Carolina. 15 p.
40072105	Velasquez, D.; Thake, D. (1986) Seven-Week Toxicity Study of Triallate Administered to Male and Female Sprague-Dawley Rats by Inhalation: ?Additional Information Relating to the Previously Submitted Study: Study No. ML-82-214. Unpublished study prepared by Monsanto Chemical Co. 7 p.
40072106	Nadeau, R.; Chott, R. (1986) The Metabolism of Triallate in the Laboratory Rat, Part II: Identification, Characterization, and Quantification of Triallate and its Metabolite After Oral Administration: ?Additional Information Relating to the Previously

MRID #	CITATION
	Submitted Study: Study No. MSL-3123. Unpublished study prepared by Monsanto Chemical Co. 16 p.
40384701	Stout, L.; Thake, D. (1987) Chronic Study of Triallate Administered in Feed to Sprague/Dawley Rats: R.D. No. 812: Laboratory Project No. EHL-83119. Unpublished study prepared by Monsanto Environmental Health Laboratory. 2732 p.
40730601	Bake, J.; Mirsalis, J. (1985) Evaluation of the Potential of Triallate to Induce Unscheduled DNA Synthesis in Primary Rat Heptocyte Cultures: Project ID LSC-8747-2. Unpublished study prepared by SRI International. 17 p.
40730602	Hinken, C.; Grimes, J. (1986) Triallate: A Dietary LC50 Study with the Mallard: Project ID. 139-230. Unpublished study prepared by Wildlife International LTD. 24 p.
40730603	Grimes, J.; Jaber, M. (1986) Triallate: A Dietary LC50 Study with the Bobwhite: Project ID. 139-229. Unpublished study prepared by Wildlife International LTD. 24 p.
40730604	Reyna, M.; Thake, D. (1988) One Year Study of Triallate Administered Orally by Gelatin Capsule to Beagle Dogs: Project ID. 85009 (MSL-7640). Unpublished study prepared by Monsanto Agricultural Co. 336 p.
41091007	Jotz, M.; Mitchell, A. (1980) An Evaluation of Mutagenic Potential of Triallate Employing the L5178Y TK+/- Mouse Lymphoma Assay: SRI Proj. LSU-7558. Unpublished study prepared by SRI International. 15 p.
41116901	Vigneault, T. (1988) Confirmatory Efficacy Data: Low Foam Tops: Proj. ID M81134. Unpublished study prepared by Northview Laboratories, Inc. 3 p.
41487001	Siglin, J. (1990) 21-Day Dermal Toxicity Study in Rats with Triallate: SLS Study No.: 3044.19; Monsanto Study No. SB-89-420; R.D. No. 986. Unpublished study prepared by Springborn Laboratories, Inc., Mammalian Toxicology Div. 180 p.
41497601	Burgess, D. (1989) Uptake, Depuration, and Bioconcentration of [carbon 14]-Triallate by Bluegill Sunfish (Lepomis macrochirus), Part I. (Part II: MSL-9549): Lab Project Number: MSL-9548. Unpublished study prepared by Monsanto Agricultural Co. 396 p.

MRID #	CITATION
41541301	Detra, R., Davis, M., Zwick, T. et al. (1990) Photodegradation of [Carbon-14] Triallate in Water under Artificial Light: Lab Project Number: SC890020: 89-12-M27. Unpublished study prepared by Battelle. 52 p.
41706906	Kier, L. (1990) Triallate: A Teratology Study in the Rat: Addendum: Lab Project Number: EHL 800320. Unpublished study prepared by Monsanto, Co. 51 p.
41892301	Jackson, S.; Wick, M.; Kesterson, A. (1991) Soil Surface Photolysis of [carbon 14]-Triallate in Natural Sunlight: Lab Project Number: 1334: 500. Unpublished study prepared by PTRL East, Inc. 69 p.
41895601	McNamara, P. (1990) Triallate-the Chronic Toxicity to Daphnia magna Under Flow-through Conditions: Lab Project Number: SB-89-122:1046. Unpublished study prepared by Springborn Laboratories, Inc. 64 p.
42192001	Bonnette, K. (1991) Acute Dermal Toxicity Study in Rats with Triallate: Final Report: Lab Project Number: SB-91-173. Unpublished study prepared by Springborn Labs., Inc. 14 p.
42304301	Hoxter, K.; Lynn, S. (1992) Triallate: An Acute Contact Study with the Honey Bee: Lab Project Number: R. D. 1091. Unpublished study prepared by Wildlife International LTD. 14 p.
42471701	Chetram, R. (1992) Tier 2 Vegetative Vigor Nontarget Phytotoxicity Study Using Triallate: Lab Project Number: BL91-482: R.D. 1125: 0612-91-2. Unpublished study prepared by Pan-Agricultural Laboratories Inc. 205 p.
42471801	Chetram, R. (1992) Tier 2 Germination/Seedling Emergence Nontarget Phytotoxicity Study Using Triallate: Lab Project Number: BL91-483]: 0612-91-1: R.D. 1126. Unpublished study prepared by Pan-Agricultural Laboratories Inc. 219 p.
42499701	Kimmel, E.; Montenegro, X.; Sprinkle, R. (1992) A Confined Rotational Crop Study with carbon 14-Triallate Using Radishes (Raphanus sativus), Lettuce (Lactuca Sativa), and Wheat (Triticum aestivum): Lab Project Number: 504 (E). Unpublished study prepared by PTRL-West, Inc. 249 p.
42651101	Shepler, K.; Estigoy, L. (1993) Laboratory Volatility of (carbon 14)-Triallate: Lab Project Number: 399W: 1157. Unpublished study prepared by PTRL-West, Inc. 63 p.

MRID #	CITATION
42908101	Li, A.; Thake, D.; Branch, D.; et al. (1993) Acute Neurotoxicity Study of Triallate in Sprague-Dawley Rats: Final Report: Lab Project Number: EHL 92021: EHL 92020: ML-92-065. Unpublished study prepared by Monsanto Co., Agricultural Group. 416 p.
43021201	Heitkamp, J.; Halls, T. (1993) Characterization of (carbon 14)-Triallate Residue in Bluegill (Lepomis macrochirus) Water and Tissue: Amended Final Report: Lab Project Number: 37194:MSL 9549: 1213. Unpublished study prepared by Analytical Bio-chemistry Labs, Inc. 73 p.
43021601	Li, A.; Branch, D.; Thake, D.; et al. (1993) Subchronic Neurotoxicity of Triallate in Sprague-Dawley Rats: Lab Project Number: ML-92-384: EHL 92125: RD 1199. Unpublished study prepared by Monsanto Co., Agricultural Group. 587 p.
43315001	Li, A. (1994) Triallate Rabbit Teratology Study: Addendum: Individual Animal Observations: Lab Project Number: RD 1258: IR-80-087. Unpublished study prepared by International Research and Development Corp. 155 p.
44308301	Blaszcak, D. (1997) Guinea Pig Maximization Test with Triallate: (Method of Magnusson and Kligman): Final Report: Lab Project Number: 96-1541: HU-96-252. Unpublished study prepared by Huntingdon Life Sciences. 36 p.
44581601	Blaszcak, D. (1998) Primary Dermal Irritation Study in Rabbits with Triallate: Lab Project Number: 96-1539: HU-96-251: 1402. Unpublished study prepared by Huntingdon Life Sciences. 24 p.
44591701	Stegeman, S.; Kier, L. (1997) Mouse Bone Marrow Micronucleus Assay of Triallate: Final Report Amendment 1: Lab Project Number: ML-90-375: EHL 90165: RD 1401. Unpublished study prepared by Monsanto Company (EHL). 48 p.
44591801	Blaszcak, D. (1998) Primary Eye Irritation Study in Rabbits with Triallate: Final Report: Lab Project Number: RD 1422: 96-1540: HU-96-250. Unpublished study prepared by Huntingdon Life Sciences. 31 p.
44611302	Oppenhuizen, M. (1983) The Comparative Environmental Chemistry Studies with Encapsulated and Unencapsulated Triallate: Lab Project Number: RD 1426: 3229. Unpublished study prepared by Monsanto Co. 57 p.

MRID #	CITATION
44660701	Blaszcak, D. (1998) Acute Oral Toxicity Study in Rats with Triallate: Lab Project Number: R.D.1439: 96-1538: HU-96-249. Unpublished study prepared by Huntingdon Life Sciences. 84 p.
44660901	Drottar, K.; Swigert, J.; Krueger, H. (1998) Triallate: An Early Life-Stage Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Lab Project Number: 139A-198B: WL-96-278: R.D.1438. Unpublished study prepared by Wildlife International Ltd. 85 p.
44694501	Li, A.; Thake, D.; Branch, D. et al. (1998) Assessment of Brain Pathology in Sprague-Dawley Rats Exposed to Triallate for Five Weeks in the Diet: Lab Project Number: ML-94-314: 94094: RD 1443. Unpublished study prepared by Neuroscience Associates and Monsanto Company. 258 p.
44700801	Hoxter, K.; Bernard, W.; Beavers, J. (1993) Technical Grade Triallate: A Dietary LC50 Toxicity Study with the Honey Bee (Apis mellifera): Lab Project Number: WL-92-264: RD 1450: 139-339. Unpublished study prepared by Wildlife International Ltd. 17 p.
44701001	Bakke, J. (1989) Evaluation of the Potential of Triallate to Induce Unscheduled DNA Synthesis in the In Vivo-In Vitro Hepatocyte DNA Repair Assay in the B6C3F1 Mouse: Lab Project Number: SR-89-186: RD 1403. Unpublished study prepared by SRI International. 31 p.
44710501	Lemen, J.; Kaempfe, A.; Thake, D. et al. (1998) Developmental Neurotoxicity Study of Triallate Administered to Pregnant/Lactating CD Rats: Lab Project Number: ML-97-129: MSE-N 97002: RD 1451. Unpublished study prepared by Monsanto Company. 1528 p.
44715501	Mackie, J. (1998) The Aerobic Degradation of (carbon 14)-Triallate in Natural Sediment/Water Systems: Lab Project Number: 390990: MSL-15172. Unpublished study prepared by Inveresk Research. 70 p.
44715502	Elliot, R.; Klemm, G. (1987) The Aquatic Metabolism of Triallate in Surface Water: Lab Project Number: MSL 6162. Unpublished study prepared by Monsanto Company. 62 p.
44715601	Mackie, J.; Saunders, L. (1998) The Degradation of (carbon 14)-Triallate in Soil Under Aerobic Conditions: Lab Project Number: 15908: MSL-15173. Unpublished study prepared by Inveresk Research. 88 p.

44767501 Swenberg, J.; Schoonhoven, R.; Alden, C. et al. (1999) Immunohistochemical Evaluation of Alpha2u-Globulin in Rat Kidneys from a Previously Conducted Three-Month Study Triallate: Lab Project Number: XX-94-126: RD 1452: 98083. Unpublished study prepared by The University of North Carolina at Chapel Hill, and Searle, a Division of Monsanto. 41 p.

92187028 Keene, E. (1990) Monsanto Company Phase 3 Summary of MRID 00144567. The Environmental Chemistry Studies of Triallate: Monsanto RD #618. Prepared by Monsanto Agricultural Products Co. 13 p.

92187054 Keene, E. (1990) Monsanto Company Phase 3 Summary of MRID 00144567. The Environmental Studies of Triallate: Monsanto RD #618. Prepared by Monsanto Agricultural Products Co. 13 p.

ACC 241961 / MRID 29470
Thompson, C.M.; Forbis, A.D.; Oleson, F.B. (1979) Acute Toxicity of Triallate Technical (AB-79-073) to Daphnia magna: Static Acute Bioassay Report #24012. (Unpublished study received March 4, 1980 under 524-145; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241961-C).

ACC 241961 / MRID 24971
Thompson, C.M., McAllister, W.A.; Griffen, J.R.; et al. (1979) Acute Toxicity of Triallate (AB-79-072) to Bluegill Sunfish (Lepomis macrochirus): Static Acute Bioassay Report #24011. (Unpublished study received March 4, 1980 under 524-145; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241961-D).

ACC 244201 / MRID 3035
Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1980) Final Report: Acute Oral LD50-Bobwhite Quail: Project No. 139-184. (Unpublished study received January 29, 1981 under 524-124; prepared by Wildlife International, LTD. and Washington College, submitted by Monsanto Co., Washington, D.C.; CDL:244201-A).

ACC 245191 / MRID 76891
Thompson, C.M.; Griffen, J. (1981) Acute Toxicity of Avadex Granular (Lot No. MUWG 0908)(AB-80-523) to Rainbow Trout: Static Acute Bioassay Report #26883. (Unpublished study, including letter dated March 9, 1981 from R.B. Oleson to E.C. Spurrier, received May 18, 1981 under 524-124; prepared by Analytical Bio

Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:245191-A).

ACC 245191 / MRID 76892

Thompson, C.M.; Griffen, J. (1981) Acute Toxicity of Avadex Granular (Lot No. MUWG 0908) (AB-80-524) to Bluegill Sunfish: Static Acute Bioassay Report # 26884. (Unpublished study, including letter dated March 9, 1981 from R.B. Oleson to E.C. Spurrier, received May 18, 1981 under 524-124; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:245191-B).

ACC 245961 / MRID 80897

Smith, S.H.; O'Loughlin, C.K.; Salamon, C.M.; et al. (1981) Two-generation Reproduction Study in Albino Rats with Metolachlor Technical: Study No. 450-0272. Final rept. (Unpublished study received Sep 30, 1981 under 100-597; prepared by Whittaker Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:245959-A; 245960; 245961) Pesticide Data for Prairie Surface Waters from Environment Canada (November 6, 1997).

Appendix E. Batching of Triallate Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing an active ingredient, the Agency generally batches products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching is 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.

For the active ingredient triallate, end-use product batching to meet the acute toxicity requirements was not considered necessary, due to the nature of the registered end-use products.

Appendix F. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program--Storage and Disposal Statements
    b. 84-1 Clarification of Label Improvement Program
    c. 86-5 Standard Format for Data Submitted under FIFRA
    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

    Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
    b. EPA Form No. 8570-4, Confidential Statement of Formula
    c. EPA Form No. 8570-27, Formulator's Exemption Statement
    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
    e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

    a. Registration Division Personnel Contact List
    b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
    c. Antimicrobials Division Organizational Structure/Contact List
    d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
    e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
    f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
    g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

   Date of receipt
   EPA identifying number
   Product Manager assignment

   Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

   To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and

trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Appendix G. Generic Data Call-In

Appendix H. Product Specific Data Call-In

Appendix I. List of All Registrants Sent This Data Call-In