United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-02-005
June 2002

# Interim Reregistration Eligibility Decision (IRED)

# Ethoprop

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-F-02-004
June 2002

# EPA Ethoprop Facts

EPA has assessed the risks posed by the use of the active ingredient ethoprop, and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted, EPA has made the determination that ethoprop fits into its own "risk cup"-- that is, its individual and aggregate risks are within acceptable levels, provided the stipulated risk mitigation measures are implemented. Thus, ethoprop products, except for the liquid formulation, are eligible for reregistration, pending consideration of the cumulative risk for all OPs. The Agency will make a reregistration eligibility decision for the liquid formulation at a later time, provided certain conditions are fulfilled.

Ethoprop residues in food do not pose risk concerns. Although there is concern for drinking water risks based on estimates from screening-level water modeling, the Agency believes actual drinking water exposures are much lower and are not of concern. With the implementation of a variety of risk reduction measures, ethoprop's worker and ecological risks will be substantially reduced. Also, ethoprop has no residential uses, and its use on golf course turf has been voluntarily canceled.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs need decisions about their eligibility for reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). OPs with residues in food, drinking water, and other non-occupational exposures also must be reassessed to make sure they meet the new Food Quality Protection Act (FQPA) safety standard.

**The OP Pilot Public Participation Process**

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/op.)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides, and will make final decisions once the cumulative risks for all the OPs are considered.

EPA's next step under FQPA is to consider the cumulative risks and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on ethoprop cannot be finalized until the cumulative risks for all the OPs are considered. Further risk mitigation may be warranted at that time.

The ethoprop interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions in this interim decision document, which concludes the OP pilot process for ethoprop.

**Uses**

- An insecticide and nematicide, ethoprop is used to control wireworms and nematodes in potatoes, sugar cane, sweet potatoes, and tobacco, with lesser usage on corn (field and sweet) , beans (lima and snap), cucumbers, and cabbage. In addition, it is used to treat pineapples, bananas, and plantains, as well as field-grown ornamentals and non-bearing citrus trees.

- According to Agency estimates, annual domestic use was approximately 700,000 pounds of active ingredient per year from 1987 through 1996. Based on usage data from the technical registrant for 1998 through 2000, about 1 million pounds of active ingredient per year is used nationally. The more recent data indicate that roughly 60% of the ethoprop applied is used on potatoes, with sugar cane and sweet potatoes accounting for the next higher usages.

**Health Effects**

- Ethoprop can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

**Risks**

- Dietary exposures from eating food crops treated with ethoprop is not of concern to the Agency for the entire U.S. population or for any population subgroup, including infants

and children. Dietary exposure from drinking water is of concern to the Agency, based on estimates from screening-level modeling for both surface and ground water sources.

- EPA has risk concerns for workers who load and apply ethoprop, both the granular and liquid formulations. For the granular formulations, the worker risk concerns are driven by the amount of dust and the potential for inhalation exposure. For the liquid formulation, the risk driver is the potential for dermal exposure. To address this concern, the registrant is conducting a worker biomonitoring study to provide highly-refined, product-specific data. A reregistration eligibility decision will not be made on the liquid formulation until these studies are completed.

- Ethoprop presents risks to non-target terrestrial wildlife species, including birds, mammals, and bees. In addition, it presents high risks to aquatic organisms, both fish and invertebrates.

**Benefits**

The benefits of ethoprop use on potatoes are estimated to be important, especially for the liquid formulation in areas with low rainfall, due to its availability to be tank-mixed and co-applied with liquid soil fumigants, and its efficacy to control nematodes and wireworms. There are benefits for the use of the liquid, as well as granular formulations, for other crops as well, such as sugar cane, sweet potatoes, bananas, plantains, and pineapples.

**Risk Mitigation**

Dietary Risk

No mitigation is necessary at this time for any dietary (food) exposure to ethoprop. The acute and chronic dietary (food) risks from ethoprop do not pose concerns to the Agency.

Drinking water risk assessments are based on screening-level modeling estimates. The Agency believes actual drinking water exposures are much lower and are not of concern. To provide actual exposure data to demonstrate that drinking water risks are not of concern, the registrant will conduct drinking water monitoring of both surface and ground water sources.

Occupational Risk

In order to mitigate occupational risks, the following risk mitigation measures are necessary:

- treatment of golf courses is being voluntarily cancelled;
- restrict the maximum number of applications for all uses to one application per year, except for use on bananas, plantains, and pineapples; and
- reduce the maximum application rates (for tobacco from 12 pounds of active ingredient per acre (lb ai/A) to 6 lb ai/A, for potatoes to treat nematodes east of the Mississippi River from 12 lb ai/A to 9 lb ai/A, for ornamentals from 6 lb ai/A to 3 lb ai/A, and for pineapples from 12 lb ai/A to 6 lb ai/A).

Specifically for the granular formulations, the following worker risk mitigation measures are necessary:

- the 10G formulation is voluntarily cancelled;
- the 15G formulation will be manufactured with an inert ingredient having lower dust content, to mitigate risks associated with inhalation exposures;
- the 20G formulation will now specify use only on sugar cane, and will be packaged solely in closed transfer containers;
- both of the remaining granular formulations are to be applied to agricultural crops only with enclosed cab equipment;
- the following applications will be prohibited:
    - all aerial applications;
    - slit treatment;
    - push-type spreaders;
    - applications to peanuts;
    - broadcast applications to sweet potatoes; and
    - all hand applications, including direct hand-held equipment, such as spoons.

Although the Agency is not making a reregistration eligibility decision concerning the liquid formulation at this time, in the interim, the following risk mitigation measures are necessary for workers handling the liquid formulation:

- prohibit applications with: liquid low-pressure handwand sprayers; liquid backpack sprayers; liquids with a sprinkler can; mixing/loading/applying liquid concentrate by a handheld measuring container; and hand-dipping of citrus seedlings in liquids;
- prohibit use on: snap beans; lima beans; field corn; sweet corn; peanuts; sugar cane; and citrus seedlings; and
- prohibit broadcast applications to cabbage and sweet potatoes.

Ecological Risk

To mitigate ecological risks, the following mitigation measures are necessary:

- all applications of ethoprop must be incorporated into the soil, either by mechanical means immediately after applications with ground equipment, or by water incorporation;
- the liquid formulation label will specify no-spray zone buffer strips for the protection of surface waters (including within 140 feet of inland freshwater habitats and along the Atlantic seaboard, within 800 feet of brackish water habitats); and
- various risk mitigation measures described above will also address ecological concerns, including:
  - restricting the maximum number of applications;
  - canceling certain uses;
  - reducing maximum application rates; and,
  - canceling broadcast applications for some uses.

**Next Steps**

- There is no additional comment period for the ethoprop IRED, which is in its final form. The registrant and stakeholders have commented on the risk assessments and the proposed risk mitigation measures. You can find more information about the Agency's public participation process for the OPs at www.epa.gov/pesticides/op. For documents specific to ethoprop, go to www.epa.gov/pesticides/reregistration/status.htm.

- EPA will revoke 9 tolerances for ethoprop as part of the IRED. When the cumulative risks are considered for the OP pesticides, the Agency will issue its final tolerance reassessment decision for ethoprop and may request further risk mitigation measures. At that time, EPA will raise and/or establish new tolerances.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

JUL 0 2 2002

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as the Agency or EPA) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate (OP) pesticide ethoprop. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from Aventis CropScience, the technical registrant, the Agency revised the risk assessments, and made the human health and environmental effects risk assessments available to the public on September 1, 1999. Additionally, the Agency held a Technical Briefing on September 2, 1999, during which the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee (TRAC), and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on September 14 1999, and closed on November 12, 1999.

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 ethoprop, and various types of additional data that are necessary to confirm these risk mitigation measures. The Agency is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of ethoprop and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for ethoprop will be issued once the cumulative risks for all of the OP pesticides are considered. The Agency may need to pursue further risk management measures for ethoprop once cumulative risks are considered. The enclosed "Interim Reregistration Eligibility Decision for Ethoprop," which was approved on September 28, 2001, contains the Agency's decision on the individual chemical ethoprop.

A Notice of Availability for this interim reregistration eligibility decision (IRED) for ethoprop is being published in the *Federal Register*. To obtain a copy of the IRED 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 IRED and all supporting documents are available on the Internet at http:www.epa.gov/pesticides/op.

The IRED is based on the updated technical information found in the ethoprop Public Docket. This docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for ethoprop, the revised human health risk assessment as of September 2, 1999 (with a revision of the worker risk assessment on May 18, 2000) and environmental effects risk assessment available on October 5, 1998 (with various subsequent errata, the most recent on March 26, 2001), and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, and responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket also includes comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For ethoprop, comments and suggestions on mitigation were submitted by Aventis CropScience, the U.S. Department of Agriculture, the National Potato Council, the Pineapple Growers Association of Hawaii, and the International Banana Association.

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 these 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 on the OP pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the TRAC, a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the OP pesticides are following this new process.

Please note that the ethoprop risk assessment and the attached IRED concern only this particular OP. This IRED presents the Agency's conclusions on the dietary risks posed by exposure to ethoprop alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of ethoprop alone. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the OPs through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire OP class of chemicals after considering the risk for the individual OPs. The Agency is working towards completion of a methodology to assess cumulative risk, and the individual risk assessments for each OP are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of ethoprop. The Agency will issue the final tolerance reassessment decision for ethoprop and finalize decisions on reregistration eligibility once the cumulative risks for all of the OPs are considered.

This document contains both 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 is due 90 days from the receipt of the DCI letter. For product-specific DCIs, the second set of required responses is due eight months from the date of the DCI.

In this IRED, the Agency has determined that ethoprop will be eligible for interim reregistration, except for the emulsifiable concentrate formulation, provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of ethoprop may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this IRED. Accordingly, registrants should implement these risk mitigation measures immediately. The Agency is not making a reregistration eligibility decision for the emulsifiable concentrate formulation at this time. Certain conditions stipulated in this IRED document need to be fulfilled in order for the Agency to make a reregistration eligibility decision for this formulation. Sections IV and V of this IRED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this IRED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by ethoprop. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, or for questions about the product reregistration and/or the product-specific DCI that accompanies this document, please contact the SRRD Chemical Review Manager for ethoprop, Anthony Britten at (703) 308-8179.

Sincerely,

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

# Interim Reregistration Eligibility Decision
# for
# Ethoprop

## CASE 0106

## TABLE OF CONTENTS


Executive Summary ..... 1

I. Introduction ..... 5

II. Chemical Overview ..... 6
- A. Regulatory History ..... 6
- B. Chemical Identification ..... 6
- C. Use Profile ..... 7
- D. Estimated Usage of Pesticide ..... 9

III. Summary of Ethoprop Risk Assessment ..... 12
- A. Human Health Risk Assessment ..... 12
  - 1. Dietary Risk from Food ..... 13
    - a. Toxicity ..... 13
    - b. Food Quality Protection Act (FQPA) Safety Factor ..... 15
    - c. Population Adjusted Dose (PAD) ..... 16
    - d. Exposure Assumptions ..... 16
    - e. Food Risk Characterization ..... 18
  - 2. Dietary Risk from Drinking Water ..... 19
  - 3. Occupational and Non-Occupational Risk ..... 22
    - a. Toxicity Profile ..... 23
    - b. Occupational Exposure ..... 24
    - c. Occupational Risk Summary ..... 27
    - d. Post-Application Exposure and Risk ..... 33
    - e. Non-Occupational Exposure and Risk ..... 34
    - f. Incident Reports ..... 35
  - 4. Aggregate Risk ..... 36
- B. Environmental Risk Assessment ..... 37
  - 1. Environmental Fate and Transport ..... 37
  - 2. Ecological Risk Assessment Analysis ..... 39
    - a. Ecological Hazard Profile ..... 39
    - b. Risk to Birds and Mammals ..... 39
    - c. Risk to Aquatic Species ..... 41
    - d. Risks to Endangered Species ..... 42

IV. Interim Reregistration Eligibility and Risk Management Decisions ..... 44
- A. Determination of Interim Reregistration Eligibility ..... 44
- B. Summary of Phase 5 Comments and Responses ..... 45
- C. Regulatory Position ..... 46
  - 1. FQPA Findings ..... 46
    - a. "Risk Cup" Determination ..... 46
    - b. Tolerance Summary ..... 46
  - 2. Endocrine Disruptor Effects ..... 51

D. Regulatory Rationale . . . . . 52
1. Human Health Risk Mitigation . . . . . 52
a. Dietary Mitigation . . . . . 52
i) Acute Dietary (Food) . . . . . 52
ii) Chronic (Non-Cancer) Dietary (Food) . . . . . 52
iii) Cancer Dietary (Food) . . . . . 52
iv) Drinking Water . . . . . 52
b. Occupational Risk Mitigation . . . . . 58
i) Agricultural Uses . . . . . 58
ii) Golf Course Uses . . . . . 67
c. Non-Occupational Risk Mitigation . . . . . 67
2. Environmental Risk Mitigation . . . . . 67
a. Nontarget Terrestrial Organisms . . . . . 67
b. Nontarget Aquatic Organisms . . . . . 69
E. Labeling . . . . . 71
1. Endangered Species Statement . . . . . 72
2. Spray Drift Management . . . . . 73

V. What Registrants Need to Do . . . . . 75
A. Manufacturing-Use Products . . . . . 76
1. Additional Generic Data Requirements . . . . . 76
2. Labeling for Manufacturing-Use Products . . . . . 78
B. End-Use Products . . . . . 78
1. Additional Product-Specific Data Requirements . . . . . 78
2. Labeling for End-Use Products . . . . . 78
C. Existing Stocks . . . . . 78
D. Labeling Changes Summary Table . . . . . 79

VI. APPENDICES . . . . . 92
Appendix A. Table of Use Patterns Eligible for Reregistration for Ethoprop . . . . . 93
Appendix B. Generic Data Requirements and Studies Utilized to Make the IRED for Ethoprop . . . . . 98
Appendix C. Technical Support Documents Utilized to Make the IRED for Ethoprop . . . . . 105
Appendix D. Citations Supporting the IRED for Ethoprop (Bibliography) . . . . . 108
Appendix E. Generic Data Call-In . . . . . 132
Appendix F. Product Specific Data Call-In . . . . . 139
Appendix G. Batching of Ethoprop Products for Meeting Acute Toxicity Data Requirements for Reregistration . . . . . 145
Appendix H. List of Registrants Sent this Data Call-In . . . . . 147
Appendix I. List of Available Related Documents and Electronically Available Forms . . . . . 149

**ETHOPROP TEAM**

**Office of Pesticide Programs:**

Health Effects Risk Assessment

Kit Farwell
Catherine Bodurow Joseph
Jeffrey Dawson
Sheila Piper
Christina Swartz
Michael Metzger

Environmental Fate, Drinking Water, and Ecological Risk Assessment

Sid Abel
Jim Cowles
Nicholas E. Federoff
Jean Holmes
Dana Spatz
Ann Stavola
Mah Shamim
Dirk Young

Use and Usage Analysis

John Faulkner
William Gross

Registration Support

Marilyn Mautz

Risk Management

Bentley C. Gregg
Michael Goodis

# GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| ai | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| ARC | Anticipated Residue Contribution |
| [$^{14}$C] | Radio-labeled Carbon Atom |
| CAS | Chemical Abstracts Service |
| ChE | Cholinesterase, an enzyme of the nervous system |
| cPAD | Chronic Population Adjusted Dose |
| CSF | Confidential Statement of Formula |
| CFR | Code of Federal Regulations |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| DWEC | Drinking Water Estimated Concentration |
| DWLOC | Drinking Water Level of Comparison |
| EC | Emulsifiable Concentrate |
| EEC | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem. |
| EFED | Environmental Fate and Effects Division |
| EP | End-Use Product |
| EPA | U.S. Environmental Protection Agency |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FQPA | Food Quality Protection Act |
| FR | Federal Register |
| FRSTR | Final Registration Standard and Tolerance Reassessment |
| FWS | United States Fish and Wildlife Service |
| G | Granular Formulation |
| GC/FPD | Gas Chromatography/Flame Phosphorus Detector |
| GLC | Gas Liquid Chromatography |
| GLN | Guideline Number |
| IR | Index Reservoir |
| IRED | Interim Reregistration Eligibility Decision |
| $LC_{50}$ | 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. |
| LOAEL | Lowest Observed Adverse Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOQ | Limit of Quantitation |
| µg/g | Micrograms Per Gram |
| µg/L | Micrograms Per Liter |
| mg/kg/day | Milligrams per Kilogram Body Weight per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MUP | Manufacturing-Use Product |
| MRID | Master Record Identification (number). The Agency's system of recording and tracking the studies submitted. |
| N/A | Not Applicable |
| NAFTA | North American Free Trade Agreement |
| NAWQA | USGS National Water Quality Assessment |
| ND | No Data available |
| NOAEL | No Observable Adverse Effect Level |

| | |
|---|---|
| NOEC | No Observable Effect Concentration |
| NPTN | National Pesticide Telecommunications Network |
| OP | Organophosphate |
| OPP | Office of Pesticide Programs |
| ORETF | Outdoor Residential Exposure Task Force |
| Pa | Pascal, the pressure exerted by a force of one newton acting on an area of one square meter. |
| PAD | Population Adjusted Dose |
| PAM | Pesticide Analytical Method |
| PCA | Percent Cropped Area |
| PDCI | Product-Specific Data Call-In |
| PDP | USDA Pesticide Data Program |
| PF | Protection Factor |
| PHED | Pesticide Handlers Exposure Database |
| PHI | Preharvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| ppm | Parts Per Million |
| PRN | Pesticide Registration Notice |
| PRZM/EXAMS | Tier II Surface Water Computer Model (Pesticide Root Zone Model/Exposure Analysis Modeling System) |
| $Q_1$* | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model (also known as the cancer slope factor) |
| QUA | Quantitative Usage Analysis |
| RAC | Raw Agricultural Commodity |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| PPM | Reasonable and Prudent Measures |
| RQ | Risk Quotient, used in the ecological risk assessment to estimate the potential risk to nontarget organisms |
| RS | Registration Standard |
| RUP | Restricted Use Pesticide |
| SCI-GROW | Tier I Ground Water Computer Model (Screening Ground Water) |
| SF | Safety Factor |
| SFWMD | South Florida Water Management District |
| SLN | Special Local Need (Registrations Under Section 24 (c) of FIFRA) |
| TGAI | Technical Grade Active Ingredient |
| torr | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions. |
| TRAC | Tolerance Reassessment Advisory Committee |
| UF | Uncertainty Factor |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| UV | Ultraviolet |
| WPS | Worker Protection Standard |

## Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its interim reregistration eligibility decision (IRED) for the active ingredient ethoprop. The decisions outlined in this document do not include the final tolerance reassessment decision for ethoprop; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. A total of 24 tolerances are reassessed as part of the ethoprop IRED. Of these, nine tolerances will be revoked; twelve will remain unchanged; two new tolerances for corn are to be listed, as a result of correcting commodity definitions; and one tolerance for snap beans is to increase. However, the final tolerance reassessment decision for this chemical, including any increase and establishment of new tolerances, will be deferred until after cumulative risks for all the organophosphate (OP) chemicals are considered, as required by FQPA. Note that the Agency may need to pursue further risk management measures for ethoprop once cumulative risks are considered.

The revised risk assessments are based on review of the required data supporting the use patterns of currently registered products and new information received in response to the preliminary risk assessment. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its IRED on ethoprop. After considering the revised risks, as well as comments and mitigation measures proposed by Aventis CropScience, the technical registrant of ethoprop; various growers groups and agricultural extension agents, including the National Potato Council; and other interested parties, EPA developed its interim risk management decision for uses of ethoprop that pose risks of concern. This decision is summarized in the discussion that follows.

### Use and Usage Summary

Ethoprop is an OP insecticide and nematicide, first registered in 1967, used on agricultural crops, field-grown ornamentals, and golf course turf. With the exception of pineapples, bananas, plantains, potatoes, peanuts, and corn, it is applied pre-plant or at-plant. Most of ethoprop is formulated as either a granular product or an emulsifiable concentrate (liquid) product. Usage data from 1987 to 1996 indicated an average domestic use of approximately 700,000 lb active ingredient (ai) per year, while more recent data provided by the technical registrant indicated that domestic use in 1998 to 2000 was about 1 million lb ai per year.

### Dietary Risks

The subpopulation with the highest exposure (infants < 1 year old) has an estimated ethoprop exposure of 75% of the acute population adjusted dose, so acute dietary (food) exposure for ethoprop is not of concern to the Agency. The population subgroup with the highest chronic exposure (children 1-6 years old) has an estimated ethoprop exposure of 1.2% of the chronic population adjusted dose, so chronic (food) dietary exposure is not of concern to the Agency. The estimated chronic carcinogenic dietary risk for ethoprop is $1.1 \times 10^{-8}$, which is below $1 \times 10^{-6}$ and not of concern to the Agency. Therefore, no mitigation is warranted at this time for any dietary (food) exposures to ethoprop.

The acute drinking water level of comparison (DWLOC) is 0.6 ppb, and the DWLOCs for chronic and cancer exposures are 1.0 ppb, which are much lower than the drinking water estimated concentrations (DWECs). Based on screening level models, the highest DWEC for acute surface water concentrations is 127 ppb, and the highest chronic and cancer DWECs for surface water concentrations are 25 ppb and 13 ppb, respectively. For ground water, the highest estimated concentration was 10.1 ppb. Thus, the DWECs for surface and ground water exceed the Agency's respective DWLOCs. To address both surface and ground water risk concerns, the technical registrant is to conduct monitoring programs in high usage areas with vulnerable soil conditions. The Agency expects the actual measured surface and ground water concentrations to be less than the DWLOCs. However, if the results of either monitoring program indicate a potential unacceptable drinking water risk level, the technical registrant has agreed to drop select uses from the technical and product labels until risk concerns are fully addressed.

Golf Course Use Risks

The post-application exposure assessment was conducted for turf management workers. When using both tractors and push-type mowers, risk assessments determined that restricted entry intervals (REIs) greater than 10 days were required before workers could re-enter treated areas for activities, such as mowing. An assessment to quantify golfer risk following ethoprop treatment was also conducted, and indicated that more than 10 days were required before golfers could enter areas that have been treated to play golf. Based on these risks to workers and golfers, and other risk concerns, all golf course turf uses for ethoprop have been voluntarily cancelled.

Aggregate Risks

For ethoprop, aggregate risk calculations are based on acute and chronic exposure from only food and drinking water sources, because ethoprop use on golf courses has been voluntarily cancelled and non-occupational or recreational (golfer) exposures need not be combined with dietary sources. As discussed above, the DWECs for surface water and ground water exceed the calculated DWLOCs, so the Agency has risk concerns. Because the drinking water risks are based on modeling estimates for both surface water and ground water, the technical registrant has agreed to conduct water monitoring to further refine these drinking water exposures for both surface and ground water sources to demonstrate that drinking water risks are not of concern. Again, the Agency expects the actual measured surface and ground water concentrations to be less than the DWLOCs and not of concern.

Occupational Risks

At the maximum label application rates, all of the handler exposure scenarios exhibited risks of concern to the Agency, even when utilizing engineering controls. The risk driver for granular products is the inhalation route of exposure, because the products are formulated with dusty clay-type material, and the risk driver for the emulsifiable concentrate (EC) product is the dermal route of exposure. To help mitigate these risks, the registrant has agreed for most granular products to substitute the clay with less dusty material, such as Biodac®. The registrant has submitted data which demonstrates that this material will reduce the level of dust to which workers could be exposed during normal handler activities. Based on this and other information,

the Agency believes that the risks associated with the use of the granular formulation are below their respective targets and not of concern, and are requiring confirmatory data to support this conclusion. The product that will remain formulated with clay material is less dusty than the other granular formulations, and the technical registrant has agreed to manufacture this formulation solely in closed transfer packaging.

To help reduce worker risks for the EC formulation, the registrant has agreed to amend the labels of these products to specify the use of engineering controls, including both the use of closed loading and mixing systems, and the use of enclosed cabs. Because further measures are needed to mitigate risk concerns, the registrant has initiated a biomonitoring study to demonstrate actual exposure to workers that mix/load and apply the ethoprop EC product are lower than indicated by the risk assessment and are not of concern. The study results are to be submitted to the Agency by March 31, 2002. The registrant has also agreed that if results of the biomonitoring study and supporting pharmacokinetics data do not demonstrate acceptable risks to workers with the EC formulation, the registrant will voluntarily cancel their registration of the EC formulation. Because the current worker risks presently assessed are extremely high and of concern to the Agency, the decision of reregistration eligibility of the EC formulation is deferred pending the results of the required biomonitoring study and other supporting data.

For ethoprop, cancer risks for workers are generally not of concern to the Agency, but some scenarios are of concern for both types of formulations. The Agency anticipates that the risk mitigation measures for the granular and EC formulations will reduce the risks for ethoprop, such that cancer risks will no longer be of concern.

Ecological Risks

The ecological risk assessment indicates that the Agency has risk concerns for birds, mammals, fish, and invertebrates. Reasons for these risk concerns include the moderate to highly toxic characteristics of ethoprop in testing with these groups of animals, as well as the exposure concentrations due to its moderate mobility in soils and its potential for runoff. To mitigate these ecological risk concerns, various measures are to be implemented, including soil incorporation, dropping certain uses, reducing maximum application rates, deleting broadcast applications for some uses, limiting the number of applications, and imposing buffer zones for the EC formulation. In addition, the Agency recognizes that there are substantial and unique benefits associated with the use of ethoprop, due to its effectiveness against various pests and its cost-competitiveness in comparison with some less efficacious alternative chemicals.

Label Changes Summary

The following is a summary of the changes to technical and product labels that are necessary to mitigate the risks discussed above. The technical registrant has agreed to cancel the following uses:

- peanuts;
- citrus seedlings; and
- golf courses.

The technical registrant has agreed to cancel the following use methods:

- all aerial applications;
- slit treatment;
- push-type spreaders;
- hand applications, including direct hand-held equipment, such as spoons;
- liquid low-pressure handwand sprayers;
- liquid backpack sprayers;
- liquids with a sprinkler can;
- mixing/loading/applying liquid concentrate by a handheld measuring container; and
- hand-dipping in liquids.

The technical registrant has agreed to modify the following use practices:

- delete post-plant treatments to corn;
- delete broadcast applications of the EC to cabbage; only banded treatments are permitted;
- delete broadcast applications to sweet potatoes; only banded treatments are permitted for both the EC and granular formulations;
- drop the following crops from the current EC label: snap and lima beans, field and sweet corn, and sugar cane;
- restrict the maximum number of applications for all uses to one application per year, except for use on bananas, plantains, and pineapples;
- reduce the maximum label rate for tobacco from 12 lb ai/A to 6 lb ai/A;
- reduce the maximum label rate for potatoes to treat nematodes east of the Mississippi River from 12 lb ai/A to 9 lb ai/A;
- reduce the maximum label rate for ornamentals from 6 lb ai/A to 3 lb ai/A;
- reduce the maximum label rate for granular treatments to pineapples (Special Local Needs label) from 12 lb ai/A to 6 lb ai/A; and
- specify immediate soil incorporation by mechanical equipment for all products as they are being applied by ground equipment, or that watering-in is to be conducted immediately following applications (for chemigation methods and for use on bananas, plantains, and pineapples only).

The Agency is issuing this IRED for ethoprop, as announced in a Notice of Availability published in the *Federal Register*. This IRED document includes guidance and time frames for adopting any necessary label changes for products containing ethoprop. Note that there is no comment period for this document.

This document consists of six sections: Section I introduces the regulatory framework for reregistration and tolerance reassessment. Section II is a chemical overview which includes a use profile of ethoprop. Section III summarizes the revised human health and ecological risk assessments. Section IV discusses the Agency's IRED and risk management approach for ethoprop and summarizes the Agency's response to public comment. Section V identifies what registrants need to do, including data and label changes required to reregister ethoprop products based on the Agency's risk mitigation decisions. Section VI contains Appendices, such as the data call-in (DCI), a list of the documents supporting this IRED and how to access them (including the full revised risk assessments), and "batching" information.

## 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 (EPA, or "the Agency") to determine whether a pesticide containing such active ingredient is eligible for reregistration. Thus, 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 the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires 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 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. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency's revised human health and ecological risk assessments; its progress towards tolerance reassessment, including a determination of safety of existing tolerances; and the interim reregistration eligibility decision (IRED) for ethoprop. It is only one of several steps in the reregistration process for ethoprop. The Agency will proceed with its assessment of the cumulative risk of the organophosphate (OP) pesticides and issue a final reregistration eligibility decision for ethoprop.

The Agency published Pesticide Registration (PR) Notice 2000-9, *Worker Risk Mitigation for Organophosphate Pesticides*, in the *Federal Register* (September 29, 2000), which presents EPA's proposed approach for managing risks from OP pesticides to occupational users. This notice describes the Agency's baseline approach to managing risks to handlers and workers of OP pesticides. Generally, basic protective measures (such as closed mixing and loading systems, enclosed cab equipment, or protective clothing), as well as increased restricted entry intervals, will be necessary for most uses where current risk assessments indicate risks that are of concern to the Agency, and where such protective measures are feasible. PR Notice 2000-9 also states that the Agency will assess each OP pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this IRED are consistent with that PR Notice.

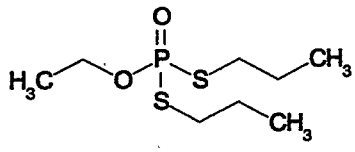
## II. Chemical Overview

### A. Regulatory History

Ethoprop was first registered in the United States in 1967 to Mobil Oil Corporation, and was transferred to Rhone-Poulenc Ag Company in 1981. In January 2000, Rhone-Poulenc merged with Hoechst Corporation (and its U.S. subsidiary, AgrEvo); the name of the registrant for technical ethoprop is now Aventis CropScience. Ethoprop is used as an insecticide and nematicide. Ethoprop is a List A reregistration chemical, and was the subject of a Registration Standard (February 28, 1983), a Final Registration Standard and Tolerance Reassessment (FRSTR; November 20, 1987), and their respective Guidance Documents (May 1983 and May 1988). These documents summarized regulatory conclusions on the available data, and specified the additional data that were required for reregistration purposes. Numerous submissions of data have been received since the FRSTR was issued.

### B. Chemical Identification

ETHOPROP:




- **Common Name:** Ethoprop
- **Chemical Name:** O-ethyl-S,S-dipropylphosphorodithioate
- **Chemical Family:** Organophosphate
- **Case Number** 106
- **CAS Registry Number:** 13194-48-4
- **OPP Chemical Code:** 041101
- **Empirical Formula:** $C_8H_{19}O_2PS_2$
- **Molecular Weight:** 242.3
- **Trade and Other Names:** MOCAP®
- **Basic Manufacturer:** Aventis CropScience

Technical ethoprop (O-ethyl-S,S-dipropylphosphorodithioate) is a colorless to yellow tinted liquid, with a strong mercaptan odor, and has a boiling point of 86-91°C at 0.2 mm Hg. Ethoprop is moderately soluble in water (843 ppm at 21°C), and is soluble in most organic solvents (hexane, xylene, acetone, and ethanol). The vapor pressure of ethoprop is $3.5 \times 10^{-4}$ mm Hg at 26°C.

**C. Use Profile**

The following information is based on the currently registered uses of ethoprop.

**Type of Pesticide:** Insecticide/nematicide

**Summary of Use Sites:**

Food: Bananas/plantains, beans (dry, snap, and lima), cabbage, corn (sweet and field), cucumber, peanuts, pineapple, sugarcane, sweet potato, and white potato.

Residential: No residential uses.

Public Health: No public health uses.

Other Nonfood: Citrus (non-bearing) and tobacco, as well as field-grown ornamentals and golf course turf.

**Target Pests:** Ethoprop is used for the control of wireworms and nematodes, which live below the soil surface.

**Formulation Types Registered:**

Aventis CropScience has registrations for technical grades (95.9% and 94.4% active ingredient (ai)), emulsifiable concentrates (EC) (one product is solely ethoprop at 69.6% ai and the other is 46% ethoprop and 23% disulfoton), granulars (3% [one product, which is a multiple ai with 10% pentachloronitrobenzene (PCNB)], 10% [one product is solely ethoprop and other products are multiple ai, one with 8.8% phorate and the other 5.6% disulfoton], 15%, and 20% ai), and a gel in water-soluble packaging (68.2% ai). Micro-Flo Co. has a registration for a granular (3% ai as a multiple ai with 10% PCNB). Note that Aventis has indicated that their gel formulation and multiple ai products (with disulfoton, phorate, and PCNB) are not currently marketed, and has requested voluntary cancellation of these products.

**Method and Rates of Application:**

Equipment - The current labels for ethoprop indicate that the products may be applied by aircraft (granulars to potatoes only), chemigation (i.e., drip irrigation and sprinkler irrigation), granule applicator (i.e., tractor-drawn mechanical spreader and push-type spreader), ground sprayer equipment, backpack-sprayer, hand-held shaker can, hand-dipping of citrus seedlings, and to golf course fairways and roughs by slit treatment (thatch mechanically lifted, and granular product placed below thatch, which is then returned to the surface of the ground).

Method - The insecticidal/nematicidal activity of ethoprop is highly dependent upon incorporating the product into the soil (mechanically or with water) soon after application to be effective, especially for those nematodes and insects which live deep in the soil (some labels specify it is necessary to incorporate at depths up to 6 inches below the soil surface to insure efficacious activity against nematodes and wireworms). Ethoprop is applied to most crops pre-plant or pre-emergent, but it can also be applied to plants, as follows: pineapple plants as a chemigation treatment (the EC label specifies application by drip irrigation be either in tubing under plastic or buried in the soil 2 to 4 inches deep); pineapple plants as a soil treatment (only granular formulations); banana and plantain plants as soil-directed liquid spray or granular broadcast (backpack spreader or by hand) around the stems of the plants up to 2 times per year; corn at cultivation after plant emergence until layby (i.e., the last time the corn plants are cultivated); and peanut plants at pegging (i.e., when the aerial shoots begin to grow into the ground, prior to maturation of the fruiting bodies). In addition, potatoes may be treated prior to crop emergence, and the single-ai granular ethoprop product labels specify there may be aerial application to potatoes.

Rate - For soil treatments of field crops, the maximum label rates range from 2 lb active ingredient per acre (ai/acre) on cucumbers to 12 lb ai/A on tobacco and potatoes for agricultural crops, and 20 lb ai/A on golf course turf (on current ethoprop labels; however, the registrant has voluntarily cancelled all golf course uses). The majority of ethoprop applications are to potatoes in the Pacific Northwest (PNW), where growers apply either granular or EC formulation at two application rates: 12 lb ai/A for control of nematodes, and 6 lb ai/A for control of wireworms. For bananas, the EC label states "apply 8 mL of MOCAP EC in a radius of 3/4 meter around each producing stem," and the 10G and 15G granular labels similarly list rates to be applied per producing stem (at

product rates which are equivalent to 6 grams or 0.2 ounces of ethoprop active ingredient per plant). For pineapples, both the EC and gel labels specify that multiple applications are permitted, but not more than 8 gallons of MOCAP® per acre per year for plant crops, or not more than 5 gallons of MOCAP® per acre per year for ratoon crops.

Timing - For field crops, applications must be pre-plant or at-plant and usually occur in the spring, before the growing season, with only one application per crop: exceptions for field crops include treatment of potatoes until crop emergence, corn until at-layby, and peanuts until at-pegging. For some ratoon row crops, such as sugar cane, applications may occur only at the time of planting, and the crop grows for 3 to 5 years before a new crop is replanted. Applications to banana plants may be up to two times per year. Concerning applications to pineapples (a crop not on any granular labels), both the current EC and gel labels specify not more than 8 applications per year for plant crops, or not more than 5 applications per year for ratoon crops, with the timing of these multiple applications to pineapples specified as "about every two months." The timing of applications to pineapples relative to the pre-harvest interval (PHI) on the current EC and gel labels state "Do not treat within 120 days of harvest of either plant crop or ratoon crop."

**Use Classification:** Ethoprop is a restricted use chemical for most products containing 10% or more of the active ingredient, due to acute dermal toxicity.

**D. Estimated Usage of Pesticide**

This section summarizes the best available estimates for many of the pesticide uses of ethoprop, based on pesticide usage information for 1987 through 1996. A full listing of all uses of ethoprop, with the corresponding use and usage data for each site, has been completed and is in the Quantitative Usage Analysis (QUA) document (*February 2, 1999, as amended*), which is available in the Public Docket, and the Internet (www.epa.gov/pesticides/op). The QUA document also lists estimates for the total acres grown to each crop, the weighted average and the estimated maximum for the acres treated, the average application rates (specifically the lb ai/A, the numbers of applications per year, and the lb ai/A/application), and indicates those states with the most ethoprop usage for each site (agricultural crop).

Table 1 summarizes some of the key data from the Agency QUA. The data utilized by the Agency to compile the QUA, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns, and include data from various information sources. The sources of data and information for compiling the QUA are from the Agency (1987-96), United States Department of Agriculture (USDA; 1990-96), National Center for Food & Agricultural Policy

(1992), and Market Asia Agricultural Information (1997). According to the QUA, approximately 700,000 lb ai was applied to treat a little more than 200,000 acres. The usage is presented as a weighted average estimate for 1987 through 1996, with the most recent years being weighted more heavily.

According to information presented in the QUA document, the largest U.S. markets of ethoprop, in terms of the total pounds active ingredient (lb ai) sold, are potatoes (35%), sugarcane (28%), and tobacco (14%). Most of the usage is in the Northwest and South, with some in the Midwest. The crops with the highest percentages of the weighted average for crop treated are sugarcane and bananas, with approximately 7% and 6%, respectively.

In general, there is little information available on trends for use of ethoprop on various crops, except for potatoes. The Agency QUA (Table 1) estimated that, for the period from 1987 through 1996, about 35% of the ethoprop applied in the United States was used to treat potatoes. The National Potato Council (NPC) provided information (letter to the Agency dated November 12, 1999) which indicated that in 1995, about 20% of the potato crop grown in the Pacific Northwest (PNW) was treated with ethoprop; however, due to the cancellation of fonofos, use of ethoprop was expected to increase, with the NPC estimating that 30-40% of the potato crop grown in the PNW would be treated with ethoprop. While the Agency QUA estimated that about 700,000 pounds of active ingredient were sold annually during the 1987 to 1996 time period, Aventis has provided data that indicates that between 1998 and 2000, about 1,000,000 pounds of active ingredient were sold annually in the United States. While the Agency QUA (Table 1) indicates that from 1987 to 1996, about 35% of the usage was on potatoes, the Aventis-supplied data indicates that for 1998 through 2000, as much as 60% of the total ethoprop active ingredient applied in the United States was used to treat potatoes.

**Table 1. Estimated Quantitative Usage Analysis of Ethoprop for Representative Sites**

| Site | % of Crop Treated | | Pounds of Active Ingredient Applied |
|---|---|---|---|
| | Weighted Average [1] | Estimated Maximum | Weighted Average |
| **Field Crops:** | | | |
| Beans, Dry | < 0.05% | 0.1% | 1,000 |
| Beans, Green | 1.4% | 2.8% | 15,000 |
| Corn (field) | < 0.05% | 0.1% | 20,000 |
| Peanuts | 0.4% | 1.6% | 10,000 |
| Sugarcane | 7.0% | 15.3% | 200,000 |
| Tobacco | 3.2% | 4.3% | 100,000 |
| **Total Field Crops:** | | | **346,000** |
| **Fruits:** | | | |
| Bananas [2] | 6.4% | 16.0% | - [3] |
| Citrus seedlings | - | - | - |
| Pineapples [4] | 1.0% | 5.0% | - |
| Plantains | - | - | - |

| Site | % of Crop Treated | | Pounds of Active Ingredient Applied |
|---|---|---|---|
| | Weighted Average [1] | Estimated Maximum | Weighted Average |
| **Vegetables:** | | | |
| Cabbage | 0.7% | 2.9% | 1,000 |
| Cucumbers | 1.0% | 2.1% | 3,000 |
| Potatoes, white | 2.8% | 5.3% | 250,000 |
| Sweet Potatoes | 4.1% | 8.2% | 40,000 |
| Sweet Corn | 3.8% | 8.9% | 30,000 |
| **Total Vegetables:** | | | **324,000** |
| **Turf & Ornamentals:** | - | - | **21,000** |
| **TOTAL** | | | **691,000** |

[1] Based on data for 1987-1996, with the most recent years and the more reliable data weighted more heavily.
[2] The estimates of the percent crop treated for bananas are based on an average of the percent of the banana crop treated in six Latin American countries, and weighted based on the quantity imported into the U.S. for each producing country.
[3] A dash (-) indicates information is not available in Agency sources or is insufficient for purposes of making estimates.
[4] The estimates for the percent crop treated for pineapples are based on an average of the percent of crop treated for pineapples in two foreign countries, and weighted based on the quantity of U.S. imports, as well as the estimate of the minimal historical United States production in Hawaii.

## III. Summary of Ethoprop Risk Assessment

The following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide ethoprop, based on the human health information fully presented in the following documents:

- *Ethoprop Revised Human Health Risk Assessment*, September 2, 1999;
- *Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000;
- *Ethoprop - Review of aldicarb (Temik 10G) granular backpack mixer/loader/applicator study (MRID 451672-01) in bananas as a source of surrogate data for ethoprop exposure and assessment*, October 17, 2000; and
- *Ethoprop - Review of fipronil granular mixer/loader/applicator study (MRID 452501-01) in bananas as a source of surrogate data and accompanying ethoprop risk assessment*, January 5, 2001.

The environmental and ecological risk findings are based on the information fully presented in the following documents:

- *Environmental Fate and Effects Division RED Chapter for Ethoprop*, October 5, 1998; and
- addenda dated November 18, 1998; February 18, 1999; August 30, 1999; and April 24, 2000.
- *Revised ethoprop drinking water assessment*, March 26, 2001

These documents may also be found on the Agency's web pages (www.epa.gov/pesticides/op). The purpose of this summary is to assist the reader by identifying the key features and findings of these human health and ecological risk assessments that provide the basis for the registration decision presented in this document.

These risk assessments were presented at the Ethoprop Technical Briefing on September 2, 1999, which was followed by an opportunity for public comment on risk management for this pesticide (Phase 5 of the TRAC process). The risk assessments presented here form the basis of the Agency's interim risk management decision for ethoprop only; the Agency must consider the cumulative risks of all the organophosphate pesticides before tolerances are reassessed in accordance with FQPA.

### A. Human Health Risk Assessment

EPA issued its preliminary human health risk assessments for ethoprop in May of 1998. In response to comments submitted by the registrant, the public, and USDA, the risk assessments were updated in September of 1999, and updated again to include additional data submitted by the registrant. Major refinements of the human health risk assessment are listed below:

- The revised risk assessments for the granular products incorporate the results of a new 28-day dermal toxicity study in the rat with a granular formulation.

- The revised worker risk assessments for the granular products also incorporate the results of a new worker exposure study with passive dosimetry methods during separate and combined loading/application activities with a granular formulation using both typical open-pour boxes and closed loading systems.

- The revised risk assessments for golf course workers (loaders/applicators and turf management professionals) incorporate data reported in an Outdoor Residential Exposure Task Force (ORETF) study in which chemicals were applied by granular mixer/loader/applicators using push spreaders to treat golf courses.

- The revised risk assessments for golf course workers and golfers (non-occupational exposures) incorporate data reported in another Outdoor Residential Exposure Task Force (ORETF) study in which turf transferability rates for ethoprop were estimated based on data for similar chemicals obtained with various sampling methods, active ingredients, and formulations.

- The revised risk assessment for workers treating bananas incorporates the results from two studies with other chemicals (Temik [aldicarb] and Regent [fipronil]), in which workers were loading and applying granular products to bananas with two different types of backpack granular spreaders, as well as from the fipronil study, utilizing a spoon to apply a granular product to assess hand-application exposures.

- The revised dietary risk assessments incorporate the results for the Agency's new Standard Reservoir Index with the percent cropped area (PCA) treated factor, in addition to the previously used PRZM model coupled to the EXAMS model, for use in developing the Tier II drinking water estimated concentrations for surface water for ethoprop.

As a result of comments from USDA and the registrant concerning the dietary risk assessment, the Agency decided not to include the Metabolite IV (known as M1) in calculation of anticipated residues or as a metabolite of concern for the non-cancer risk assessments, although the Agency determined that M1 is a metabolite of concern in cancer risk assessments. (The decision to not include M1 in the calculation of anticipated residues and non-cancer risk assessments has been supported by a toxicity study for this metabolite, submitted by the registrant in December 1999. Data from that study indicated that M1 is not as toxic as the parent ethoprop or some of the other metabolites, since M1 was reported as not being a significant cholinesterase inhibitor in the rat).

### 1. Dietary Risk from Food

#### a. Toxicity

The Agency has reviewed all toxicity studies submitted for ethoprop and has determined that the available toxicity studies are satisfactory to support an IRED for all currently registered ethoprop uses. In discussing the dietary risk assessment for ethoprop, it is of background interest to characterize the acute oral toxicity; ethoprop is classified in Toxicity Category I for acute oral

toxicity, based on $LD_{50}$ values to male and female rats of 61.0 mg/kg and 32.8 mg/kg, respectively. Details concerning the toxicity of ethoprop can be found in the 1999 *Ethoprop Revised Human Health Risk Assessment*, which is available in the Public Docket and may also be found on the Agency's web page (www.epa.gov/pesticides/op). (Additional types of acute toxicity data for ethoprop are discussed later in this IRED document in Section III.A.3. Occupational and Non-Occupational Exposure.)

In the subchronic and chronic studies with ethoprop, the main toxic effects seen were decreased cholinesterase activity, cholinergic signs, anemia, and weight loss. Mild liver toxicity also occurred in the chronic dog study. The dose-response curve for ethoprop is steep in acute, subchronic, and chronic studies (e.g., in a combined chronic feeding toxicity and carcinogenicity study in the rat, mortality occurred at doses only slightly higher than those causing clinical signs).

The Agency has classified ethoprop as a "likely" human carcinogen, due to the occurrence of malignant adrenal pheochromocytomas in male Sprague-Dawley rats. This classification is supported by the occurrence of thyroid C-cell adenomas and/or carcinomas in three other rat studies, and by results from *in vitro* mutagenicity testing that ethoprop causes clastogenicity. The Agency re-evaluated the carcinogenicity of ethoprop, because the registrant submitted new historical control data and various arguments against ethoprop's cancer classification. The Agency retained the classification of ethoprop as a "likely" human carcinogen.

The Agency has determined that, in addition to parent ethoprop, four of its metabolites are also of toxicological concern in conducting risk assessments (Table 2). Parent ethoprop and SME and OME are included in non-cancer assessments because they are cholinesterase inhibitors, and M1 and M2 are included because of their structural similarity with parent ethoprop, which the Agency has determined to be a "likely" carcinogen. M1 is an important metabolite in food and water, while M2 has been detected in water, but not as an important residue in plant metabolite studies.

**Table 2. Chemical Names of Residues of Toxicological Concern (Parent Ethoprop and its Important Metabolites) in Various Risk Assessments Conducted**

| **Common Name**; Residue Designation (Chemical Name) | **Non-Cancer** (acute and chronic) Food and Water | **Cancer** Food | **Cancer** Water |
|---|---|---|---|
| **Parent Ethoprop** (O-ethyl-S,S-dipropylphosphorodithioate) | X | X | X |
| **SME**; Metabolite II (O-ethyl-S-methyl-S-propylphosphorodithioate) | X | X | X |
| **OME**; Metabolite III (O-ethyl-O-methyl-S-propylphosphorothioate) | X | X | X |
| **M1**; Metabolite IV (O-ethyl-S-propylphosphorothioate) | | X | X |

| **Common Name**; Residue Designation (Chemical Name) | **Non-Cancer** (acute and chronic) Food and Water | **Cancer** Food | **Cancer** Water |
|---|---|---|---|
| **M2** (S,S-dipropylphosphorodithioate) | | | X |

As background for describing the results of the dietary assessments, it is also of interest to characterize the relative oral acute toxicity of the metabolites of ethoprop. Results from an acute oral toxicity study in the rat indicated SME has an $LD_{50}$ very similar to that for parent ethoprop (50.0 mg/kg vs 55.8 mg/kg, respectively), while OME is more toxic ($LD_{50}$ of 22.4 mg/kg), but M1 is not as toxic by the oral route ($LD_{50}$ of 1608 mg/kg). Although M1 is relatively non-toxic via the acute oral route (Toxicity Category III), the Agency has determined that this metabolite is of concern in the cancer risk assessments, both food and water, due to its structural similarity. This acute oral toxicity study in the rat which compared ethoprop and some of its metabolites did not include M2, and relative oral acute toxicity data is not available; however, due to similarity in its chemical structure, the Agency has determined that M2 is also a metabolite of toxicological concern for cancer (water only) assessments.

**b. Food Quality Protection Act (FQPA) Safety Factor**

The FQPA Safety Factor (SF) to account for increased sensitivity of infants and children was removed for ethoprop (equivalent to 1x). In evaluating ethoprop, the Agency reviewed the ethoprop toxicity database, including developmental toxicity studies conducted in the rat and the rabbit. In the rat study, no developmental toxicity was observed, and there was no indication of increased sensitivity of the rat offspring at the highest dose tested (18 mg/kg/day). In the rabbit developmental toxicity study, neither developmental nor maternal toxicity was observed at the highest dose tested (2.5 mg/kg/day), and there was also no indication of increased sensitivity of the rabbit offspring.

The Agency also evaluated a 2-generation rat reproduction study. The Agency determined that there was no indication of increased susceptibility to offspring in this study, because the no observable adverse effect level (NOAEL) for offspring toxicity (2.3 mg/kg/day) was greater than the parental NOAEL (0.08 mg/kg/day). The neurotoxicity studies with ethoprop have also been evaluated, and no changes were observed in brain weight, brain dimensions, or nervous system histopathology in acute and subchronic neurotoxicity studies, nor in the chronic studies in the dog, rat, or mouse. In addition, no alterations in development of the central nervous system were observed in the rat and rabbit developmental studies, and there were no observations of neurotoxicity in the offspring in the 2-generation reproduction study in rats. On the basis of the absence of any observed developmental effects and the lack of evidence for the potential for exposure, the Agency concluded that the FQPA SF (10x) should be removed (equivalent to 1x).

### c. Population Adjusted Dose (PAD)

The Population Adjusted Dose (PAD) 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 SF. The acute PAD (aPAD) is an estimate of the one-day dietary exposure to a pesticide residue which is believed to have no significant deleterious effects. The chronic PAD (cPAD) is an estimate of the level of daily dietary exposure to a pesticide residue which, over a 70-year human life span, is believed to have no significant deleterious effects.

In the case of ethoprop, the FQPA SF has been removed (equivalent to a factor of 1x), so the acute or chronic RfD is identical to the respective aPAD or cPAD. In addition, an uncertainty factor is determined for each chemical. In the acute and chronic dietary risk assessments for ethoprop, the total uncertainty factor (UF) is 100x, based on the uncertainty factor of 10x for interspecies extrapolation and the 10x for intraspecies variability. The aPAD and cPAD are determined by dividing the NOAEL from the selected study by the uncertainty factor and safety factor. A risk estimate of less than 100% of the aPAD or cPAD is not of concern to the Agency.

Ethoprop is a potent cholinesterase (ChE) inhibitor. The toxicity endpoints and doses for dietary risk assessment are shown in Table 3. The endpoints for estimating the non-cancer risks from exposure to ethoprop are all based on ChE inhibition in the plasma of dogs.

**Table 3. Summary of Toxicological Endpoints and Other Factors Used in Human Dietary Risk Assessment for Ethoprop**

| EXPOSURE | DOSE | ENDPOINT | STUDY |
|---|---|---|---|
| Acute | NOAEL = 0.025 mg/kg/day | Plasma ChE inhibition at 0.075 mg/kg/day on day 2. | 90-day Feeding study in Dog |
| | **UF = 100 FQPA SF = 1 aPAD = 0.00025 mg/kg /day** | | |
| Chronic (Non-Cancer) | NOAEL = 0.01 mg/kg/day | Plasma ChE inhibition at 0.025 mg/kg/day. | Combined data from a 5-month and a 1-year Gavage study in Dog |
| | **UF = 100 FQPA SF = 1 cPAD = 0.0001 mg/kg/day** | | |
| Chronic (Cancer) | Classified as a **"likely"** human carcinogen, due to the occurrence of malignant adrenal pheochromocytomas in male Sprague-Dawley rats, with a $Q_1^* = 2.81 \times 10^{-2}$ $(mg/kg/day)^{-1}$. | | |

### d. Exposure Assumptions

The Agency usually prefers to utilize data from USDA's Pesticide Data Program (PDP) for the dietary risk assessments. However, for ethoprop, these data could not be quantitatively used in the risk assessment, because the Agency usually requires that there be at least 100 samples for each commodity to incorporate the USDA PDP monitoring data into risk assessments. Not enough samples were monitored among the crops for which the Agency needed to establish ethoprop tolerances, and many of the commodity groups for which the Agency has tolerances for ethoprop were not even included in the USDA PDP monitoring program. In addition, the limit-of-detection (LOD) from the USDA PDP monitoring data (0.03

ppm) would yield a less refined risk estimate than using field trial data (LOD: 0.003 ppm). The other data set which the Agency frequently utilizes, Food and Drug Administration (FDA) monitoring data, reported that almost all the samples had non-detectable levels of ethoprop (except for 1 trace residue among a total of 684 green bean samples, a total of 3531 samples among all six other crops with residues were analyzed, and all were reported as less than detectable residue levels). However, the Agency determined it would not be appropriate to use these non-detects data quantitatively in the risk assessment, because the LOD from the FDA monitoring data (0.015 ppm) was higher than the LOD used in field trial data (0.003 ppm), and would also provide a less refined estimate of risk.

In addition, neither the USDA PDP nor the FDA monitoring programs tested residues for any of the ethoprop metabolites. Therefore, the Agency utilized field trial data developed by the registrant, based on residue analyses of both ethoprop and M1. These data were based on the best analytical method currently available to the registrant. This method has been proposed by the registrant as the enforcement method for determining residues of ethoprop and M1, but because of uncertainties in the method, the registrant has not yet submitted this method to the Agency for validation.

For the reasons discussed above, the Agency utilized field trial data for ethoprop and M1 to perform a refined dietary assessment. The residue analyses in field trials were below the LOD in all crops, except for lima beans, snap beans, and peanuts. It is not surprising that all the other crops had residues which were less than the LOD because, for most agricultural field crops, ethoprop is applied pre-plant or at-plant and is soil incorporated. However, because residue data were submitted only for parent ethoprop and the M1 metabolite, the Agency developed a methodology for addressing the risk from all the metabolites of toxicological concern. This procedure was based on a calculation procedure to reflect the residues of toxicological concern (Table 2). (For details of the metabolite estimation/calculation procedure, see the 1999 *Ethoprop Revised Human Health Risk Assessment, Executive Summary*, as well as its *Attachment 4: Response to the USDA Comments to EPA's Monte Carlo Dietary Exposure Estimate for Ethoprop and Using Further Refinements.*)

Both the acute and chronic dietary risk assessments were conducted with the Dietary Exposure Evaluation Model (DEEM™) software and consumption data from USDA's 1989-1992 Continuing Survey of Food Intake by Individuals. This DEEM™ model utilizes a Monte Carlo procedure for the acute dietary assessment, which results in an acute probabilistic dietary exposure analysis. The Agency refined this analysis by using the percent crop-treated information (Table 1), with the estimated maximum percent crop treated utilized for the acute dietary assessment, and the weighted average percent crop treated for the chronic dietary assessment. The exposure estimates are largely based on residue values estimated from available field trial data and metabolism studies. The resulting residue estimates are higher than the existing tolerances for some commodities, due to the inclusion of adjustment factors, with an estimation procedure utilized for two of the three metabolites of concern. This is because the existing analytical method does not provide residue data for other than M1 metabolites. Additional refinement of dietary risk may be possible, if a refined analytical method were validated and if additional field trials were conducted, with the submission of residue data in

which all the residues of concern were quantified, including parent ethoprop and the various metabolites of toxicological concern specified in Table 2.

### e. Food Risk Characterization

The results of the dietary (food only) risk assessments are summarized in Table 4. These assessments are based on the assumption that the non-detectable residues are present at one-half the LOD for the analytical method from the respective database for each specific commodity, and include the use of percent-crop-treated data, as well as tolerance level residues for dry lima beans and the field trial data for all other registered commodities.

The acute dietary (food only) exposure for ethoprop is less than 100% of the aPAD, and therefore is not of concern to the Agency. The population with the highest exposure was infants younger than 1 year old, with an estimated exposure of about 75% of the aPAD. Because ethoprop residues were non-detectable for many commodities, and because the Agency has employed conservative (i.e., health-protective) assumptions to account for metabolites not measured in field trials, it is likely that the actual risks could be lower. (See the 1999 *Ethoprop Revised Human Health Risk Assessment, Attachment 4: Response to the USDA Comments to EPA's Monte Carlo Dietary Exposure Estimate for Ethoprop and Using Further Refinements*, for further details.)

**Table 4. Dietary Exposure and Risk for Ethoprop[1]**

| Population Subgroup | Acute | | Chronic | |
|---|---|---|---|---|
| | Exposure (mg/kg/day) | Risk as % of aPAD | Exposure (mg/kg/day) | Risk as % of cPAD |
| U.S. Population | 0.000096 | 38.5 | < 0.000001 | <1.0 |
| All Infants (<1yr) | 0.000188 | 75.4 | 0.000001 | 1.0 |
| Children (1-6 yrs) | 0.000168 | 67.2 | 0.000001 | 1.2 |

[1] The anticipated residues included tolerance levels for dry lima beans, and field trial data for all other registered commodities.

The chronic dietary (food only) analysis (Table 4) also indicates that chronic dietary exposure for ethoprop is less than 100% of the cPAD, and therefore not of concern to the Agency. The results of the chronic DEEM™ analysis indicate that the most highly exposed population subgroup (children 1-6 years old) has an exposure of 1.2% of the cPAD. (See the 1999 *Ethoprop Revised Human Health Risk Assessment, Attachment 5, Revised Chronic Dietary Exposure Analyses for the HED Risk Assessment*, for further details.)

The chronic (cancer) dietary risk is calculated by using the average consumption values for food and the average residue values for those foods, and assuming 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. For ethoprop, the $Q_1$* is $2.81 \times 10^{-2}$ $(mg/kg/day)^{-1}$ in human equivalents. The Agency generally considers $1 \times 10^{-6}$ (1 in 1 million) or less as negligible risk for cancer dietary exposure. The results of this cancer dietary (food only) analysis indicate that the carcinogenic dietary risk for ethoprop exposure for the general U.S. population associated with

the uses supported through reregistration is estimated to be $1.1 \times 10^{-8}$, and is therefore not of concern to the Agency. (For more information on the chronic (cancer) dietary risk assessment, see the 1999 *Ethoprop Revised Human Health Risk Assessment, Attachment 5, Revised Chronic Dietary Exposure Analyses for the HED Risk Assessment.*)

### 2. Dietary Risk from Drinking Water

To determine the maximum allowable concentration from water allowed in the diet, the Agency first evaluates how much of the overall allowable risk is contributed by food and residential exposure, then the Agency determines a drinking water level of comparison (DWLOC) to determine whether modeled or monitoring concentrations exceed this level. The Agency uses the DWLOC as a surrogate to express risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary and/or residential exposure, does not exceed 100% of the PAD or $1 \times 10^{-6}$ for cancer risk, and is not of concern to the Agency. Once the respective DWLOCs are calculated, they are compared with the upper bound of drinking water estimated concentrations (DWECs).

Ethoprop is mobile to very mobile in soil. It has also been found to be persistent, with soil metabolism studies in the laboratory (both an aerobic and an anaerobic study) showing half-life values of about 100 days, and aquatic half-life values of 75 to 90 days from an aerobic sediment/water metabolism laboratory study.

#### *Surface Water*

There are some limited surface water monitoring data for ethoprop from various sources. In the Agency STORET database, from 1978 to 1997, more than 6,000 surface water samples were collected throughout the United States from a variety of surface water sources (lakes, reservoirs, streams, and canals) in many ethoprop use areas. Almost all (> 90%) samples did not detect ethoprop. The limits of detection (LODs) ranged from 0.003 to 1.0 ppb. The highest reported concentration of 3.1 ppb was sampled in Marion County, Oregon in 1994, which is where other samples were also measured above the limit of detection. At that time, ethoprop was registered for use on turf for sod and seed, which is grown in the area and may have been treated at a maximum application rate of 20 lb ai/A. Marion County is within the Willamette Valley watershed, a major agricultural region, and other uses for ethoprop in this region include beans, sweet corn and ornamentals, which may have contributed as the source of these detections. (For additional details concerning the surface water monitoring data, see the *Environmental Fate and Effects Division RED Chapter for Ethoprop* (October 5, 1998) and the *Revised ethoprop drinking water assessment* (March 26, 2001)).

According to the United States Geological Survey National Water Quality Assessment (USGS NAWQA) database from 1991-1995, a total of 5,119 analyzed samples were collected throughout the United States. The maximum reported concentration was 2.0 ppb from a sample collected in the Willamette River Basin of Oregon. A more recent NAWQA study conducted in

1996[1] focused on the Willamette River Basin. Of the 95 samples collected, 21 showed detectable levels of ethoprop; however, the maximum concentration reported was 0.44 ppb.

The South Florida Water Management District (SFWMD) also sampled surface waters for pesticide residues, including ethoprop, from 1988 to 1993 at 27 sites. Samples collected at various times during the year (biannually to every 2 months) did not detect concentrations of ethoprop (LODs ranged from 0.06 ppb to 0.731 ppb). All the sugarcane grown in Florida (approximately 428,000 acres), in addition to golf courses (approximately 44,000 acres) and truck crops (approximately 155,000 acres), are located within the SFWMD, on which ethoprop may have been applied. Approximately 40 tons/year of ethoprop were reported to have been used in the SFWMD during the study period.

Although the levels of ethoprop found in the various studies suggest that ethoprop does not appear to exceed the DWLOCs, the reported samples were not correlated with use patterns, were collected randomly throughout the year, and were of insufficient numbers to make definitive statements as to extent of concentrations of ethoprop in surface waters. Additionally, information on the site characteristics within the monitored basins would be necessary to understand the relative vulnerability of the recipient surface waters. Thus, the DWECs are based on modeling estimates.

For surface water, the DWECs of ethoprop were calculated by Tier II modeling procedures, which included PRZM-EXAMS, with the Agency Standard Index Reservoir and the percent cropped area factor (PCA). For all surface water model scenarios, except for ethoprop use on corn, the default PCA value of 87% was used to predict surface water DWECs. The model results indicated that the surface water source DWECs exhibited the highest acute risk concentration for use on sweet potato in Louisiana, 127 ppb (Table 5), with other acute DWECs estimated for the following uses: tobacco in North Carolina, 92 ppb; sugar cane in Louisiana, also 92 ppb; potatoes in Maine, 21 ppb; and corn in Ohio, 15 ppb. The chronic (non-cancer) DWECs were the highest for use on tobacco in North Carolina, 25 ppb (Table 6), with other chronic DWECs estimated for the following uses: sweet potatoes in Louisiana, 22 ppb; sugar cane in Louisiana, 12 ppb; potatoes in Maine, 8 ppb; and corn in Ohio, 5 ppb. The chronic (cancer) DWECs were the highest for use on sweet potatoes in Louisiana, 13 ppb (Table 7), with other cancer DWECs estimated for the following uses: tobacco in North Carolina, 8.4 ppb; sugar cane in Louisiana, 3.9 ppb; potatoes in Maine, 3.7 ppb; and corn in Ohio, 2.6 ppb.

***Ground Water***

As with surface water, there are limited monitoring data available to assess drinking water risks from ground water sources. The STORET database reported that over 5,300 samples had been analyzed for ethoprop concentrations between 1981 and 1997. Of these, less than 0.1% showed ethoprop detections (LODs ranged from 0.003 to 2.5 ppb), and all detected values were less than 1 ppb. One set of samples collected from public drinking water wells located near

---

[1] Anderson CW, Wood TM, Morace JL. 1997. Distribution of Dissolved Pesticides and Other Water Quality Constituents in Small Streams, and their Relation to Land Use, in the Willamette River Basin, Oregon, 1996. US Geological Survey. Water Resources Investigations Report 97-4268.

Hermiston, Oregon, reported ethoprop concentrations from below the LOD of 0.03 ppb to 0.19 ppb. (For additional details concerning the ground water monitoring data, see the *Environmental Fate and Effects Division RED Chapter for Ethoprop* (October 5, 1998) and the *Revised ethoprop drinking water assessment* (March 26, 2001)).

In addition, the USGS NAWQA database reported 2,549 samples were analyzed during 1991 to 1995 in about 20 of the major watersheds within the United States. The highest reported concentration of 0.009 ppb occurred in an agricultural watershed. All other samples were reported to be less than the LOD of 0.003 ppb. In addition, the EPA Pesticide in Ground Water Database reported that 1,368 samples had been analyzed for ethoprop, but that no measurable concentrations were reported. It is important to note that the sampling was not conducted to specifically identify concentrations of ethoprop in verified use areas. No information on the use patterns of ethoprop were available at well locations, although ethoprop is known to be used in most of the watersheds sampled.

Similarly, ground water DWECs for ethoprop were also developed from modeling estimates, rather than monitoring data. Ground water DWECs were estimated by the screening-level Tier I SCI-GROW model, which estimates the "maximum" ground water concentrations from the application of a pesticide to crops. SCI-GROW is based on the fate properties of the pesticide, the annual application rate, and the existing body of data from small-scale ground water monitoring studies. The model assumes the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimates. From these model predictions, the highest DWEC was 10.1 ppb, based on crops treated at the 8 lb a.i./A application rate, and the next highest was 7.6 ppb for crops treated at 6 lb a.i./A.

***Summary of DWLOC and DWEC Comparisons***

**Table 5. Summary of DWLOC Calculations for Acute Risk**

| Population Subgroup [1] | Acute PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Allowable Water Exposure (mg/kg/day) | Ground Water: SCI-GROW (ppb) [2] | Surface Water: PRZM-EXAMS (ppb) [3] | DWLOC (ppb) |
|---|---|---|---|---|---|---|
| U.S. Population | 0.00025 | 0.000096 | 0.000154 | 10.1 | 127 | 5 |
| Infants <1 yr | 0.00025 | 0.000188 | 0.000062 | 10.1 | 127 | 0.6 |

**Table 6. Summary of DWLOC Calculations for Chronic Non-Cancer Risk**

| Population Subgroup [1] | Chronic PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Allowable Water Exposure (mg/kg/day) | Ground Water: SCI-GROW (ppb) [2] | Surface Water: PRZM-EXAMS (ppb) [4] | DWLOC (ppb) |
|---|---|---|---|---|---|---|
| U.S. Population | 0.0001 | <0.000001 | 0.000100 | 10.1 | 25 | 4 |
| Children (1-6 yrs) | 0.0001 | 0.000001 | 0.000099 | 10.1 | 25 | 1 |

**Table 7. Summary of DWLOC Calculations for Chronic Cancer Risk**

| Population Subgroup [1] | $Q_1$* (mg/kg/day)$^{-1}$ | Food Exposure (mg/kg/day) | Allowable Water Exposure (mg/kg/day) | Ground Water: SCI-GROW (ppb) [2] | Surface Water: PRZM-EXAMS (ppb) [3] | DWLOC (ppb) |
|---|---|---|---|---|---|---|
| U.S. Population | $2.81 \times 10^{-2}$ | 0.000004 | 0.000035 | 10.1 | 13 | 1 |

[1] The infant/child subgroup with the highest exposure was used. The models assume a 70 kg body wt for U.S. population and 10 kg for infants/children, and assume a water consumption of 2 L/day for adults and 1 L/day for infants and children.
[2] The highest estimated ground water concentrations from SCI-GROW modeling are based on an 8 lb ai/A application rate for agricultural crops. The registrant has voluntarily cancelled all uses on golf course turf, which had a maximum label rate of 20 lb ai/A and resulted in an estimated concentration of 25 ppb.
[3] The highest estimated surface water exposure from PRZM-EXAMS with Standard Index Reservoir is based on the Louisiana sweet potatoes scenario at an application rate of 6 lb ai/A.
[4] The highest estimated chronic (non-cancer) risk surface water exposure from PRZM-EXAMS with Standard Index Reservoir is based on the North Carolina tobacco scenario at an application rate of 12 lb ai/A.

Although the Agency has determined that four ethoprop metabolites/environmental degradates are of toxicological concern for water (cancer risk) (Table 2), the PRZM-EXAMS with the Standard Index Reservoir modeling did not include any of the environmental degradates of ethoprop due to a lack of fate information. However, results from various aquatic and soil metabolism studies indicated that none of the individual environmental degradates were ever present at greater than about 4% of the applied ethoprop concentration. The Agency does not generally conduct modeling for environmental degradates that account for less than 10% of the applied radioactive parent compound. Considering the limited presence of these degradates in the laboratory and field studies, ethoprop degradates are not expected to add appreciably to the concentration of total ethoprop in ground or surface water in most use areas. However, because modeled DWECs exceed corresponding DWLOCs, additional fate information on ethoprop degradates may be necessary to more fully understand its contribution to drinking water risks.

### 3. Occupational and Non-Occupational Risk

Occupational workers can be exposed to ethoprop through mixing, loading, and/or applying onto agricultural crops, loading and/or applying onto golf courses, treating ornamental plants, hand-dipping of citrus seedlings in liquids, and re-entering sites which have been treated with ethoprop (golf course turf maintenance workers and agricultural workers). Since there are no residential uses of ethoprop, there are no non-occupational risks from residential exposures; however, there can be non-occupational exposures for golfers after golf course turf is treated with ethoprop.

Non-cancer dermal and inhalation risks for potentially exposed populations are assessed by a margin of exposure (MOE) approach, which determines how close the exposure comes to the toxicity endpoint (usually selected as a No Observed Adverse Effect Level (NOAEL) from an animal study). The target MOE is defined by the uncertainty factor, and MOEs which are greater than the target MOE are not of concern to the Agency. However, for MOEs below the target level for pesticide handlers, the Agency approach is to apply further levels of worker protection (starting with baseline clothing, and adding various personal protective equipment (PPE), then various engineering controls) to determine whether these levels of protection result in MOEs that

exceed the target MOE and therefore are not of concern to the Agency. In addition to the MOE approach for worker risk assessments, cancer risk assessments are also conducted. The Agency generally considers occupational cancer risks of $1 \times 10^{-6}$ (1 in 1 million persons) or less to be negligible, but will consider risks as high as $1 \times 10^{-4}$ when all mitigation measures that are feasible have been applied, and when evaluating the benefits associated with the use of the pesticide.

### a. Toxicity Profile

The results of acute toxicity studies with ethoprop are listed in Table 8. Ethoprop is classified in Toxicity Category I for all acute endpoints, except acute inhalation which is classified in Toxicity Category II.

**Table 8. Acute Toxicity: Technical Ethoprop**

| STUDY | MRID | RESULTS | TOXICITY CATEGORY |
|---|---|---|---|
| **81-1 Acute Oral - Rat** | 00078035 | Male: $LD_{50}$ = 61.0 mg/kg<br>Female: $LD_{50}$ = 32.8 mg/kg | I |
| **81-2 Acute Dermal - Rabbit** | 429795-02 | $LD_{50}$ = 8.5 mg/kg | I |
| **81-3 Acute Inhalation - Rat** | 00128218 | $LC_{50}$ = 0.123 mg/L | II |
| **81-4 Eye Irritation - Rabbit** | 00078036 | 0.1 mL killed all 3 rabbits | I |
| **81-5 Skin Irritation - Rabbit** | 00048774 | 0.5 mL killed all 6 rabbits | I |
| **81-6 Dermal Sensitization [1]** | N/A | N/A [1] | N/A |

[1] Requirement for a Dermal Sensitization study is waived due to high acute dermal toxicity of ethoprop in rabbits.

All risk calculations performed by the Agency are based on the most current toxicity information available for ethoprop. The toxicological endpoints and other factors used in the occupational and non-occupational risk assessments for ethoprop are listed in Table 9. In addition, an uncertainty factor is determined for each toxicological endpoint. The total uncertainty factor (UF) is 100x, based on the uncertainty factor of 10x for interspecies extrapolation and the 10x for intraspecies variability, for all endpoints where there is an NOAEL.

**Table 9. Summary of Occupational Toxicological Endpoints for Ethoprop**

| EXPOSURE | DOSE | ENDPOINT | STUDY (MRID No.) | UF |
|---|---|---|---|---|
| **Short-Term Dermal with Liquids** | Dermal NOAEL = 0.1 mg/kg/day | Plasma, red blood cell (RBC), and brain cholinesterase (ChE) inhibition at 1.0 mg/kg/day. | 21-day dermal toxicity in rabbit with technical (413044-04) | 100 |
| **Short-Term Dermal with Granulars** | Dermal NOAEL = 20 mg/kg/day | Plasma ChE inhibition at 100 mg/kg/day. [2] | 28-day dermal toxicity in rat with a granular product, Mocap 20G (450348-01) | 100 |
| **Short-Term Inhalation [1]** | Oral NOAEL = 0.025 mg/kg/day | Plasma ChE inhibition at 0.075 mg/kg/day. [3] | 90-day feeding in dog with technical (00075240) | 100 |

| | | | | |
|---|---|---|---|---|
| **Intermediate and Long-Term Dermal or Inhalation** | None | There are currently no intermediate- or long-term exposures, so these risk assessments are not required for non-cancer risk assessments. | None | N/A |
| **Chronic (Cancer)** [4] | $Q_1^* = 2.81 \times 10^{-2}$ $(mg/kg/day)^{-1}$ | Classified as "likely" human carcinogen, based on malignant adrenal pheochromocytomas in male rats. | Chronic feeding/carcinogenicity in rat (425302-01) | N/A |

[1] Inhalation absorption is assumed to be equivalent to oral absorption (100%) for risk assessment purposes.
[2] Although plasma ChE inhibition was observed in this study at the lowest dose tested (20 mg/kg/day), it was in males only, and only on days 19 and 26; inhibition of RBC and brain ChE were observed in the 100 mg/kg/day dose, but not at the lowest dose tested.
[3] This toxicological endpoint is based on plasma ChE inhibition only, but is supported by a 5-month dog study, in which the NOAEL for plasma, RBC, and brain ChE inhibition at 2 and 4 weeks were observed at the identical dose for each compartment.
[4] Dermal absorption is assumed to be equivalent to oral absorption (100%) for cancer risk assessment.

The registrant submitted a 28-day dermal toxicity study in the rat with MOCAP® 10G (a 10% ai granular product) to further refine the occupational risk assessment for granular products. The Agency utilized this study for the short-term dermal toxicity endpoints for all granular materials. For determining inhalation risks, there are no inhalation studies with ethoprop of longer durations than 4 hours (acute exposures). Therefore, the Agency is utilizing the endpoints from oral dosing studies.

No dermal absorption studies are available for ethoprop. Because the occupational cancer risk assessment was based on an oral endpoint, an estimated dermal absorption value was calculated by comparing oral and dermal endpoints from various studies. Based on comparing the results from a 28-day dermal and a 28-day oral study in the rabbit, the relative dermal absorption was determined to be equivalent to oral exposure, and the 100% dermal absorption value was retained for use in occupational cancer risk assessments. Also, since there are no long-term inhalation studies, the same estimation procedure was used to develop an inhalation absorption estimate; thus, inhalation absorption was also assumed to be equivalent to the oral exposure at 100%.

### b. Occupational Exposure

Data from the Pesticide Handlers Exposure Database (PHED), Version 1.1 (August, 1998) were used to complete the occupational risk assessments, including all exposure scenarios for the liquid formulation, as well as all granular scenarios not addressed in certain studies submitted by the registrant. Those granular-specific studies submitted by the registrant include a product-specific worker exposure study with workers applying the 10G clay-based granular product to potato fields at-planting, and two worker exposure studies with other chemicals being used to treat bananas and plantains. In addition, for one set of scenarios with the granular products (the combined loader/applicator scenarios for tractor-drawn spreaders), the risk assessments were conducted, for comparative purposes, with exposure data both from the product-specific study and PHED data.

The registrant markets the granular ethoprop in 1000 lb plastic fiber bag packaging, called Supersaks, used primarily by custom applicators. The PHED database contains exposure data for

another chemical in 1500 lb Supersak-like containers. Thus, for purposes of conducting exposure assessments for the ethoprop 1000 lb Supersaks, the Agency used PHED data to estimate loader exposure.

The registrant also has a registration for a gel product in water soluble packaging. Aventis CropScience, the technical registrant, reported that this product was produced and marketed for only one year and has since elected to voluntarily cancel the product registration; therefore, risk calculations for this formulation were not conducted and are not included in this document.

Exposure data from the Pesticide Handler Exposure Database (PHED) Version 1.1 garden hose-end sprayer scenario were also used as surrogate data for the mixing/loading/applying with the sprinkler can. However, there are neither exposure data nor pesticide application information available for mixing/loading/applying liquid concentrate by handheld measuring containers or for dipping seedlings in liquid formulations, so these scenarios are referenced in the Table 11 as "No Data."

When the May 18, 2000 revised risk assessment was conducted for ethoprop, a short-term exposure was defined as less than 7 days, and an intermediate-term exposure was from 7 days to several months, so both short- and intermediate exposure and risk were assessed for ethoprop. On June 6, 2001, the Agency revised these definitions, and now the short-term exposure duration is defined as lasting from 1 day to 1 month, and the intermediate-term exposure duration is now defined as lasting from 1 to 6 months. Because of the use pattern, it is reasonable to believe that handlers will not treat crops with ethoprop for a duration of more than one month, and consequently, there are no longer any intermediate-term exposure durations for ethoprop. For instance, based on an informal survey, private potato growers will take 1 to 5 days per year to treat their own properties. Custom potato applicators average 7 days per year and range to 20 applications per year over a 3 to 4 week interval. In addition, the available toxicity studies (i.e., 21-/28-day dermal studies) are appropriate to assess risks to workers within this redefined short-term duration (1 month or less).

Chronic (long-term) occupational exposures to ethoprop also do not occur (agricultural crops and vegetables) because the current labels specify that applications are to be made only pre-plant, at-plant, or pre-emergent, and specify only one application per year. A few sites allow more than one application per crop or per year (bananas/plantains and pineapples), but the current labels specify discrete time intervals between applications; thus, it is assumed that even custom applicators would not receive long-term, chronic exposures (i.e., greater than 180 days).

Numerous scenarios were evaluated for mixer/loader, applicator, mixer/loader/applicator, and flagger scenarios, based on the types of application equipment and crop sites listed on the various ethoprop labels. (For details, see *Ethoprop Revised Human Health Risk Assessment, Attachment 6, Revised Occupational/Non-Occupational/Residential Exposure Assessment for the Reregistration Eligibility Decision*, September 2, 1999, as well as *Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000.)

Use patterns, application methods, application rates, and daily amount treated were derived from current labeling, as well as based on information concerning typical use practices submitted by Aventis CropScience that have been verified by the Agency. Application rates specified on current ethoprop labels range from 0.1323 pounds of active ingredient per acre (lb ai/A) for bananas and plantains to 12.0 lb ai/A for tobacco and white potatoes in agricultural settings. (In addition, the current ethoprop labels permit golf course turf treatments at application rates of up to 20 lb ai/A, but all golf course turf uses are being voluntarily cancelled.).

The types of protection, including personal protective equipment (PPE) and engineering controls, that are the basis for exposure during ethoprop activities in the risk assessments include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline clothing, plus chemical resistant gloves, and a dust/mist respirator with an assumed Protection Factor (PF) of 5.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, and an organic vapor respirator (with an assumed PF of 10).
- Engineering controls: Closed mixing/loading systems, such as on-farm closed mechanical transfer systems for liquids (e.g., dripless couplings) or packaging-based systems for granulars (e.g., Lock 'N Load). Also enclosed systems for application, such as a closed cab tractor for ground equipment, closed cockpit for pilots, and closed trucks for flaggers (which for some enclosed system include air filtration to provide either dermal or inhalation protection). Note that some engineering controls are not feasible for certain scenarios (e.g., for handheld application methods).

On the current ethoprop labels, the equipment specified to be used by agricultural workers includes the following:

- coveralls, either over a short-sleeved shirt and short pants (on the 10% and 15% granular product labels) or over a long-sleeved shirt and long pants (on the 20% granular label and on the labels for the EC and the gel);
- chemical-resistant footwear plus socks;
- gloves, either waterproof gloves (on the granular labels) or gloves of chemical-resistant materials (on the labels for the EC and the gel);
- protective eyewear (on the 20% granular label and the labels for the EC and the gel);
- chemical-resistant headgear for overhead exposure;
- chemical-resistant apron when cleaning equipment, mixing, or loading; and
- respirator, with a dust/mist filtering respirator (on the granular labels) or the choice of either an organic vapor-removing cartridge with a prefilter approved for pesticides or a canister approved for pesticides (on the labels for the EC and the gel).

For workers using granular ethoprop products to treat golf courses, the current labels specify the following equipment:

- for loaders, coveralls over short-sleeved shirt and short pants, waterproof gloves, shoes and socks, and a dust/mist respirator; and
- for applicators, long-sleeved shirt and long pants, shoes and socks.

Some of the ethoprop granular formulations (both the 10G and 20G product) are marketed in Lock 'n Load™ packaging, which qualify as engineering controls (closed loading systems) under the Worker Protection Standard; thus, the following equipment is specified for loaders on these product labels:

- long-sleeved shirt and long pants;
- shoes and socks;
- waterproof gloves; and
- chemical-resistant apron.

### c. Occupational Risk Summary

For purposes of calculating risk, a margin of exposure (MOE) is calculated. The MOE is a ratio obtained by dividing the selected NOAEL by the estimated dose to which an individual is exposed. MOEs of 100 or greater are considered protective.

In addition to the MOE approach for worker dermal and inhalation risk assessments, cancer risk assessments were also conducted for ethoprop following exposures to occupational handlers, post-application workers, and those individuals receiving non-occupational exposures (i.e., golfers). The Agency considers cancer risks of $1 \times 10^{-6}$ (1 in 1 million) or less to be negligible.

The anticipated use patterns and current labeling for ethoprop indicate there are numerous exposure scenarios, based upon the types of equipment that potentially can be used to make ethoprop applications. These scenarios, which serve as the basis for the quantitative exposure and risk assessments, are as follows:

1a loading granulars for aerial application;
1b loading granulars for tractor-drawn spreader application;
2a mixing/loading EC for chemigation application;
2b mixing/loading EC for groundboom application;
3a applying granulars with fixed-wing aircraft;
3b applying granulars with a tractor-drawn spreader;
4 applying liquids with a groundboom sprayer;
5a loading/applying granules with a tractor-drawn spreader to treat agricultural field crops, with PHED exposure data;
5b loading/applying granules with a tractor-drawn spreader to treat agricultural field crops, with product-specific Aventis exposure data;
5c loading/applying granules with a tractor-drawn spreader to treat golf course turf;

5d loading/applying granules with a push-type granular spreader to treat golf course turf, with PHED exposure data;
5e loading/applying granules with a push-type granular spreader to treat golf course turf, with ORETF/Aventis exposure data;
5f loading/applying granules by hand (includes information provided by the registrant for banana acres treated);
6a mixing/loading/applying sprays with a low pressure handwand;
6b mixing/loading/applying sprays with a backpack sprayer;
6c loading/applying granules with a granular backpack spreader;
7 mixing/loading/applying liquids with a sprinkler can;
8 mixing/loading/applying liquid concentrate by handheld measuring container;
9 dipping seedlings in liquid formulations; and
10 flagging for granular application with fixed-wing aircraft.

***Non-Cancer Worker Risks***

Non-cancer risks for workers, based on cholinesterase inhibition, are presented below. The results of the worker risk assessments with only baseline clothing indicated risk concerns for every scenario (i.e., most MOEs are less than 1, only a very few are above 1, even at the lowest application rates, and none of the MOEs are above 100). Therefore, to present risks with the types of worker protection listed on current ethoprop labels and to determine what levels of protection are needed for new labels as part of the ethoprop reregistration process, the data summarized in this IRED document presents worker risk assessments where engineering controls are feasible (Table 10). For some scenarios and application equipment, engineering controls are not feasible (such as treatments with hand-held equipment). For these scenarios, the maximum worker protection is personal protective equipment, and these worker risk results are presented in Table 11. (For detailed presentations of results, see *Ethoprop Revised Human Health Risk Assessment, Attachment 6, Revised Occupational/ Non-Occupational/Residential Exposure Assessment for the Reregistration Eligibility Decision*, September 2, 1999, as well as *Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000).

Note that for the granular products, the inhalation MOEs are usually lower than the dermal MOEs. Thus, the inhalation exposure is considered to be the risk driver for granular products. Conversely, due to the toxic properties of the liquid via the dermal route of exposure, for the EC formulation, the dermal MOEs are lower than the inhalation MOEs. Thus, the dermal exposure is considered to be the risk driver for liquid products.

Granular Formulations

For those granular product scenarios where engineering controls are feasible, which are generally associated with use on agricultural field crops, such as potatoes, sweet potatoes, sugar cane and tobacco, the Agency has worker risk concerns for most of the combined (dermal plus inhalation) exposures (Table 10). For those granular product scenarios where no engineering controls are possible and only PPE is feasible, which are generally associated with use on tropical

crops, such as bananas, plantains, and pineapples, the Agency also has worker risk concerns, because none of the combined exposure MOEs are greater than about 11 (Table 11).

Exposure and risk assessments for workers who are both loaders and applicators are estimated based on both PHED exposure data (scenario 5a) and exposure data from the product-specific study submitted by Aventis (scenario 5b). This study, conducted with the granular ethoprop 10G product, reported passive dosimetry exposure data indicating that worker exposures are about 6 times greater than those with the Agency PHED exposure data, with combined short-term loader/applicator MOEs of 1.2 and 7.2, respectively (at a label rate of 12 lb ai/A). Furthermore, this study provided exposure data for both SureFill Boxes (closed loading system) and open pour boxes (not an engineering control). Thus, exposure data for workers with PPE handling open pour boxes are assessed and are detailed in the supporting technical documents, but are not listed in either Table 10 or 11.

In summary, the dermal MOEs for loaders and/or applicators with maximum PPE (i.e., double layer clothing and chemical-resistant gloves) range from 192 to 2574, depending upon the activity, application rate and acres treated. For these same scenarios, the inhalation MOEs with a respirator (protection factor of 5) range from 3.1 to 45.6, and the combined dermal and inhalation MOEs range from 3.1 to 44.6. (For further details see *Ethoprop Revised Human Health Risk Assessment, Attachment 6, Revised Occupational/ Non-Occupational/Residential Exposure Assessment for the Reregistration Eligibility Decision*, September 2, 1999, as well as *Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000.)

Liquid Formulations

For ethoprop liquid formulations, the Agency has risk concerns for dermal risks and most inhalation risks across most scenarios. For applications of the EC to agricultural field crops, such as potatoes, sweet potatoes, and tobacco, the combined dermal and inhalation exposure scenarios with the highest MOE with engineering controls for mixer/loaders were only about 5 (scenario 2b), and about 9 for those applying the liquid with ground-boom equipment (scenario 4). For scenarios where engineering controls are not feasible (Table 11), which include treatment of ornamentals, non-bearing citrus plants, tropical fruits, and hand-dipping of citrus seedlings, the risk estimates indicate even lower MOEs.

***Cancer Risks***

Cancer risks are also listed for the respective maximum protection scenarios, both engineering controls (Table 10) and only PPE (Table 11). These cancer risks are based on custom applicators making 10 applications of ethoprop per year. This is the "typical" number of applications that custom applicators would make in a year, based on data submitted by Aventis CropScience and confirmed by the Agency. (For more details on occupational cancer risks, typical application rates, typical acreages for each crop, and typical numbers of applications per year, see *Ethoprop Revised Human Health Risk Assessment, Attachment 6, Revised Occupational/Non-Occupational/Residential Exposure Assessment for the Reregistration Eligibility Decision*, September 2, 1999, as well as *Ethoprop: Revised Occupational/Non-*

*Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000.)

For granular formulations, in those scenarios involving ground equipment where engineering controls are feasible, some had cancer risks which were less than $1 \times 10^{-6}$, and are not of concern to the Agency, and others greater than $1 \times 10^{-6}$ (i.e., $2.0 \times 10^{-6}$ to $5.9 \times 10^{-5}$) (Table 10). Note that cancer risks for pilots applying granulars (scenario 3a) range from $6.9 \times 10^{-5}$ to $1.4 \times 10^{-4}$, and these cancer risks are of concern to the Agency. However, the registrant has agreed to cancel all aerial applications of ethoprop.

For the occupational exposure scenarios with the EC where engineering controls are feasible (Table 10), most of the cancer risks are greater than $1 \times 10^{-6}$, and are thus of concern to the Agency. The only scenario with engineering controls having cancer risks exceeding $1 \times 10^{-4}$ is mixing/loading for chemigation of 350 acres at 12 lb ai/A (scenario 2a: cancer risk $2.1 \times 10^{-4}$).

For scenarios where engineering controls are not feasible, and only PPE protection is available to workers (Table 11), cancer risks are greater than $1 \times 10^{-4}$ for those mixing/loading/applying with a liquid backpack sprayer (scenario 6b) and with a sprinkler can (scenario 7). These scenarios exhibit cancer risks of concern to the Agency. In addition, there are no data for estimating cancer risks for two of the other hand-held types of equipment, mixing/loading/applying liquid concentrate by hand-held measuring container (scenario 8) and hand-dipping citrus seedlings in liquids (scenario 9).

**Table 10. Occupational Risks for Use Scenarios for which Engineering Controls are Feasible**

| Scenario | Application Rate (lb ai/A) | Acres Treated | Risk Estimates with Engineering Controls | | | |
|---|---|---|---|---|---|---|
| | | | Short-Term MOEs | | | Cancer (10 appls/yr) |
| | | | Dermal | Inhalation | Combined | |
| **Mixers/Loaders** | | | | | | |
| (1a) Loading Granulars for Aerial Application by Fixed-Wing Aircraft | 6 | 350 | 3968 | 24.5 | 24.4 | 4.6E-6 |
| | 12 | | 1984 | 12.2 | 12.1 | 9.2E-6 |
| (1b) Loading Granulars for Application with a Tractor-Drawn Mechanical Spreader | 2 | 80 | 52080 | 322 | 320 | 1.8E-7 |
| | 6 | | 17360 | 107 | 107 | 5.3E-7 |
| | 12 | | 8681 | 53.6 | 53.3 | 1.1E-6 |
| | 20 (Golf Course Turf) | 40 | 10420 | 64.3 | 63.9 | 8.9E-7 |
| (2a) Mixing/Loading EC for Chemigation | 2 | 350 | 1.1 | 31 | 1.1 | 3.4E-5 |
| | 6 | | 0.4 | 10 | 0.4 | 1.0E-4 |
| | 12 | | 0.2 | 5.2 | 0.2 | 2.1E-4 |
| | 2 | 80 | 5.1 | 132 | 4.9 | 7.6E-6 |

| Scenario | Application Rate (lb ai/A) | Acres Treated | Risk Estimates with Engineering Controls | | | |
|---|---|---|---|---|---|---|
| | | | Short-Term MOEs | | | Cancer (10 appls/yr) |
| | | | Dermal | Inhalation | Combined | |
| | 6 | | 1.7 | 43.9 | 1.6 | 2.3E-5 |
| | 12 | | 0.8 | 22.0 | 0.8 | 4.5E-5 |
| (2b) Mixing/Loading EC for Groundboom Application | 2 | 80 | 5.1 | 132 | 4.9 | 7.6E-6 |
| | 6 | | 1.7 | 43.9 | 1.6 | 2.3E-5 |
| | 12 | | 0.8 | 22.0 | 0.8 | 4.5E-5 |
| **Applicators** | | | | | | |
| (3a) Applying Granulars with Fixed-Wing Aircraft | 6 | 350 | 392 | 0.64 | 0.64 | 6.9E-5 |
| | 12 | | 196 | 0.32 | 0.32 | 1.4E-4 |
| (3b) Applying Granulars with a Tractor-Drawn Mechanical Spreader | 2 | 80 | 4167 | 49.7 | 49.1 | 2.0E-6 |
| | 6 | | 1389 | 16.6 | 16.4 | 6.1E-6 |
| | 12 | | 694 | 8.3 | 8.2 | 1.2E-5 |
| | 20 (Golf Course Turf) | 40 | 833 | 9.9 | 9.8 | 1.1E-5 |
| (4) Applying Sprays with Groundboom | 2 | 80 | 8.8 | 254 | 8.5 | 4.4E-6 |
| | 6 | | 2.9 | 84.8 | 2.8 | 1.3E-5 |
| | 12 | | 1.5 | 42.4 | 1.4 | 2.7E-5 |
| **Loaders/Applicators** | | | | | | |
| (5a) Loading/Applying Granulars with Tractor-Drawn Mechanical Spreader, with PHED Exposure Data | 2 | 80 | 3804 | 43.8 | 43.3 | 2.2E-6 |
| | 6 | | 1268 | 14.6 | 14.4 | 6.7E-6 |
| | 12 | | 634 | 7.3 | 7.2 | 1.3E-5 |
| (5b) Loading/Applying Granulars with Tractor-Drawn Mechanical Spreader, with Aventis Exposure Data | 2 | 80 | 1458 | 7.3 | 7.3 | 9.8E-6 |
| | 6 | | 468 | 2.4 | 2.4 | 2.9E-5 |
| | 12 | | 243 | 1.2 | 1.2 | 5.9E-5 |
| (5c) Loading/Applying Granules with Tractor-Drawn Spreader, with PHED Exposure Data | 20 (Golf Course Turf) | 40 | 761 | 8.8 | 8.7 | 1.1E-5 |

| Scenario | Application Rate (lb ai/A) | Acres Treated | Risk Estimates with Engineering Controls | | | |
|---|---|---|---|---|---|---|
| | | | Short-Term MOEs | | | Cancer (10 appls/yr) |
| | | | Dermal | Inhalation | Combined | |
| **Flaggers** | | | | | | |
| (10) Flagging for Aerial Applications with Granulars | 6 | 350 | 11900 | 278 | 271 | 1.4E-6 |
| | 12 | | 5952 | 139 | 136 | 2.8E-6 |

**Table 11. Occupational Risks for Those Use Scenarios for which Engineering Controls are Not Feasible, and the Maximum Worker Protection is Only Provided with PPE**

| Scenario | Application Rate | Acres Treated or Gallons Applied | Risk Estimates with Personal Protective Equipment (PPE) | | | |
|---|---|---|---|---|---|---|
| | | | Short-Term MOEs | | | Cancer (10 appls/yr) |
| | | | Dermal | Inhalation | Combined | |
| **Loader/Applicators and Mixer/Loader/Applicators** | | | | | | |
| (5d) Loading/Applying Granulars with Push-Type Spreader, with PHED Exposure Data | 20 lb ai/A (Golf Course Turf) | 5 A | 19.2 | 27.8 | 11.3 | 4.0E-4 |
| (5e) Loading/Applying Granulars with Push-Type Spreader, with Exposure Data from ORETF/Aventis | 20 lb ai/A (Golf Course Turf) | 5 A | 58.3 | 12.5 | 10.3 | 1.3E-4 |
| (5f) Loading/Applying Granulars by Hand: additional registrant data for ethoprop, bananas/plantains | 5.5 lb ai/A | 1 A | 0.033 | 6.8 | 0.033 | 1.1E-3 |
| (5f) Loading/Applying Granulars by Hand: data from fipronil study, applied with spoon to bananas/plantains | 10.6 lb ai/A | 5 A | 13.4 | 0.74 | 0.70 | 5.9E-4 |
| (6a) Mixing/Loading/ Applying Liquids with Low-Pressure Handwand Sprayer | 5 lb ai/gal | 20 gal | 0.77 | 23 | 0.74 | 5.0E-5 |
| (6b) Mixing/Loading/ Applying Liquids with Backpack Sprayer | 5 lb ai/gal | 20 gal | 0.18 | 23 | 0.18 | 9.0E-4 |
| (6c) Loading/Applying Granulars (Temik) with Swissmex Backpack Spreader | 10.6 lb ai/A | 5 A | 266 | 7.9 | 7.6 | 3.0E-5 |

| Scenario | Application Rate | Acres Treated or Gallons Applied | Risk Estimates with Personal Protective Equipment (PPE) | | | |
|---|---|---|---|---|---|---|
| | | | Short-Term MOEs | | | Cancer (10 appls/yr) |
| | | | Dermal | Inhalation | Combined | |
| (6c) Loading/Applying Granulars (Fipronil) with Horstine-Farmery Microspread Backpack Spreader | 10.6 lb ai/A | 5 A | 44.2 | 0.76 | 0.74 | 1.9E-4 |
| (7) Mixing/Loading/ Applying Liquids with Sprinkler Can | 3 lb ai/gal | 1 gal | 0.56 | 620 | 0.56 | 6.7E-5 |
| | 6 lb ai/gal | 1 gal | 0.27 | 310 | 0.27 | 1.4E-4 |
| (8) Mixing/Loading/ Applying Liquid Concentrate by Handheld Measuring Container (bananas/plantains) | 5.5 lb ai/gal | 1 A | ND [1] | ND | ND | ND |
| (9) Dipping Citrus Seedlings in Liquids | 0.0075 lb ai/gal | ND | ND | ND | ND | ND |

[1] "ND" indicates that no data are available either in PHED or from the registrant for this scenario, even for the Baseline Clothing scenarios.

### d. Post-Application Exposure and Risk

***Restricted Entry Intervals***

The current labels for ethoprop list a restricted entry interval (REI) of 48 hours, with the REI increased to 72 hours in outdoor areas where average rainfall is less than 25 inches per year. The current labels also specify that ethoprop products be soil incorporated or watered-in; thus, providing there is no disturbance of the soil (i.e. digging or hoeing), the Agency has no concerns for workers re-entering a site treated with ethoprop, provided that they comply with current REIs.

For most field crops, the current labels require that ethoprop be applied pre-plant or at-plant. The exceptions for this pre-plant/at-plant use pattern include ethoprop applications to potatoes until emergence of the potato shoots (granulars only), treatment of corn during cultivation until lay-by (granulars only), to peanut plants at pegging (granulars only), and to mature tropical/sub-tropical plants, including pineapples (EC only), and bananas and plantains (both granulars and EC).

For these field crops which may be treated post-plant, only the granular labels specify post-plant treatment. The current labels specify that corn treatments may be made until layby, and the granules are to be covered with soil, "by making application immediately ahead of cultivation equipment." For treatment of peanuts at-pegging, the labels indicate the "pegging treatment should be incorporated lightly into the soil." For potatoes, the EC label indicates "do not apply once plants have begun to emerge." All labels specify that potatoes treated pre-plant/at-plant would require soil-incorporation (generally to 2 to 4 inches, with the EC label

specifying soil incorporation to 4 to 8 inches for nematodes in the Pacific Northwest); however, the granular labels permit post-plant treatment of potatoes until emergence, and specify "If applied after planting, apply 1/4 to 1/2 inch of water to incorporate in soil. Uniformity of application is important for best results." Based on these label instructions involving soil incorporation, the Agency does not have worker risk concerns for post-application exposures for those three field crops which may be treated after crop planting.

Fields treated with ethoprop grown to tropical/sub-tropical plants (pineapples, bananas, and plantains) are generally not reentered by workers to conduct routine activities required for the production of the crop soon after the ethoprop applications. For the EC product, as well as a 24(c) Special Local Need granular 10G label for Puerto Rico, pineapples may be treated at various times for plant crops (up to 8 times per year) or ratoon crops (up to 5 times per year) during the growing season, with applications permitted at 2 month intervals. Because the current EC and gel labels establish a 120-day post-harvest interval for pineapples, and there are no other routine activities in pineapple culture that would contribute to worker exposure, the Agency generally has no post-application worker risk concerns for the limited number of acres of pineapples that are hand harvested. Similarly, banana and plantain applications with the granular products are conducted with a backpack spreader or hand-spreading with a spoon. The current granular labels specify that ground litter be removed before applying, and to apply evenly; then irrigation should follow, unless during a rainy period; if applications are made during a dry period or if irrigation is not available, then the ethoprop is to be mixed into the soil (top 2 cm or 1 inch) with a rake. Once treated by this procedure, there are few cultural practices requiring reentry to banana and plantain fields. Thus, the Agency has no worker concerns for post-application exposures for pineapples or bananas and plantains.

***Post-Application Assessments for Applications to Golf Course Turf***

A post-application exposure and risk assessment was conducted for turf management professionals (e.g., conducting mowing and movement of pins). When using both tractors and push-type mowers following application of rates of 10 and 20 lbs ai/A, REIs of 10 days or longer were required before the MOEs would be greater than 100 and the workers could re-enter to conduct such activities as mowing and maintenance (i.e., the calculated REIs are 10 days after treatments following applications of 10 lb ai/A, and 17 days following applications of 20 lb ai/A).

In addition, post-application cancer risks were also calculated for these turf management professionals. Using the Agency-selected transferability factor as a basis for the cancer risk assessment (see the *Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document*, May 18, 2000), all cancer risks were less than $3.1 \times 10^{-7}$ on the day of application.

**e. Non-Occupational Exposure and Risk**

Ethoprop is not registered for use on general turf or sod (these uses were taken off the labels in 1995), or for applications to vegetable gardens, home ornamentals, or other residential uses, but it is registered for use on golf course turf. Thus, to conduct the non-occupational

exposure and risk assessments for ethoprop, an assessment was conducted to quantify golfer risk following ethoprop treatment of golf course turf, including treatment of the entire golf course, fairways and roughs, in addition to tees and greens. On the day of ethoprop treatment at 10 and 20 lbs ai/A, the calculated MOEs for golfers were 70 and 35, respectively. To exceed MOEs of 100, the risk assessment indicated that 4 or 10 days needed to elapse after these respective 10 and 20 lbs ai/A application rates before golfers could enter ethoprop treated areas.

The cancer risks associated with golfer exposures were also calculated. The cancer risks were less than $1.0 \times 10^{-7}$, and therefore are not of concern to the Agency.

**f. Incident Reports**

The review of the incident report databases for ethoprop lists some occupational instances in which symptoms have been reported, including evidence of cholinesterase inhibition. In the OPP Incident Data System, 6 incidents were listed, including ingestion by an adult and child, as well as reports involving pesticide handlers, with 2 of 4 handler incidents not providing information on the symptoms, and the other 2 incidents reporting "dizziness, nausea, headaches, vomiting, and pinpoint/constricted pupils." According to information available from the National Pesticide Telecommunications Network (NPTN), of top 200 chemicals with calls received by the NPTN, ethoprop was "ranked 182$^{nd}$ with 13 incidents in humans reported and 3 incidents in animals (mostly pets)." Based on a survey of the Poison Control Centers, the information indicated that ethoprop was likely to result in "... above average evidence of effects .... nearly twice as likely to require hospitalization as did cases due to other cholinesterase inhibitors." However, the information from these three sources is based on a relatively small number of incidents.

In addition, there are reports of incidents available from the California Department of Food and Agriculture. Based on their records, ethoprop was ranked "76$^{th}$ as a cause of systemic poisoning in California." In all, 11 cases were reported, all in 1989. Among these cases, 8 persons exhibited systemic illnesses from their exposure to ethoprop, although only 1 person was hospitalized. Of these 8 persons, one was a worker performing ground application, and the remaining 7 cases were people exposed in a single incident by drift from an air-blast application onto soil. This incident was further investigated by the California Department of Environmental Health, which reported that there were incidents of headache, diarrhea, runny nose, sore throat, burning/itching eyes, fever, and hay fever or asthma attacks. These symptoms were partly attributed to the presence of n-propyl mercaptan, an ethoprop contaminate/degradate with a strong, offensive odor. Note also that the incident resulted from air-blast application to soil, but this type of equipment is no longer listed on ethoprop labels.

There are also some more recent incident reports from the State of Washington (3 "possible" cases involving Mocap 10G granules). In addition, there are reports from the State of Oregon (2 cases, each involving workers exposed to various pesticides, including ethoprop, and one other case involving wind drift towards a home adjacent to a nursery, before the ethoprop was disced into soil, in which 1 adult and 2 children showed symptoms).

The information available indicates that when ethoprop incidents have been reported, the incidents have a higher probability of resulting in more serious health outcomes (such as hospitalizations) than other OPs. However, the Agency only has a limited number of human incident reports from which to base conclusions on the safety of ethoprop when used in accordance with label requirements.

### 4. Aggregate Risk

An aggregate risk assessment involves multiple routes of exposure, including food, drinking water, and non-occupational (residential and recreational [i.e., golfer]) exposures. Generally, all risks from these exposures must be less than 100% of the respective PAD, or have MOEs which are greater than 100, to be not of concern to the Agency. (See the 1999 *Ethoprop Revised Human Health Risk Assessment*, for details concerning the aggregate risk assessments.)

#### *Acute*

The acute aggregate risk assessment, by definition, addresses the one-day oral exposure, and for ethoprop, includes only the combined risk from dietary exposures via food and drinking water routes. As indicated in Table 4, acute dietary (food) risk consumes 75% of the acute PAD for all infants less than 1 year old (the most highly exposed population subgroup). Based on this level of exposure, the calculated acute risk DWLOC is 0.6 ppb for infants less than 1 year old. As indicated in Table 5, the estimated acute (peak) drinking water estimated concentrations (DWECs) are 127 ppb for surface water sources, and 10.1 ppb for ground water sources where applications were made at 8 lb ai/A. Thus, both the surface and ground water DWECs exceed the acute DWLOC; therefore, an acute aggregate assessment was not conducted. Since adequate drinking water monitoring data are not available for ethoprop, the acute aggregate assessment is based on estimated concentrations of ethoprop in drinking water from screening level models, and may be lower than currently predicted.

#### *Chronic (Non-Cancer)*

The Agency defines a chronic (non-cancer) aggregate, long-term risk assessment as involving continuous exposures of greater than 6 months in duration. Since a chronic recreational exposure is not anticipated, the chronic (non-cancer) aggregate risk assessment for ethoprop includes only food and drinking water routes of exposure. As indicated in Table 4, chronic (non-cancer) dietary (food) risk consumes 1.2% of the chronic PAD for children 1-6 years old (the most highly exposed population subgroup), and 1.0% for all infants less than 1 year old. Based on these levels of exposure, the calculated chronic (non-cancer) risk DWLOC is 1.0 ppb for infants less than 1 year old. As indicated in Table 6, the estimated chronic (average) drinking water estimated concentrations (DWECs) are 25 ppb for surface water sources, and 25 ppb for ground water sources from golf course uses and 10.1 ppb for ground water sources where applications were made at 8 lb ai/A. Both the surface and ground water DWECs exceed the chronic (non-cancer) DWLOC; therefore, an chronic (non-cancer) aggregate assessment was not conducted. Since adequate drinking water monitoring data are not available for ethoprop, the chronic (non-cancer) aggregate assessment is based on estimated concentrations of ethoprop in drinking water from screening level models, and may be lower than currently predicted.

*Chronic (Cancer)*

By definition, the carcinogenic aggregate risk assessment includes food, drinking water, and non-occupational/recreational (golfer) exposures. Because the Agency's level of concern was already exceeded for golfer risk, a carcinogenic aggregate assessment was not originally performed. However, if exposure from golf course uses is excluded, a carcinogenic aggregate risk assessment would be based on food and drinking water routes of exposure. The carcinogenic dietary (food) risk was $1.1 \times 10^{-8}$ for the general U.S. population. From this exposure, the calculated chronic (cancer) risk DWLOC is 1.0 ppb. As indicated in Table 7, the estimated chronic (average) drinking water estimated concentrations (DWECs) are 13 ppb for surface water sources, and 10.1 ppb for ground water sources where applications were made at 8 lb ai/A. Both the surface and ground water DWECs exceed the chronic (cancer) DWLOC; therefore, a carcinogenic aggregate assessment, even with non-occupational/recreational (golfer) exposures excluded, is of concern to the Agency. Since adequate drinking water monitoring data are not available for ethoprop, the chronic (cancer) aggregate assessment is based on estimated concentrations of ethoprop in drinking water from screening level models, and may be lower than currently predicted.

*Short-Term and Intermediate-Term*

By definition, the short-term aggregate risk addresses exposure durations of 1 day to 1 month, and intermediate-term aggregate risk addresses exposure durations of 1 to 6 months. For ethoprop, short- and intermediate-term aggregate risk includes food, drinking water, and non-occupational/recreational (golfer) routes of exposure. Since the MOEs for golfer exposure already exceeded the target MOE and are of concern, the exposures for food, drinking water, and non-occupational/recreational activities were not combined, and these short- and intermediate-term aggregate assessments were not conducted. However, if exposure from golf course uses are excluded, the short- and intermediate-term aggregate risk assessment would be based on food and drinking water exposure only, and would be identical to the chronic dietary aggregate risk assessment discussed above.

**B. Environmental Risk Assessment**

For detailed discussions of the environmental risk assessment, see the *Environmental Fate and Effects Division RED Chapter for Ethoprop* (October 5, 1998, with addenda dated 10/18/98, 2/18/99, 8/30/99, and 4/24/00), which is available in the Public Docket and the Agency's web page (www.epa.gov/pestidices/op). A summary of ecological risk concerns is presented below.

**1. Environmental Fate and Transport**

Ethoprop is a soluble (aqueous solubility: 843 ppm), somewhat volatile (vapor pressure: $3.5 \times 10^{-4}$ mm Hg at 26°C) insecticide/nematicide. Based on laboratory data, ethoprop is fairly persistent; however, in field studies, dissipation was more rapid than expected, especially under warm, moist conditions. The difference in half-lives between laboratory and field studies may be

partially due to leaching/runoff, as well as to the increased soil moisture and temperature in the field soils, which might result in increased microbial degradation and volatilization.

Because of its high solubility and moderately low soil sorption potential ($K_d$: 2.1 L/kg in silt loam soil; $K_{ads}$: 1.08-3.78), ethoprop has the potential to contaminate surface water through dissolved runoff. Ethoprop is, however, either mechanically incorporated or watered into the soil, which will reduce the runoff potential. Its persistence and mobility in laboratory studies suggest that ethoprop and its degradates could also pose a threat to ground water resources.

Ethoprop is stable to hydrolysis, and does not readily undergo photodegradation in water or on soil. The results from the available aerobic soil metabolism study established a half-life of 100 days. At 252 days post-treatment, 24.8% of the applied radioactivity was undegraded ethoprop. The major degradate was $CO_2$ (accounting for 53.9% of the applied radioactivity by the end of the study); the major nonvolatile degradates were identified as O-ethyl-S-methyl-S-propylphosphorodithioate (SME), O-ethyl-O-methyl-S-propylphosphorodithioate (OME), and O-ethyl-S-propylphosphorothioate (M1), with the measured amount of each accounting for less than 4% of the applied, at every sampling interval. In addition, an anaerobic soil metabolism study showed a similar rate of degradation, with the half-life of approximately 100 days. During the 56-day anaerobic incubation test, a total of 2.25% of the radioactivity had been volatilized, and 10.5% was remaining in the soil in an unextractable form. The degradates OME and M1 each accounted for less than 1% of the applied radiolabeled parent ethoprop.

Ethoprop is considered to be mobile in soil. The Freundlich $K_d$ values determined from a batch equilibrium study were found to be moderately low, suggesting a limited potential for sorption to soil. The reported ethoprop $K_d$ values increase with an increase in the amount of organic carbon in the soils. Mobility information on M1 indicates that it also is highly mobile; however, the mobility of the other degradates (OME, SME, and S,S-dipropylphosphorodithioate [M2]) is not known; however, the similarities in structure of these compared with parent ethoprop and M1 suggest that these other three degradates will all have similar, moderately low soil sorption values.

An aerobic aquatic metabolism laboratory study was conducted with sediment/water systems. The reported data indicated a half-life value 75 days in the sand sediment/water system, and a half-life of 90 days in the silt loam sediment/water system. Nonextractable residue amounts were reported, and in addition, specific degradates were analyzed. Of the degradates, M1 was identified as the degradate reported to be present at the greatest concentration, but it was never reported at greater than about 1% at any of the time intervals of analysis.

In a laboratory volatility study, the resulting volatiles comprised only a small amount of the applied dose, with parent ethoprop being about one-quarter to one-half of the volatile components on day 7, the last day of sampling. The vapor pressure of ethoprop is considered to be somewhat moderate ($3.5 \times 10^{-4}$ mm Hg), and it has a Henry's Law Constant which is moderately low ($1.5 \times 10^{-7}$ atm $m^3$/mol), suggesting that ethoprop would not be expected to volatilize from water to any great extent.

## 2. Ecological Risk Assessment Analysis

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of ethoprop products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as the median lethal dose ($LD_{50}$) or the median lethal concentration ($LC_{50}$). These RQ values are then compared to the Agency's levels of concern (LOCs), which provide an indication of the relative risk that the particular pesticide and/or use may pose for nontarget organisms. LOCs address the following risk presumption categories: (1) acute high: the potential for acute risk is high and regulatory action may be warranted, in addition to restricted use classification; (2) acute restricted use: the potential for acute risk is high, but may be mitigated through restricted use classification; (3) acute endangered species: endangered species may be adversely affected; and (4) chronic risk: the potential for chronic risk is high and regulatory action may be warranted. Currently, the Agency does not perform assessments for acute or chronic risks to nontarget insects (except bees), or chronic risk to birds or mammals from granular formulations.

### a. Ecological Hazard Profile

The testing data for terrestrial animals showed that ethoprop is moderately to very highly toxic. Data for birds showed ethoprop to be moderately to very highly toxic, in both acute and subacute testing. The effects in avian reproduction testing included reductions in eggs laid, eggs set, viable and live embryos, and in live embryos at 3 weeks. The Agency has determined that these avian reproduction studies must be repeated, because these data are necessary to fulfill the test guideline. The results of acute studies on mammals indicated that ethoprop is highly toxic to rats from both acute oral and dermal routes of exposure. Ethoprop is also reported to be moderately toxic to honey bees.

The laboratory data for freshwater fish showed variable results which indicated that ethoprop is slightly to highly toxic in acute tests, with most data showing moderately toxic effects. Ethoprop also has a potential to affect freshwater fish in chronic tests, with significant effects on larval growth. For freshwater invertebrates, ethoprop is very highly toxic in acute tests, and it significantly reduced both growth and reproduction in chronic tests. For estuarine/marine fish, ethoprop is highly to very highly toxic in acute tests, and in chronic tests, ethoprop significantly affected growth as well as juvenile and embryo survival. In testing with estuarine/marine invertebrates, ethoprop is in general, moderately to very highly toxic in acute tests, and significantly reduced the numbers of offspring produced per female and significantly reduced the growth of male offspring in chronic tests, and in another chronic study, caused a reduction in survival.

### b. Risk to Birds and Mammals

In assessing the ecological risks, the Agency calculates risk quotient (RQ) values, and compares these values with the levels of concern (LOCs). For acute high risks, the Agency has concerns if the RQs to terrestrial species exceed 0.5; for acute risks that may be mitigated

through restricted use classification, the Agency has concerns if RQs exceed 0.2; for acute risks to endangered species, the Agency has concerns if the RQs exceed 0.1; and for chronic risks and chronic effects that may occur in endangered species, the Agency has concerns if the RQs exceed 1.0. Based on the results of the ecological risk assessments for terrestrial animals, the Agency has concerns regarding both the acute and chronic risks of ethoprop to both terrestrial birds and mammals. (See the *Environmental Fate and Effects Division RED Chapter for Ethoprop* [October 5, 1998] for details concerning the exposure methods and risk calculations.)

The ecological risk assessments for terrestrial animals assume that the nongranular (liquid) products are applied by broadcast applications, and that granular products are applied by either broadcast or banded or in furrow applications. For broadcast applications, the ethoprop is applied onto the soil surface, but not soil incorporated. For the risk assessments where there are banded or in furrow applications, the assessments assume that soil incorporation immediately after application results in 15% of the product remaining on the soil surface and is available to expose terrestrial species.

***Avian Risk***

For the liquid products, the acute high risk and chronic avian LOCs are exceeded for single broadcast applications. At the 1 lb ai/A application rate, the acute RQs range from 0.5 to 7.3, and the chronic RQs range from 2.0 to 32. At the remaining maximum registered application rate of 12 lb ai/A, the ranges are 5.4 to 87.3 for acute RQs, and 24 to 384 for the chronic RQs.

In addition, RQs for the liquid products have also been calculated for multiple broadcast applications (for use on both pineapples and golf course turf [note that golf course turf use has since been voluntarily cancelled]). At two applications at a rate of 6 lb ai/A, the acute and chronic avian risks are also exceeded, with the acute RQs ranging from 5 to 73 for the maximum EEC, and 2 to 35 for time-weighted average EECs. The respective chronic RQs ranged from 20 to 319 for maximum EECs, and 10 to 156 for time-weighted average EECs.

For granular products, the risk assessments for broadcast applications indicated that the acute risk avian LOC is exceeded, with RQs ranging from 0.2 to 27.8 at an application rate of 1.5 lb ai/A, and ranging from 1.5 to 222 at the registered maximum application rate of 12 lb ai/A. In addition, for banded/in-furrow applications at the maximum application rates of 2 lb ai/A to 12 lb ai/A, the acute RQs range from 1.1 to 3.0 for waterfowl, from 10.1 to 28.2 for upland gamebird, and from 161.6 to 452.7 for songbirds.

Ethoprop was reported to have been implicated in at least one bird kill, in which 9 adult Canada Geese died in Georgia. Ethoprop was detected in the gastrointestinal tracts of the geese, and the brain cholinesterase activity was inhibited in the three birds tested. (For additional details concerning this bird kill incident, see the August 30, 1999 addendum to the *Environmental Fate and Effects Division RED Chapter for Ethoprop* document.)

*Mammalian Risk*

For the liquid products, the acute high risk LOC is exceeded for single broadcast applications for all feed items other than seeds, at application rates equal to or above 3 lb ai/A, with acute RQs for other than seeds ranging from 0.50 to 1.10. The chronic LOC is exceeded for all feed items other than seeds at application rates equal to or above 1 lb ai/A, with chronic RQs for other than seeds ranging from 4.5 to 8.0. At an application rate of 3 lb ai/A, the chronic LOC is exceeded for all feed items, with chronic RQs ranging from 1.5 to 24.0.

For banded/in-furrow granular applications, the acute high risk mammalian LOC is exceeded at the registered maximum application rates for some of the crops assessed. At application rates from 2 lb ai/A to 12 lb ai/A, the acute RQs for the various crops and size classes of mammalian species assessed for the granular ethoprop products range from 0.4 to 77.4.

**c. Risk to Aquatic Species**

For aquatic species, the water concentration model is based on the crops and the respective maximum application rate on the labels. The aquatic LOCs that the Agency utilizes as risk thresholds are slightly different from the terrestrial LOCs listed above; for acute high risks, the Agency has concerns if the RQs to aquatic species exceed 0.5; for acute risks that may be mitigated through restricted use classification, the Agency has concerns if RQs exceed 0.1; for acute risks to endangered aquatic species, the Agency has concerns if the RQs exceed 0.05; and for chronic risks and chronic effects that may occur in aquatic endangered species, the Agency has concerns if the RQs exceed 1.0. Based on the ecological risk assessment which have been conducted for ethoprop and these levels of concern, the Agency has both acute and chronic ecological risk concerns regarding ethoprop exposures to both freshwater fish and invertebrates, as well as both marine/estuarine fish and invertebrates. The only use of ethoprop that does not result in risks of concern to aquatic species is the slit treatment to golf courses with RQ of 0.0; however, ethoprop use on golf courses has since been cancelled.

*Risk to Freshwater Fish*

The acute RQ values reported for freshwater fish range from 0.05 to 0.4; therefore, for some crops, the Agency has restricted use and endangered species risk concerns, but not acute high risk concerns. The chronic risk LOC is exceeded for most modeled crop uses, because the chronic RQs to freshwater fish range from 0.58 to 5.6.

The Agency also assessed fish kill incident reports for ethoprop. Six fish kills have been reported, of which three were attributed to the use of ethoprop on golf course turf. While the direct cause of the other three incidents are not determined, ethoprop use on tobacco and/or corn in the area may have been a contributing factor. Details concerning these seven fish kills are reported in the EFED environmental risk assessment (see *Environmental Fate and Effects Division RED Chapter for Ethoprop* [October 5, 1998, with addenda dated 10/18/98, 2/18/99, 8/30/99, and 4/24/00]).

*Risk to Freshwater Invertebrates*

The acute high risk LOC is exceeded for most crops, and the acute restricted use LOC is exceeded for all agricultural crops, with the acute RQ for freshwater invertebrates ranging from 0.34 to 3.1. The chronic LOC is exceeded for all agricultural uses, with chronic RQs for freshwater invertebrates ranging from 17.5 to 168.8.

*Risk to Estuarine and Marine Animals*

The Agency also has concerns for the risks of ethoprop to marine and estuarine fish and invertebrates. For all the uses, the acute high risk LOC and the chronic LOC are exceeded for estuarine/marine fish, with acute RQs for fish ranging from 2.4 to 21.4 and chronic RQs ranging from 2.4 to 21.7. Estuarine/marine invertebrates are more sensitive; thus, the acute RQs range from 2.3 to 21.1, and chronic RQs range from 38.9 to 375. Because the guideline is not fulfilled, an estuarine/marine fish life-cycle test is required for ethoprop.

*Risks to Other Organisms*

Because ethoprop is moderately toxic to honeybees, precautions with respect to spray drift to flowering plants should be followed. The ecological risk assessment did not indicate any apparent risks to aquatic plants that are associated with the current uses and rates of ethoprop.

The risk assessments for aquatic vertebrates assume that amphibians exhibit similar toxicity profiles to the toxicity data which are available for fish. In addition, the risk assessments also make the assumption that avian and reptilian toxicity are similar.

**d. Risks to Endangered Species**

Endangered species LOCs for ethoprop are exceeded for birds, mammals, and both freshwater fish and invertebrates and estuarine fish. However, there are no estuarine invertebrates which are Federally listed as endangered species. While moderately toxic to insects, as indicated by the honeybee toxicity data, Federally listed insects are not likely to be exposed from the remaining uses of ethoprop, based on the risk mitigation measures to be implemented as part of the ethoprop IRED.

The U.S. Fish and Wildlife Service (FWS) has assessed the potential impacts of ethoprop on endangered species. In 1983, under EPA's "Corn Cluster" consultation, risks to birds, mammals, fish, reptiles, and aquatic species were triggered as being in jeopardy. Also in 1983, ethoprop was evaluated under the "Soybean Cluster" consultation, and triggered risks to birds, fish, and aquatic invertebrates (note that soybeans have subsequently been dropped from ethoprop labels). In a case-by-case consultation in 1987 for grapes and brussels sprouts, similar concerns for individual endangered species were listed (note that grapes and brussels sprouts have also subsequently been dropped from ethoprop labels). In a "reinitiation" of the assessment for all crops in 1989, the FWS found jeopardy to endangered birds and seven fish species, and provided several Reasonable and Prudent Alternatives to remove the jeopardy determination. In addition, the FWS had Reasonable and Prudent Measures (RPMs) to reduce incidental take of 24

fish species, 25 mussel species, two aquatic crustaceans species, and one bird specie. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures, and an older approach to consultation which is currently being revised through interagency collaboration. Because the Agency's current assessment of ecological risks uses both more refined methods to define ecological risks of pesticides and new data, such as that for spray drift, the RPMs in the Biological Opinion(s) may need to be reassessed and modified based on these new approaches. (See the August 30, 1999 addendum to the *Environmental Fate and Effects Division RED Chapter for Ethoprop* document for additional details concerning each of the respective endangered species identified in the various consultations with FWS.)

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of ethoprop use to Federally listed threatened and endangered species. At that time, the Agency will also consider any regulatory changes implemented as a result of the ethoprop IRED. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets (described in Section IV of this IRED document) which address ethoprop, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to ethoprop at levels of concern.

## IV. Interim Reregistration Eligibility and Risk Management Decisions

### A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing an 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 ethoprop active ingredients.

The Agency has completed its assessment of the dietary, occupational (except for the EC formulation), non-occupational, and ecological risks associated with use of ethoprop. Because there are no residential uses, a residential risk assessment was not conducted, but a non-occupational risk assessment was conducted for golfers, who may be exposed following golf course applications. Note also that the ethoprop-specific dietary risk assessment has not considered the cumulative effects of OPs as a class. Based on a review of available data and public comments on the Agency's assessments for the active ingredient ethoprop, the Agency has sufficient information on the human health and ecological effects of ethoprop to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that ethoprop is eligible for reregistration, except for the EC formulation, provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risks considered for the OPs support a final reregistration eligibility decision (RED). The Agency is not making a reregistration eligibility decision of the emulsifiable concentrate formulation at this time. Certain conditions stipulated in this IRED document need to be fulfilled in order for the Agency to make a reregistration eligibility decision for this formulation. Label changes are described in Section V. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of ethoprop, and lists the submitted studies that the Agency has found acceptable.

Although the Agency has not yet considered cumulative risks for the OPs, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of ethoprop. Based on its current evaluation of ethoprop alone, the Agency has determined that ethoprop products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Thus, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of ethoprop.

When the cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For ethoprop, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. But, because this is an IRED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for ethoprop after considering the cumulative risks of the OP class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each OP in turn and

identifying appropriate risk reduction measures, the Agency is addressing the risks from the OPs in as timely a manner as possible.

Because the Agency has not yet finalized its consideration of the cumulative risks for the OPs, this IRED does not fully satisfy the reassessment of the existing ethoprop food residue tolerances as called for by FQPA. When the Agency has completed its consideration of the cumulative risks for the OPs, ethoprop tolerances will be reassessed in that light. At that time, the Agency will consider ethoprop, along with the other OP pesticides, to complete the FQPA requirements and make a final reregistration eligibility decision. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical ethoprop, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the RED, that any of the determinations described in this IRED are no longer appropriate, the Agency will pursue appropriate action, including reconsideration of any portion of this IRED.

**B. Summary of Phase 5 Comments and Responses**

When making its interim reregistration decision, the Agency took into account all the comments received during Phase 5 of the OP Public Participation Process. These comments and the Agency's Response to Comments document are available in the Public Docket and/or the Internet (www.epa.gov/pesticides/op).

A total of nineteen comment letters were received during Phase 5. Fourteen of these letters were received from individual growers or groups, with each of these supporting continued use of ethoprop. However, another letter was received from an individual in the Department of Fisheries and Wildlife at Michigan State University expressing concern regarding ethoprop, requesting its withdrawal from all agricultural uses and also that a substitute be found for turf use, due to its health threat to fish and wildlife populations.

Comments were also received from the Pineapple Growers Association of Hawaii, the International Banana Association, and two letters from the National Potato Council concerning uses, application rates and frequencies, and agricultural practices. The Agency has evaluated the information provided by the commenters, and has found it useful in understanding the use of ethoprop. The Agency has considered the views expressed and has taken the information into account when making the IRED concerning ethoprop use.

## C. Regulatory Position

### 1. FQPA Findings

#### a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, the Agency assessed the risks associated with the organophosphate ethoprop. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the OPs through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of OPs once the methodology is developed and the policy concerning cumulative assessments is resolved.

The Agency has determined that the dietary risk from exposure to ethoprop is within its own "risk cup." In other words, if ethoprop did not share a common mechanism of toxicity with other chemicals, the Agency would be able to conclude today that the food tolerances for ethoprop meet the FQPA safety standards. In reaching this determination concerning the FQPA safety standards, the Agency has considered the available information on the special sensitivity of infants and children, as well as both the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water. Based on the results of this aggregate assessment, the Agency has determined that the human health risks from these combined exposures are considered to be within acceptable levels. While the combined risks from all exposures to ethoprop "fill" the aggregate risk cup, the water exposures are based on modeling estimates and the food exposures reflect hypothetical residues below the level of detection of the analytical methodology. The Agency has determined these modeling estimates overestimate the actual drinking water and food exposures, and the Agency, therefore, has made a regulatory determination that ethoprop does "fit" within the dietary risk cup. Except for those tolerances that are to be revoked, the current ethoprop tolerances will remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphate pesticides is considered.

#### b. Tolerance Summary

Tolerances for residues of ethoprop in/on plant raw agricultural commodities are to continue to be expressed in terms of parent ethoprop alone (*O*-ethyl-*S,S*-dipropylphosphorodithioate) [40 CFR §180.262 (a) and (b)]. As detailed in Table 2, the residues of toxicological concern for primary and rotational crops include parent ethoprop and Metabolites II, III, and IV (respectively, SME, OME, and M1). However, the studies which have been submitted to date concerning the data to satisfy the magnitude of the residue guidelines have contained only residue data for the parent ethoprop and Metabolite IV (M1). Also, the studies accepted by the Final Registration Standard and Tolerance Reassessment (FRSTR; issued in 1987) reported data only on parent ethoprop. Because of these limitations, the dietary exposure assessment conducted to support the ethoprop IRED used the available data on ethoprop and Metabolite IV, and included conservative assumptions regarding the levels of

Metabolites II and III from metabolism study data. (For further details, see Section III.A.1.d of this IRED document, or the 1999 *Ethoprop Revised Human Health Risk Assessment, Executive Summary*, as well as its *Attachment 4: Response to the USDA Comments to EPA's Monte Carlo Dietary Exposure Estimate for Ethoprop and Using Further Refinements.*)

While the current tolerance levels of ethoprop are expressed in terms of parent ethoprop alone, the Agency concludes that the tolerance expression should include all ethoprop residues of toxicological concern. Therefore, to support the reregistration of ethoprop uses, the registrant must:

- Conduct residue field trials on snap beans, cabbage, and potatoes, and submit for each crop, two field trials in representative geographic locations.
- Determine residues of parent ethoprop and metabolites II, III and IV, and must submit residue analytical methods along with the field trial data.
- Provide supporting storage stability data.

After the data have been submitted and reviewed by the Agency, the decision to include metabolites II, III and IV in the risk assessment and tolerance expression may be revisited. Also, additional field trial data may be required to support the remaining registered uses.

Note that the term "reassessed tolerances," as used in this section of the IRED, is not meant to imply that the tolerances have been reassessed as required by FQPA. These tolerances may only be reassessed once the cumulative risk of all of the OPs is considered, as required by FQPA. Rather, this ethoprop IRED provides "reassessed" tolerance levels for various commodities, as supported by submitted residue data, only for the single OP chemical ethoprop, and EPA will finalize these tolerances after considering the required cumulative risks for all the OPs.

***Tolerances Listed Under 40 CFR §180.262 (a)***

Sufficient data are available to determine the adequacy of the established tolerances on the following commodities: bananas, beans (lima and snap), cabbage, corn (fodder, forage, fresh, and grain), cucumbers, pineapples, potatoes, sugarcane, and sweet potatoes. Specifically, reassessed/redefined tolerances for ethoprop residues in supported crops/commodities are assessed at the limit of quantitation (LOQ) for the parent, 0.02 ppm, with the exception of snap beans, for which the tolerance is 0.2 ppm, based on detectable residues in submitted field trials (Table 12).

For corn, the Agency had identified additional field trial data requirements to account for residues from post-plant uses (until layby). The registrant has agreed to delete post-plant use of ethoprop on corn (until layby). Provided the labels are amended to delete the post-plant use of ethoprop on corn (until layby), the tolerances can be reassessed for fresh corn, corn grain, corn forage, and corn fodder. The registrant has also requested cancellation of all ethoprop uses on peanuts; therefore, the tolerances for peanuts and peanut, hay are to be revoked.

Because there are no longer any registered uses on mushrooms or soybeans, the tolerances for residues in/on mushrooms and soybean commodities have recently been revoked, and these tolerances are not listed in Table 12. In addition, the tolerances for residues in/on lima and snap bean forage, pineapple fodder and forage, and sugarcane fodder and forage are also to be revoked, because the Agency no longer considers these commodities to be significant livestock feed items.

In addition, the "(N)" designation for negligible residues, as listed in the current 40 CFR §180.262 (a) entries, is now being deleted from all those entries. The ethoprop tolerance summary and recommended modifications in commodity definitions are presented in Table 12.

***Tolerances Listed Under 40 CFR §180.262 (b)***

The current tolerance of 0.02 ppm for parent ethoprop had been established for regional registration on the commodity okra. Because there are currently no registered uses for ethoprop on okra, the tolerance for ethoprop residue in/on okra is to be revoked. (Note that the FRSTR (1988) had reported then that the okra tolerance was "to be rescinded.")

***Residue Analytical Methods***

The Pesticide Analytical Manual (PAM), Vol. II, lists Method I for ethoprop, which has undergone a successful EPA method validation. This is a gas-liquid chromatography/sulfur microcoulometric detection method, which involves solvent extraction and then clean-up by sweep co-distillation. PAM, Vol. II, also lists Method A, which uses the same principles as Method I, but employs different parameters for extraction and gas chromatography. The limit of quantitation (LOQ) for ethoprop in or on plant commodities is 0.01 ppm in each method.

A new gas chromatography/flame phosphorus detector (GC/FPD) method has been proposed as an enforcement method for determining residues of ethoprop and Metabolite IV in plant commodities. The Agency determined that in some other methods evaluated, Metabolite IV can be converted to Metabolite III by methylation. This GC/FPD method has been validated by an independent laboratory, with LOQs of 0.01 ppm for each analyte in plant commodities; however, the registrant has not yet submitted this method to the Agency for validation.

However, the Agency has determined that there are additional metabolites of toxicological concern, other than Metabolite IV and the parent. Therefore, the registrant shall develop, evaluate, and validate a new method which determines parent ethoprop and Metabolite IV, as well as SME and OME (Metabolite II and III, respectively). The registrant must also submit this analytical method of enforcement for Agency method validation. In addition, the Agency is also specifying that the registrant must conduct concurrent storage stability studies in conjunction with the new field trial studies, because the existing data have demonstrated stability problems of Metabolite IV during frozen storage.

**Table 12. Tolerance Summary for Ethoprop**

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment [1] (ppm) | Comment/ *Corrected Commodity Definition* |
|---|---|---|---|
| **Tolerances listed under 40 CFR §180.262 (a)** | | | |
| **Bananas** | 0.02 (N) [2] | 0.02 | *Banana* |
| **Beans, lima** | 0.02 (N) | 0.02 | *Bean, lima* |
| **Beans, lima, forage** | 0.02 (N) | Revoke [4] | No longer a regulated feed item. |
| **Beans, snap** | 0.02 (N) | 0.2[3] | *Bean, snap, succulent* |
| **Beans, snap, forage** | 0.02 (N) | Revoke [4] | No longer a regulated feed item. |
| **Cabbage** | 0.02 (N) | 0.02 | |
| **Corn, fodder** | 0.02 (N) | 0.02 | *Corn, sweet, stover* [5] |
| | | 0.02 | *Corn, field, stover* [5] |
| **Corn, forage** | 0.02 (N) | 0.02 | *Corn, sweet, forage* [5] |
| | | 0.02 | *Corn, field, forage* [5] |
| **Corn, fresh (inc. sweet) (K+CWHR)** | 0.02 (N) | 0.02 | *Corn, sweet, kernel plus cob with husks removed* |
| **Corn, grain** | 0.02 (N) | 0.02 | *Corn, field, grain* |
| **Cucumbers** | 0.02 (N) | 0.02 | *Cucumber* |
| **Peanuts** | 0.02 (N) | Revoke | Will no longer be registered for this use in the United States. *Peanut* |
| **Peanut, hay** | 0.02 (N) | Revoke | Will no longer be registered for this use in the United States. |
| **Pineapples** | 0.02 (N) | 0.02 | *Pineapple* |
| **Pineapples, fodder** | 0.02 (N) | Revoke [4] | No longer regulated feed items. |
| **Pineapples, forage** | 0.02 (N) | Revoke [4] | No longer regulated feed items. |
| **Potatoes** | 0.02 (N) | 0.02 | *Potato* |
| **Sugarcane** | 0.02 (N) | 0.02 | *Sugarcane, cane* |
| **Sugarcane, fodder** | 0.02 (N) | Revoke [4] | No longer regulated feed items. |
| **Sugarcane, forage** | 0.02 (N) | Revoke [4] | No longer regulated feed items. |
| **Sweet potatoes** | 0.02 (N) | 0.02 | Data can be translated from potatoes. *Sweet potato* |

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment [1] (ppm) | Comment/ *Corrected Commodity Definition* |
|---|---|---|---|
| **Tolerance with Regional Registration listed under 40 CFR §180.262 (b)** | | | |
| **Okra** | 0.02 | Revoke | No registered uses on okra. |

[1] The term "reassessed" is not meant to imply that the tolerance has been reassessed as required by FQPA. These tolerances may only be reassessed once the cumulative risk of all of the OPs is considered, as required by FQPA. Rather, the tolerance levels for the various commodities, as supported by submitted residue data, are for ethoprop only, as if no cumulative assessment were required.
[2] The "(N)" designation represents "negligible residues," as listed in current 40 CFR § 180.262 entries. A Final Rule was published in the Federal Register (66 FR 38950-38955, July 26, 2001), effective October 24, 2001, removing this designation from all entries.
[3] The reassessment by raising certain tolerances for ethoprop from their current values will be deferred, pending the outcome of the consideration of the cumulative risks for all organophosphate pesticides.
[4] A Final Rule was published in the Federal Register (66 FR 38950-38955, July 26, 2001), effective October 24, 2001, revoking the tolerance for these commodities, because these commodities are no longer considered significant animal feed items and therefore no longer need tolerances.
[5] These commodities do not represent "new commodities," but instead are the addition of corrected commodity definitions where more than one commodity had previously been included within the single current commodity.

### *Codex Harmonization*

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for "ethoprophos" (the name by which the active ingredient is known in Europe, and which has been adopted by the Codex Alimentarius Commission) for residues in/on various plant commodities (see the *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Currently, the Codex MRL residue definition for "ethoprophos" includes only parent ethoprop, and does not include any of its metabolites, and is compatible with "reassessed" U.S. tolerances. However, pending the outcome of required field trial and other supporting data, if the U.S. tolerance definition for ethoprop is modified to include Metabolites II, III, and/or IV, the Codex MRLs and U.S. tolerances will no longer be compatible. A comparison of the Codex MRLs and the corresponding U.S. "reassessed" tolerances is presented in Table 13.

**Table 13. Codex Maximum Residue Limits for "Ethoprophos" and Current U.S. Tolerances**

| Codex | | | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments |
|---|---|---|---|---|
| Commodity (As Defined) | MRL (mg/kg) | Step | | |
| **Banana** | 0.02 (*)[1] | CXL [2] | 0.02 | |
| **Beetroot** | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| **Cabbages, Head** | 0.02 (*) | CXL | 0.02 | |
| **Cucumber** | 0.02 (*) | CXL | 0.02 | The tolerance for cucumber includes gherkins in the U.S. |
| **Gherkin** | 0.02 (*) | CXL | | |
| **Grapes** | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| **Lettuce, Head** | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| **Maize** | 0.02 (*) | CXL | 0.02 | (These commodities are listed under the definition for "corn" in the U.S.) |

| Codex | | | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments |
|---|---|---|---|---|
| Commodity (As Defined) | MRL (mg/kg) | Step | | |
| Maize fodder | 0.02 (*) | CXL | | |
| Maize forage | 0.02 (*) | CXL | | |
| Melons, except watermelon | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Onion, Bulb | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Peanut | 0.02 (*) | CXL | Revoke | Will no longer be registered for this use in the U.S. |
| Peanut fodder | 0.02 (*) | CXL | Revoke | Will no longer be registered for this use in the U.S. |
| Peas | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Peppers | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Pineapple | 0.02 (*) | CXL | 0.02 | |
| Pineapple fodder | 0.02 (*) | CXL | Revoke | No longer regulated as feed items in the U.S.; tolerances to be revoked. |
| Pineapple forage | 0.02 (*) | CXL | Revoke | |
| Potato | 0.02 (*) | CXL | 0.02 | |
| Soya bean fodder | 0.02 (*) | CXL | None | No longer registered for this use in the U.S.; tolerances have been revoked. |
| Soya bean (dry) | 0.02 (*) | CXL | None | |
| Strawberry | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Sugar cane | 0.02 (*) | CXL | 0.02 | |
| Sugar cane fodder | 0.02 (*) | CXL | Revoke | No longer regulated as feed items in the U.S.; tolerances to be revoked. |
| Sugar cane forage | 0.02 (*) | CXL | Revoke | |
| Sweet potato | 0.02 (*) | CXL | 0.02 | |
| Tomato | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |
| Turnip, Garden | 0.02 (*) | CXL | None | Not registered for this use in the U.S. |

[1] The asterisk (*) signifies that the MRL was established at or about the limit of detection.
[2] "CXL" indicates that the Codex Alimentarius Commission accepted this as the final MRL for this commodity.

## 2. Endocrine Disruptor Effects

The Agency 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 the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), the Agency determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. The Agency also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency 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 Agency's EDSP have been developed, ethoprop may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

## D. Regulatory Rationale

The following is a summary of the rationale for managing the risks associated with the current uses of ethoprop in support of the IRED. Where labeling revisions are warranted, specific language is set forth in Table 14 of Section V of this document.

### 1. Human Health Risk Mitigation

#### a. Dietary Mitigation

##### i) Acute Dietary (Food)

Based on a Tier III dietary analysis, the acute dietary (food) risk estimates for the most highly exposed subpopulation (all infants less than 1 year old) is 75% of the aPAD (Table 4). Therefore, the acute dietary (food) risk estimates are not of concern to the Agency, and no mitigation measures are necessary.

##### ii) Chronic (Non-Cancer) Dietary (Food)

The chronic (non-cancer) dietary (food) risk estimate is 1.2% of the cPAD for the most highly exposed subpopulation (children 1-6 years old) (Table 4). Therefore, chronic (non-cancer) dietary (food) risks are not of concern to the Agency, and no mitigation measures are necessary.

##### iii) Cancer Dietary (Food)

The Agency uses a cancer risk of $1 \times 10^{-6}$ (1 person in 1 million) as the level having negligible cancer risk. For ethoprop, the estimated carcinogenic dietary (food) risk for the general U.S. population is $1.1 \times 10^{-8}$. Therefore, no mitigation measures are necessary to address the dietary risk for cancer from food.

##### iv) Drinking Water

The lowest acute, chronic (non-cancer), and cancer drinking water levels of comparison (DWLOCs) for ethoprop are 0.6 ppb, 1.0 ppb, and 1.0 ppb, respectively. The modeled drinking water estimated concentrations (DWECs) exceed the acute, chronic non-cancer, and cancer DWLOCs for both surface water and ground water drinking water sources (Tables 5, 6, and 7).

The drinking water assessments for both surface and ground water sources are based on screening-level model estimates designed to provide high-end estimates of potential pesticide exposure. Some monitoring data are available, and the results are substantially lower than the modeling estimates. However, EPA cannot determine how accurately these monitoring data reflect actual exposure owing to concerns regarding the manner in which the data were collected. In addition, both the dietary (food) risk analysis and surface water model estimates may be overestimates of dietary risks. Therefore, the Agency has required both surface and ground water monitoring studies which are expected to demonstrate that actual measured drinking water concentrations are less than the DWLOCs. However, if the results of the monitoring data should indicate that there are drinking water exceedances of concern, the technical registrant has agreed in a September 28, 2001 letter to the Agency to drop uses from the labels until risk concerns are fully addressed. Further details describing the Agency's risk management approach to modeled aggregate dietary risk concerns are provided below.

As discussed in the dietary (food) exposure section of this IRED, the dietary (food) risk assessment is based on commodities where there were no detects (below the level of detection [LOD]) for all crops from field trials, except for lima beans, snap beans, and peanuts. It is not unexpected that nearly all crops had residues which were less than the LOD, because for most crops, ethoprop is applied pre-plant or at-plant, and is soil incorporated. Consistent with Agency policy, for those commodities where there were no detects of ethoprop residues, the dietary (food) risks were assessed assuming that residues are present at ½ LOD. These assumptions resulted in 75% of the aPAD being consumed by food only (Table 4). Moreover, since the time of this assessment, the registrant has agreed to cancel the use of ethoprop on peanuts, drop post-plant treatment to corn, and reduce the maximum application rate for some crops, measures which would further reduce the potential for ethoprop residues being available in treated commodities. Because of these conservative assumptions and subsequent changes in the use of the pesticide, the dietary (food) assessment may be an overestimate of dietary risk.

The endpoint of red-blood cell ChE inhibition is often at a higher dose than plasma ChE inhibition in the same study. In the case of ethoprop, had red-blood cell ChE inhibition been selected as the dietary endpoint, this would result in an increase in the NOAEL and PADs used to assess dietary (food) risk. Moreover, the endpoint and dose selected to assess dietary risk for ethoprop were based on toxicity studies in dogs (Table 3). However, a range-finding study for the acute neurotoxicity study in the rat indicates a NOAEL of 0.7 mg/kg/day, based on red-blood cell ChE inhibition at the low dose of 2 mg/kg/day. For acute dietary exposure, this NOAEL from the rat study is 28-times greater than the NOAEL from the dog study, which was based on plasma ChE inhibition. Because of the observed differential sensitivity between the dog and the rat, it may be more appropriate to select the dose from the rat study as being more representative of human dose-response to assess dietary risk. Thus, the current endpoint and dose selected from the dog study may overestimate the dietary (food) contribution to ethoprop aggregate risk.

The dietary risk assessment is also based on the assumption that an individual would consume both the high-end estimate of ethoprop concentrations in drinking water on the same day as consuming the predicted maximum level of ethoprop residues in treated food. While these assumptions and methods are necessary to protect against multiple combinations of conditions and scenarios, they are inherently conservative.

Accordingly, the dietary (food) risk assessment is likely an overestimate of the contribution of ethoprop residues on food. Such an overestimate would provide for more room in the "risk cup" for the dietary contribution from drinking water sources, and increase the associated DWLOCs for this aggregate analysis.

***Surface Water***

Surface water DWECs were derived from the PRZM-EXAMS model with the Standard Index Reservoir and percent cropped area (PCA) factor, and are screening level estimates designed to provide high-end estimates of potential pesticide exposure. Model predictions provide a screen to eliminate those chemicals that are not likely to cause concerns in drinking water. Exceedances in drinking water risk assessments using the screening model estimates do not necessarily mean a risk of concern actually exists, but indicate the need for better data (e.g., monitoring studies specific to use patterns and drinking water sources) on which to make a finding.

As stated above, the screening-level models to assess drinking water exposure are designed to provide high-end estimates. For instance, except for ethoprop use on corn, which resulted in the lowest acute DWEC (15 ppb), all surface water model scenarios include the default PCA value of 87%. This factor translates to 87% of the modeled drainage basin is planted with crops which are treated with ethoprop. This default value may be an overestimate for the remaining modeled areas. Louisiana (sweet potatoes and sugar cane) and North Carolina (tobacco) are areas which are highly mixed agricultural regions where other crops, such as corn, beans, cucumbers, and cabbage are also grown, but these other crops are very minor in terms of ethoprop usage, according the QUA (Table 1). In addition, the QUA indicates that the percent crop treated estimates for most of these crops are low, but the PRZM-EXAMS Standard Index Reservoir assumes that 100% of the crops (of the 87% PCA) are treated with ethoprop. Moreover, the Agency model utilizes a 172 hectare (430 acres) watershed, and it is likely that the Louisiana and North Carolina watersheds may be planted to other crops which are not listed on ethoprop labels.

The model also employed other methods to provide high-end results. To estimate the 1-in-10 year peak (acute) concentration of a pesticide in surface water, a rainfall value is generated as an input parameter to the model. This value is extrapolated between the 3$^{rd}$ and 4$^{th}$ highest annual rainfall from 36 years of daily water concentrations (where available) for the modeled region, and may represent between the 90$^{th}$ and the 99.9th percentile value.

The Agency also usually utilizes the maximum application rates in surface water modeling. However, the registrant has submitted data to the Agency concerning typical application rates for selected crops, which are generally lower than the maximum label rate. For example, the crop which had the highest acute DWEC (127 ppb) for surface water was sweet potatoes based on an application rate of 6 lb ai/A. The registrant has submitted or referenced data sources which indicate that growers of sweet potatoes typically apply ethoprop at rates of about 3.0 lb ai/A. In addition, the registrant has agreed to reduce the maximum label rate on tobacco from 12 lb ai/A to 6 lb ai/A. Utilizing these typical values in the surface water model estimates would reduce the estimated peak (acute) DWECs for ethoprop use on sweet potatoes in

Louisiana and tobacco in North Carolina by 2x. Similarly, the estimated chronic and cancer DWECs may also be comparatively lower, when applying these same PCA and typical application rate assumptions.

In addition, some regions of the country where there is high use of ethoprop and/or those modeled as representative use areas may not have conditions that lend to high concentrations of ethoprop in drinking water from surface water sources. For example, two of the higher modeled ethoprop concentrations in surface water were from its use on sweet potatoes and sugarcane in Louisiana. However, the Agency has other information which indicates that not very many community drinking water systems in Louisiana utilize reservoirs. Also, usage information indicates that a large portion of the total amount of ethoprop used is applied to potatoes growing areas of the Pacific Northwest that are low in rainfall and are often irrigated. This use practice in such areas would significantly reduce the potential of runoff of ethoprop residues to nearby surface water bodies that may feed to community drinking water reservoirs. The practice of incorporating the pesticide immediately after application, which is currently stipulated on the product labels, would also further reduce runoff potential for ethoprop.

Furthermore, the registrant has submitted preliminary information indicating that ethoprop and its various degradation products may be degraded by treatment with chlorine. Thus, if any ethoprop or its environmental degradates should reach a drinking water treatment system that employs chlorination as a disinfection procedure, it is likely that the concentrations of ethoprop and the degradates could be reduced. Not all the United States drinking water systems utilize chlorine disinfection, so the Agency has not factored chlorination degradation of ethoprop or its degradates into the models for DWECs. Although the Agency recognizes that chlorination degradation might result in lower DWECs, the Agency does not rely on information concerning water treatment systems to mitigate concerns for drinking water.

There are also limited monitoring data available for conducting an assessment of the drinking water concentrations of ethoprop. Although the levels of ethoprop found in the various monitoring studies suggest that ethoprop may be much lower than the screening level model estimates, the reported samples were not correlated with use patterns, were collected randomly throughout the year, and were of insufficient numbers to make definitive statements as to the extent of concentrations of ethoprop in surface waters. Additionally, information on the site characteristics within the monitored basins would be necessary to understand the relative vulnerability of the recipient surface waters. However, while the information from the surface water monitoring databases are limited in assessing drinking water risks, these data sources provide some insight that the modeling estimates may be higher than actual concentrations measured in a directed monitoring program.

Risk Mitigation

Earlier drinking water model estimates (based on PRZM-EXAMS without the Standard Index Reservoir) that were included in the preliminary human health risk assessment, resulted in concentrations of ethoprop in drinking water as high as 650 ppb from broadcast applications to golf turf. At that time, the registrant voluntarily canceled ethoprop use on golf courses; therefore,

refined drinking water assessment for golf course use was not conducted and is not included in the revised human health risk assessment.

Because modeling was employed to develop DWEC values to assess drinking water risks for ethoprop, the Agency has some level of uncertainty of whether actual concentrations of ethoprop in surface water sources of drinking water would be as high as the model predictions discussed above. For many chemicals, where there are uncertainties in the modeling estimates, the Agency relies on actual monitoring data to confirm resultant expectations. Thus, for ethoprop, since the DWECs exhibit exceedances from the DWLOCs, these exceedances have triggered the need for monitoring data to evaluate actual human exposure concentrations in the drinking water in various locations.

To address these risk concerns and uncertainties, the registrant has committed to conduct a 3-year sampling program involving community water systems from surface water sources in five locations in different states to represent different use sites, crops, soil types, and rainfall regimes. Raw (at the drinking water intake) water samples will be analyzed to determine the concentrations of parent ethoprop and each of the four environmental degradates/metabolites of toxicological concern (Table 2). The states and associated community water systems currently selected for surface water monitoring include: North Carolina (Wilson system); Oregon (Willamette River Basin [Jefferson system] and Columbia River Basin [Ontario system]); California (Lodi system); and Louisiana (Berwick system).

The surface water monitoring program is projected to begin early in 2002, in conjunction with the usage of ethoprop on the various crops treated in the respective areas selected for monitoring. The registrant is to submit quarterly reports for the surface water monitoring program to the Agency to provide interim results of the study.

The surface water sampling program is considered as confirmatory data, because the Agency expects the actual measured surface water concentrations to be less than the DWLOCs. However, if the results of the monitoring data should indicate that there are drinking water exceedances of concern, the technical registrant has agreed to drop uses from its technical and product labels until risk concerns are fully addressed.

***Ground Water***

As with surface water sources, screening-level modeling was employed to develop DWEC values to assess drinking water risks from ethoprop contamination of ground water sources. Similarly, while the levels of ethoprop found in the various monitoring studies suggest that ethoprop may be much lower than the screening-level model estimates, the information is too limited to make definitive statements as to extent of contamination of drinking water from ground water sources.

For similar reasons discussed above for the surface water assessment, the Agency has some level of uncertainty of whether actual concentrations of ethoprop in ground water sources of drinking water would be as high as the model predictions. Such factors include the following: overestimation of dietary (food) exposure; maximum application rate used in the model; major

use areas may not be vulnerable to ground water contamination; potential reduction of residues from chlorination; and lack of measurements of high ethoprop concentrations from limited ground water sampling programs.

Risk Mitigation

To confirm these expectations and refine the risks associated with exposures to drinking water from ground water sources, the Agency is requiring ground water monitoring data to determine actual ethoprop concentrations available in drinking water. To satisfy the ground water monitoring requirements, the registrant may conduct any of the following three ground water monitoring programs:

1. A three-year prospective ground water (PGW) program consisting of studies in three different regions and soil types around the country to represent the full use pattern of ethoprop.

2. A three-year retrospective monitoring program of multiple fields with observation wells installed down gradient from previously treated fields.

3. A sample program of existing private and Community Water System (CWS) wells in high use ethoprop regions with vulnerable soil conditions.

Irrespective of the option chosen, the registrant must:

A. Locate wells in hydrologic group A soils.

B. Monitor near areas where ethoprop is used, and document current and historical ethoprop use.

C. Establish a direct hydraulic connection between the pesticide application area and the aquifer volume which provides water to monitoring wells. If a connection can not be established, the results of monitoring concentration in the wells will be ambiguous.

D. Provide the characteristics of the existing wells (e.g., screened interval, well diameter, depth to groundwater).

E. Submit a monitoring protocol for approval. If using option 2 or 3, the registrant must discuss the statistical significance of the sampled wells in relation to the population consuming ground water within the entire ethoprop use area.

F. The registrant must determine the concentrations of parent ethoprop and the four metabolites/residues of toxicological concern, specifically SME, OME, M1, and M2. The registrant must also submit quarterly reports to the Agency to document the ground water analyses conducted.

The ground water sampling program is considered as confirmatory data, because the Agency expects the actual measured ground water concentrations to be less than the DWLOCs. However, if the results of the monitoring data should indicate that there are drinking water exceedances of concern, the technical registrant has agreed to drop uses from its technical and product labels until the risk concerns are fully addressed.

### b. Occupational Risk Mitigation

As described in PR Notice 2000-9, *Worker Risk Mitigation for Organophosphate Pesticides,* it is the Agency's policy to mitigate occupational risks to the greatest extent necessary and feasible with personal protective equipment and engineering controls. In managing risk, EPA must take into account the economic, social, and environmental costs and benefits of the pesticide's use. A wide range of factors are considered in making risk management decisions for worker risks. These factors include, in addition to the calculated MOEs, consideration of pesticide exposure, incident data, the nature and severity of adverse effects, uncertainties in the risk assessment, the cost, availability and relative risk of alternatives, and importance of the chemical in IPM programs.

Consistent with PR Notice 2000-9, EPA considers occupational cancer risks of $1 \times 10^{-6}$ (1 in 1 million) and less to be negligible. For risks between $1 \times 10^{-4}$ and $1 \times 10^{-6}$, the Agency generally examines occupational risks to determine whether or not the benefits of use outweigh the risks, and will seek ways to mitigate these 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 $1 \times 10^{-6}$ or less. The goal is to ensure that there is an adequate level of protection from exposure to pesticides for workers. Through the reregistration process and taking benefits into account, additive protective clothing or equipment, or changes in application methods may be necessary.

#### i) Agricultural Uses

The risk assessments for workers who are mixing, loading, and applying ethoprop indicate that the Agency has worker risk concerns for both the granular and liquid (EC and gel) formulation products (Tables 10 and 11). Additionally, for some scenarios, the Agency also has cancer risk concerns for the EC formulation, as well as to a lesser degree for the granular formulations. Therefore, there are specific mitigation measures and additional data needs which are necessary to address these risk concerns. The measures necessary to be implemented to address these risks of concern, and the supporting rationale for these decisions, are discussed below. A list of these specific measures is provided in Section 4.E (Labeling) and Table 14.

***Granular Formulations***

For the granular formulations, the primary risk concern (risk driver) is inhalation exposure, because the products are formulated with dusty clay-based material. The current worker risk assessments for the granular formulations are based on a product-specific worker

exposure study completed with the clay-based 10G product. To help mitigate these risks, the registrant has agreed for most granular products to substitute the clay with a cellulose-based material that has been found to release less dust than the clay-based products, such as Biodac®. The registrant has submitted data which demonstrates that cellulose is a less dusty material and will reduce the level of dust to which workers could be exposed during normal handler activities. Based on this and other information, and the Agency believes that the risks associated with the use of the granular formulation are below their respective targets and not of concern, and are requiring confirmatory data to support this conclusion. Furthermore, it is clear that ethoprop plays a significant role in controlling nemotodes and wireworms for various crops, and the Agency believes that the benefits offered by this compound outweigh the potential risks from its use. Further details describing the Agency's risk management approach to this risk concern is provided below.

Scenarios of Concern

All loading and applying worker scenarios with the granular formulation result in combined (dermal plus inhalation) risks which are of concern to the Agency. These scenarios include: 1a, 1b, 3a, 3b, 5a, 5b, 5c, and 10, for which engineering controls are feasible (Table 10); and 5d, 5e, 5f, and 6c, for which engineering controls are not feasible (Table 11).

Additionally, cancer risks for granular ethoprop formulations are also of concern to the Agency for the scenarios which are remaining (i.e., those scenarios which are not being voluntarily canceled by the registrant). The calculated cancer risks for all these remaining scenarios with the granular formulations (Tables 10 and 11) range from $1.1 \times 10^{-3}$ to $1.8 \times 10^{-7}$. Scenarios for the granular formulations having cancer risks greater than $1 \times 10^{-6}$ are 1a, 3a, 3b, 5a, 5b, 5f, 6c, and 10; those scenarios that have cancer risks greater than $1 \times 10^{-4}$ are 3a and 5f.

Because of occupational and other risk concerns, including the drinking water risks discussed earlier, the registrant has agreed to cancel ethoprop use on golf courses. Thus, risks from scenarios 5c, 5d, and 5e, which assess risk to workers loading and applying granular ethoprop products to treat golf course turf, and which also exhibited occupational and cancer risks of concern, do not need to be further mitigated nor addressed in this risk management section.

Risk Mitigation

To reduce occupational exposures and to mitigate some of these risk concerns, the registrant has agreed in a September 28, 2001 letter to the Agency to cancel the 10G registration and produce their 15G product solely with cellulose by December 31, 2001. The 15G product is a dusty, clay-based formulation. The cellulose-based inert ingredient has been found to release less dust than the clay-based formulation, and may substantially reduce the inhalation exposure to workers, the major risk driver for the current granular products. Based on a preliminary review of available data which indicate that inhalation exposures are about 90 times lower than for the clay-based formulation, the Agency has determined that the 15G product formulated with cellulose should not represent worker risks of concern to the Agency for scenarios 1b, 3b, 5a, and 5b. Further information leading to this conclusion is discussed below.

The 20G product will continue to be formulated as the clay-based formulation, because of reported technical difficulties in "loading" 20% active ingredient onto cellulose-based granules (i.e., due to the specific gravity and the density of the technical grade active ingredient, it is only possible to load about 17% of the active ingredient, by weight, onto cellulose-based granules). The 20G is described as an "oily" product, because of the increased amount of active ingredient present in the 20G formulation. Based on a preliminary review of the data submitted, the Agency has data which indicates that amount of dust released from this 20G formulation is much less than from the clay-based 10G and 15G products, and is similar to the amount of dust released from the 15G cellulose-based formulation. In addition, in an effort to reduce potential risks to other handlers of ethoprop granular products (scenarios 1b and 3b), the registrant has agreed to amend the 20G master label by deleting use on corn and potatoes, thus limiting the 20G to use on sugar cane only. To further protect handlers of the 20G product, the registrant has also agreed to package the product in a closed transfer system (i.e., Lock 'N Load) by December 31, 2001, as defined PR Notice 2000-9 and the Worker Protection Standard.

In addition, the current worker risk assessments were performed utilizing the same inhalation rate (29 L/min) for all workers. However, more refined North American Free Trade Agreement (NAFTA) breathing rates have recently become available, which the Agency intends on using in future risk assessments. Had the Agency utilized the NAFTA recommended values for the breathing rate, rather than the single rate in Series 875 Group A (i.e., previously known as Subdivision U), the worker risks would have been lower. Series 875 Group A recommends an inhalation rate of 29 L/min. The new NAFTA recommended inhalation rates are 8.3 L/min for sedentary activities (e.g., driving a tractor), 16.7 L/min for light activities (e.g., flaggers and mixer/loaders < 50 lb containers), and 26.7 L/min for moderate activities (e.g., loading > 50 lb containers, handheld equipment in hilly conditions). These inhalation rates would result in reductions for the current worker inhalation exposures or comparable increases in corresponding MOEs by factors of 3.5 for tractor drivers, 1.7 for mixer/loaders and flaggers, and 1.1 for handheld equipment.

Also, because of these reduced inhalation rates and decreases in the amount of dust released from the cellulose-based formulation, which are expected to substantially reduce potential inhalation risk, and because dermal risks are currently assessed as being very low (dermal MOEs in excess of 1000), the Agency believes that risks to handlers of the granular cellulose-based 15G product in 1000 lb Supersaks are not of concern. For these reasons, no further mitigation measures are necessary to address risks to workers handling the cellulose-based 15G product in 1000 lb Supersaks.

To further mitigate risks to workers that load and apply granular products for aerial applications, the registrant has agreed to cancel all aerial applications of ethoprop granular formulations. Also, to mitigate risks to workers from granular ethoprop applications to bananas and plantains, which involve spoons or other direct hand-held equipment, the registrant has agreed to cancel all spoon and hand-held equipment (except granular backpack spreaders). Thus, in order to support a reregistration eligibility decision for ethoprop, the worker scenarios involving both loading and applying with fixed-wing aircraft, and flagging for aerial applications (scenarios 1a, 3a, and 10, respectively), and hand-held equipment (except granular backpack spreaders) for applying to bananas and plantains (scenarios 5f) are to be deleted from the current labels.

Reduction of Granular Dust Levels with Biodac

The worker risks for the granular formulations presented in Tables 10 and 11 are based on a product-specific worker exposure study conducted with the clay-based 10G product. As stated above, the Agency believes that a cellulose-based formulation will reduce substantially (i.e., by as much as 90-fold) the inhalation exposure (the driver for the current granular formulation risks) to workers that handle granular ethoprop products. In response, the registrant has submitted some preliminary data which indicate that the amounts of dust associated with the 20G clay-based and 15G cellulose-based formulations are much lower than the amounts of dust associated with the current 10G clay-based and 15G clay-based formulations. These data concerning the dust levels are based on the registrant's Perceived Dust method, which measures the amount of small particulate matter which is released and trapped onto a filer, when placed in a rotating drum system for a specified period of time.

Based on this data for Perceived Dust of the ethoprop 15G cellulose-based and 20G clay-based formulations, and to further demonstrate that the exposure estimates are lower than currently assessed, the registrant has cited a worker exposure study (MRID 438525-01) that was used to support the registration of the Temik 15G (15% aldicarb) product. This aldicarb product was specifically formulated with an inert ingredient to produce a less-dusty formulation to also reduce worker inhalation exposures of concern. The Agency's preliminary evaluation of the submitted dust data suggests that the ethoprop 15G cellulose-based and 20G clay-based formulations have dust levels similar to the Temik 15G. This Temik 15G worker exposure information was cited to be bridged with the ethoprop granular formulations to confirm that use of less dusty inert ingredients, such as cellulose, will result in lower inhalation exposure to workers. Based on preliminary evaluation of this data, the Agency believes that it is appropriate to bridge Temik 15G exposure data with ethoprop 15G cellulose-based and 20G clay-based formulations to refine inhalation exposures for scenarios involving engineering controls (Table 10).

To further confirm the Agency's understanding that cellulose-based formulations release less dust than the clay-based formulations, specialty studies to characterize the percent dust, respirable and otherwise in various formulations of ethoprop and aldicarb are required to be submitted to the Agency. The type of information that comprise these studies may include, but not be limited to: properties of cellulose-based granules themselves; the physical properties of cellulose-based ethoprop granules; methods to collect and analyze the very small dust particles released; determinations of whether these small particles contain ethoprop or are just fragmented cellulose; and additional information on the Perceived Dust method (including quality control data). In addition, the Agency is also reserving at this time an inhalation toxicity study to refine the inhalation endpoint and dose selected to assess inhalation risks. Pending final review and conclusions of the confirmatory dust data and its bridging to the Temik 15G exposure data, if further inhalation toxicity refinements are appropriate, the inhalation toxicity study will then be required.

Cancer Risks

For some of the granular ethoprop formulations, application scenarios have been voluntarily cancelled by the registrant due to dermal and/or inhalation worker risk concerns. Of the remaining application methods that utilize engineering controls (scenarios 1b, 3b, 5a, 5b), the cancer risks range from $5.9 \times 10^{-5}$ to $1.8 \times 10^{-7}$ (Table 10). Note that the Agency has mitigated these risks to the greatest extent feasible. For example, in addition to formulating the 15G product with cellulose, engineering controls are to be implemented, including the use of closed loading/transfer systems and enclosed cabs, and reduced maximum application rates for some crops (i.e., 12 lb ai/A to 6 lb ai/A for tobacco, and from 12 lb ai/A to 9 lb ai/A for treatment against nematodes in potatoes east of the Mississippi River). In addition, the Agency recognizes that ethoprop is the most, if not the only, effective chemical control against wireworms, which are one of the critical pests which infest potatoes.

The only application scenarios which remain on the labels for which engineering controls are not feasible (Table 11) are those involving granular backpack spreaders for treating banana and plantain plants. The calculated cancer risks for workers utilizing these types of equipment (scenario 6c) are $1.9 \times 10^{-4}$ (associated with the Horstine-Farmery Microspread granular spreader) and $3.0 \times 10^{-5}$ (associated with the Swissmex granular backpack spreader).

The above cancer risk assessment is based on a product-specific study with the clay-based 10G formulation, and thus overstates the risks that workers will face in the future. As discussed above, the registrant has agreed to convert their formulation processes of the granular products to produce only less dusty granular formulations (15G cellulose-based and 20G clay-based products). With the conversion to these less dusty products, it is expected that cancer risks for the granulars will also be lower than those currently assessed and will not be of concern. Also, information available to the Agency indicates that ethoprop is an important chemical to control nematodes which infest banana and plantain plants. According to the International Banana Association (IBA), ethoprop is utilized as part of an Integrated Pest Management (IPM) program with other pesticides (including other OPs) to minimize the development of resistance by nematodes to each chemical product and to lessen the likelihood of accelerated microbial degradation of the chemicals in the soil. Therefore, provided application equipment with similar or better performance to the Horstine-Farmery Microspread granular spreader and the Swissmex granular backpack spreader are utilized to treat banana and plantain plants, no further mitigation measures are necessary to address worker cancer risks for the granular formulations.

***Emulsifiable Concentrate Formulation***

Unlike the granular formulation, the risk driver for the emulsifiable concentrate (liquid) formulation is dermal exposure. To help reduce these risks, the registrant has agreed to amend the labels of these products to specify the use of engineering controls, including both the use of closed loading and mixing systems, and the use of enclosed cabs for applying. Nevertheless, even with these measures, occupational risks are still of concern. However, the registrant has stated their belief that actual exposures to workers that mix/load and apply the ethoprop EC product are lower than indicated by the risk assessment presented in this document, and that further data would corroborate that worker risks are not of concern. To demonstrate this, the registrant has initiated a biomonitoring study with workers who are routinely mixing/loading and

applying the ethoprop EC product to potatoes. The study results are to be submitted to the Agency by March 31, 2002. The registrant has also agreed that if results of the biomonitoring study and supporting pharmacokinetics data do not demonstrate acceptable risks to workers with the EC formulation, the registrant will voluntarily cancel their registration of the EC formulation. Because the current worker risks presently assessed are extremely high (some MOEs are less than 1) and of concern to the Agency, the Agency is not making a reregistration eligibility decision of the EC formulation at this time; however, the conditions of reregistration eligibility for this formulation are stipulated in this section.

Scenarios of Concern

All mixing/loading and applying worker scenarios with the ethoprop EC formulation are of concern to the Agency. These scenarios include: 2a, 2b, and 4 for those where engineering controls are feasible (Table 10); and 6a, 6b, 7, 8, and 9 for those where engineering controls are not feasible (Table 11).

Cancer risks for the ethoprop EC formulation are also of concern to the Agency. The calculated cancer risks for all remaining scenarios with the granular formulations (Tables 10 and 11) range from $9.0 \times 10^{-4}$ to $4.4 \times 10^{-6}$. Those scenarios that have cancer risks greater than $1 \times 10^{-6}$ are 2a, 2b, 4, 6a, 6b, and 7; and those scenarios that have cancer risks greater than $1 \times 10^{-4}$ are 2a, 6b, and 7. Cancer risks were not assessed for scenarios 8 and 9, because no data are available to adequately assess these handler methods.

Biomonitoring Study

To address the occupational risks for the EC formulation, the registrant has agreed to amend the current label for the EC product to specify engineering controls, including both closed mixing/loading and enclosed applying systems. The closed mixing/loading system involves dripless couplings for the transfer system and closed mixing tanks, while the engineering controls for applying include enclosed cabs for workers using groundboom equipment for treating agricultural crops. Nevertheless, as indicated in Tables 10 and 11, even with the implementation of these engineering controls, the combined MOEs for all EC scenarios (2a, 2b, 4, 6a, 6b, 7, 8, and 9) are still well below their respective targets and are of concern to the Agency. However, the registrant has indicated that the actual exposures to workers that mix/load and apply the ethoprop EC product are possibly lower than indicated by the risk assessment presented in this document, because of an extrapolation from the existing PHED data.

To investigate this, the registrant has volunteered to conduct a biomonitoring study with workers who are routinely mixing/loading and applying the ethoprop EC product to potatoes in the Pacific Northwest. Potatoes are the crop with the highest remaining application rate and have the highest usage. The mixer/loaders will be monitored while routinely utilizing closed loading systems and closed mixing tanks, and applicators are to be monitored while operating enclosed cab tractors/ground boom applicators. These workers will be monitored using conventional industrial hygiene air sampling equipment to assess the inhalation exposures. In addition, biological monitoring techniques will be employed to measure levels of ethoprop and its related residues in urine samples to infer an absorbed dose in both these mixer/loaders and applicators. The registrant submitted a detailed protocol for the conduct of the field and laboratory portions of

this biomonitoring study, which has been reviewed by the Agency, and the registrant has agreed to submit a final report of this biomonitoring study to the Agency by March 31, 2002.

Typically, these absorbed dose determinations are based on only a single biomarker; therefore, these calculated estimates of the absorbed dose of ethoprop are highly dependent on an accurate understanding of the human pharmacokinetics (PK) of ethoprop and all of its metabolites. If the biomonitoring study provides equivocal results concerning worker exposures, PK data may be necessary for the Agency to calculate the dose levels in humans, based on the concentrations of ethoprop and related metabolites found in the urine of the exposed workers, especially the selection of the human biomarker. To this end, the registrant has committed to conduct a human PK study, if it is determined that additional data are needed.

Note that the Agency recognizes the high benefits of ethoprop availability for key crops, including especially potatoes, since ethoprop is one of the only effective chemical controls against wireworms. In addition, the Agency agrees with the position stated by potato growers that the ethoprop EC formulation is effective in certain areas with limited rainfall, and that because the EC is a liquid and can be tank mixed with other liquid insecticides (such as metam-sodium), growers can achieve even more efficacious results against wireworms and nematodes.

Additional Risk Reduction Measures

To determine that ethoprop is eligible for reregistration, it is necessary for worker scenarios of mixing/loading/applying liquids with low-pressure handwand sprayers, liquid backpack sprayers, and sprinkler cans (scenarios 6a, 6b, and 7, respectively) to be deleted from ethoprop labels. The registrant has voluntarily agreed to cancel all these uses and application methods.

For those scenarios where exposure data are not available, worker risk and cancer risk assessments were not conducted. To support a reregistration decision of ethoprop, it is necessary for these worker scenarios, specifically mixing/loading/applying liquid concentrate by handheld measuring container and dipping citrus seedlings in liquids (scenarios 8 and 9, respectively), to be deleted from ethoprop labels. The registrant has also agreed to cancel these uses and application methods. Note that as a result of these voluntary cancellations, the only worker scenarios which will remain on the EC formulation label are those where engineering controls are feasible and employed.

Cancer Risks

Consistent with EPA's policy to reduce individual cancer risks to the greatest extent feasible, preferably to $1 \times 10^{-6}$ or less, with the implementation of engineering controls and the deletion of various worker scenarios from ethoprop labels, the resultant cancer risks for the remaining worker scenarios with the EC formulation (scenarios 2a, 2b, and 4) range from $2.1 \times 10^{-4}$ to $4.4 \times 10^{-6}$. As stated above, the Agency recognizes the benefits of ethoprop and especially the EC formulation, especially for potato growers, the highest use crop, as well as tobacco, sweet potato, cabbage, and cucumber growers.

The highest cancer risk ($2.1 \times 10^{-4}$) is from scenario 2a (chemigation to 350 acres at the highest application rate). It is worth noting that these are the cancer risks which represent exposures over a lifetime for custom applicators. These calculated risks represent five to ten times the level of exposure as a private applicator, since the Agency cancer risk assessments in Tables 10 and 11 are estimates for custom applicators who handle ethoprop for 10 applications per year, while private applicators only handle ethoprop 1 or 2 times per year, depending on the crop. Moreover, it is expected that data from the required biomonitoring study may also refine the occupational cancer risk assessment. Provided the data from this study indicate dermal and inhalation exposures are lower than the current estimates, cancer risks to workers will also be lower than currently assessed.

Conditions of Reregistration Eligibility

As stated above, the current worker risks presently assessed are extremely high and of concern to the Agency. Because of the registrant's belief that actual risks to workers with the EC formulation are much lower than presently assessed; their efforts to provide refined biomonitoring and supporting PK data; and the benefits associated with the EC formulation in certain areas with limited rainfall and its ability to be tank mixed with other liquid insecticides to achieve even more efficacious results; the Agency is not making a reregistration eligibility decision of the EC formulation registration (MOCAP® EC Nematicide-Insecticide, EPA Reg. No. 264-458) at this time. The Agency is deferring its reregistration eligibility determination for the EC formulation until the data described below are submitted or the deadline(s) for submission of these data is reached.

1. The registrant is to provide EPA with a final report from the ongoing biomonitoring study of mixer, loaders, and applicators working with the EC formulation by no later than March 30, 2002.

2. The registrant is to provide EPA with sufficient data comparing ethoprop metabolites in rat and human urine, in combination with a previously submitted rodent metabolism/PK study by no later than March 30, 2002.

3. If, upon a written review of the new PK data, the Agency determines it is not scientifically acceptable or upgradable, and justifies the need for additional data, the registrant is to conduct a human PK study within 12 months of Agency approval of the protocol. It is expected that approximately two years will be necessary for: (1) Agency review the biomonitoring and supporting rodent PK data; (2) an Agency determination of whether additional PK or other data are needed; and (3) registrant completion of a human PK study. Therefore, these activities should be completed by no later than March 2004.

The measures described above reflect commitments the registrant, Aventis CropScience made to the Agency in a letter dated September 28, 2001. In that letter, the registrant stated that they will provide the final report of the above biomonitoring study and data comparing ethoprop metabolites in rat and human urine to the Agency by no later than March 30, 2002. The registrant also stated in the letter that if this data is not submitted to the Agency by this deadline, they will voluntarily cancel the EC formulation registration. Moreover, if the Agency determines that a human PK study is necessary, the registrant also agreed in the letter to conduct the study

within 12 months of Agency approval of the protocol, and to voluntarily cancel and phase out the liquid formulation if the Agency ultimately determines that the risks to workers from this formulation are unacceptable.

The Agency believes this approach provides ample opportunity for the registrant to develop the data to address uncertainties in the risk assessment in support of grower identified needs. And, in fact, the studies to provide the requisite data are currently ongoing. This approach represents responsible environmental stewardship by establishing rigorous data submission deadlines to ensure the worker risk assessment can be expeditiously refined and any unreasonable risks expeditiously addressed by a voluntary registrant action.

If the deadlines stipulated above for submission of data that are included in the data call-in notice accompanying this IRED are not met, the registration for the EC formulation may be subject to suspension in accordance with FIFRA Section 3(c)(2)(B). Also, if upon review of the biomonitoring study and the supporting PK data, the Agency determines that the data is inadequate or that the risks to workers are unacceptable, the Agency will take appropriate regulatory action, if necessary. Such action may include determining the EC formulation is ineligible for reregistration based on the data available at that time.

***Gel Formulation in Water-Soluble Packaging***

There are no chemical-specific studies for the gel formulation. However, because of concerns regarding production costs and the packaging size, the registrant has agreed to voluntarily cancel the registration of the gel formulation in the water-soluble packaging.

***Post-Application Risk Mitigation***

For ethoprop, the Agency believes that the potential for post-application worker exposure is low. Ethoprop is applied once, either pre-plant, at-plant, or pre-emergent for most field crops. There are no routine activities for most field crops that lead to potential exposures during the restricted entry interval. In addition, the time when crops are treated is well before plants are mature, which mitigates the potential for post-application exposure from contact with foliage. Note that peanuts are listed on current labels for treatment at pegging; however, the registrant has cancelled peanuts as a crop which may be treated with ethoprop. Note also that corn is listed on the current labels for treatment after plant emergence, until lay-by; however, the registrant has also dropped all uses on corn that are post-plant.

In addition, for all crops, ethoprop products are to be soil incorporated or watered-in immediately after application. For these types of application methods, the Worker Protection Standard designates the restricted entry interval (REI) to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches. Therefore, the Agency has no risk concerns for the post-application exposures to agricultural workers, and no risk mitigation measures beyond the 48 or 72 hour REI are necessary to protect post-application field worker and crop harvesters, providing the soil is not disturbed during the REI.

#### ii) Golf Course Uses

The risks for loading and applying ethoprop to golf course turf were of concern to the Agency (Tables 10 and 11). In addition, the Agency had concerns for golf course maintenance workers who would re-enter the golf course after the turf had been treated to conduct such activities as mowing and maintenance. Although the post-application cancer risks were calculated to be less than $3.1 \times 10^{-7}$ on the day of application, and not of concern to the Agency (i.e., less than $1 \times 10^{-6}$), the dermal MOEs were less than 100 until 17 days following treatment at the maximum label rate, and thus the worker risks are of concern to the Agency. Therefore, to address these and other risk concerns, the registrants have agreed to voluntarily cancel all golf course uses of ethoprop.

### c. Non-Occupational Risk Mitigation

There are no homeowner uses for ethoprop, so there are no residential and homeowner exposures. Regarding other types of non-occupational exposures for ethoprop, the Agency had concerns regarding the risks to golfers playing on golf course turf which had been recently treated with ethoprop (i.e., the MOEs for golfers exhibited risks which were of concern to the Agency until 10 days had elapsed following treatment at the maximum label rate). Based on these golfer risk concerns, as well as the other concerns associated with uses on golf courses, the registrants of golf course use products have agreed to voluntarily cancel all golf course uses to mitigate these risks.

## 2. Environmental Risk Mitigation

The Agency has ecological risk concerns regarding the acute and chronic risks of ethoprop to terrestrial birds and mammals, freshwater fish and invertebrates, marine and estuarine fish and invertebrates, as well as to endangered species. The ecological risk assessments for both the EC and granular formulations exhibit RQ values which exceed the various target levels of concern (LOCs).

### a. Nontarget Terrestrial Organisms

The RQs for terrestrial birds and mammals are of concern to the Agency. The avian RQ values for the liquid product are as high as 384 for chronic risks, and RQs for granular products are even higher, with banded/in-furrow applications showing a maximum acute RQ value of 452. While the terrestrial mammal RQ values are not as great, with a maximum acute RQ value of 77, they are of concern as well.

Laboratory testing results indicate that ethoprop is moderately toxic to very highly toxic to terrestrial animals, both birds and mammals, from both oral and dermal exposures. Therefore, to help protect terrestrial birds and mammals, it is very important to minimize their potential exposure to ethoprop products that have been applied. Soil incorporation, dropping certain uses, reducing maximum application rates, deleting broadcast applications for some uses, and limiting the number of applications are among the measures to be implemented to minimize potential exposure to ethoprop.

For instance, ethoprop products are to be applied with soil incorporation following broadcast or banded treatment. While current labels specify soil incorporation, they are to be amended to specify that soil incorporation will occur during or immediately following application, either as part of the application equipment itself or with other equipment performing soil incorporation directly behind the applicator. In addition, the registrant has agreed to restrict current labels to limit the number of applications of ethoprop to one per season, except for use on bananas, plantains, and pineapple.

For some crops, such as sugar cane, potatoes, and sweet potatoes, the banded treatment with ethoprop actually involves placement of the liquid or granules into the furrow with the planted material, and is then buried by the planting equipment. This direct burial should insure that essentially no ethoprop material remains on the soil surface. The ecological risk assessments for banded applications of the granular product assumed that 15% of the applied material remains on the soil surface. However, the direct soil incorporation practices involved in the at-planting applications for these specific crops accounted for about 70% of the total amount of ethoprop applied from 1987-96 based on the Agency QUA, and about 85% of the total amount of ethoprop applied, based on registrant usage data from 1998-2000.

In addition, the ecological risks of the EC formulation were assessed with scenarios involving ethoprop that is broadcast onto fields of short grass, tall grass, or broadleaf plants, and not soil incorporated. Because ethoprop is mostly applied at plant, broadcast treatment with the EC formulation is usually made to bare soil fields and is to be immediately incorporated into the soil for all crops. Considering the lack of grass and plant vegetation in the field during treatment, and the immediate incorporation of ethoprop into the soil, the availability of ethoprop to remain on the soil surface is significantly reduced, thereby further mitigating the exposure to terrestrial wildlife.

Thus, actual exposure for terrestrial animals is likely much lower than assessed. This conclusion is supported by the assessment of the golf course turf slit treatment use, in which the turf is mechanically lifted and the granules inserted onto the exposed soil and the turf replaced above the granules. The resulting exposure for this use was assumed to be zero, indicating no ethoprop runs off for exposure to aquatic animals and suggesting little material would be available for exposure to terrestrial animals.

To further mitigate ecological risks, the registrant has agreed to reduce the maximum label rates for some uses of ethoprop. The use which formerly had the highest label rate, 20 lb ai/A, was golf course turf treatment, and this use has been voluntarily cancelled. For tobacco, the registrant has agreed to reduce the maximum label rate from 12 lb ai/A to 6 lbs ai/A. In addition, for potatoes, the registrant will be voluntarily enacting geographical restrictions for uses against nematodes; east of the Mississippi River, the maximum label rate against nematodes is being reduced from 12 lbs ai/A to 9 lb ai/A, but will remain at 12 lb ai/A for uses against nematodes west of the Mississippi River; and for applications to treat wireworms and garden symphylans, the maximum label rate in the United States will remain at 6 lb ai/A. Thus, the maximum application rate for new labels for ethoprop will be 12 lb ai/A only for potatoes against nematodes only, and restricted to treatments west of the Mississippi River.

In addition, for most of the other crops, the registrant has submitted data indicating that typical application rates utilized by growers are less than the maximum label rates. The Agency has reviewed these data concerning typical application rates, and has agreed that growers do not always utilize the maximum label rate for ethoprop products to control their pests. Thus, for many crops, including tobacco, potatoes, and sweet potatoes, the actual exposures to terrestrial birds and mammals associated with these lowered maximum and typical application rates may be lower than the calculated RQ values presented to assess ecological risks.

The Agency also recognizes that there are benefits to potato growers for using ethoprop to treat nematodes, symphylans, and wireworms. Ethoprop is one of the only effective chemical controls against wireworms. The Agency has also determined that there is a greater effectiveness of the ethoprop EC formulation in certain areas with limited rainfall; in addition, because the EC is a liquid and can be tank mixed with other liquid insecticides (such as metam-sodium), this formulation can achieve even more efficacious results against wireworms and nematodes. These benefits are of special concern, because recent information indicates that more than 50% of the usage of ethoprop in the United States is on potatoes.

Note that the Agency also recognizes the high benefits to growers as a result of the availability of ethoprop for treatments of other crops. The Agency has information concerning the benefits of ethoprop for treating pests in tobacco, sweet potatoes, cabbage, and cucumber. While alternative chemicals are available for each of these crops, an assessment for each crop indicates that the use of the alternative chemicals would be less effective as well as more expensive.

**b. Nontarget Aquatic Organisms**

The highest RQ value reported for an aquatic animal species is 375, the chronic RQ for estuarine/marine invertebrates. The freshwater fish and invertebrates are less sensitive than the marine/estuarine fish and invertebrates, and the fish are less sensitive than the invertebrates; however, the estimated RQ values are of concern for most aquatic animals. The RQ values developed to assess risks to aquatic species were based on estimates of EECs generated from the PRZM-EXAMS model (without the Standard Index Reservoir component which is used to assess drinking water only), and were based on broadcast application without soil incorporation. Based on the RQ exceedances for these aquatic animals, additional ecological risk mitigation is warranted for ethoprop.

However, as part of the risk management discussion addressing drinking water risk, there were thousands of surface water samples from the STORET and NAWQA databases which resulted in few ethoprop detections, and where there were detections, they were significantly less than estimates generated by the model. This information was not used to directly assess aquatic exposures just as it was only of limited use in assessing drinking water risks for ethoprop. But it does indicate that actual exposures and risks to aquatic species may be less than the modeling predicts.

Similar measures to address risk to terrestrial species are to be employed for aquatic species as well, such as soil incorporation, dropping certain uses, reducing maximum application rates, deleting broadcast applications for some uses, and limiting the number of applications, in

addition to imposing buffer zones for the EC formulation. As with terrestrial species, to partly address the risk concerns for aquatic species, the labels will be amended to specify immediate soil incorporation either during or following all applications of ethoprop. In addition, the registrant has agreed to reductions in the maximum application rates for tobacco and potatoes, and the number of applications. Also, the Agency recognizes that for some crops, most growers actually apply ethoprop at rates below the maximum rate listed on the label, so for these crops, the risks estimated by the Agency may be overestimates of actual risks to aquatic species.

In addition, the ecological risks assessments for the EC formulation included scenarios where ethoprop is broadcast onto fields and not soil incorporated. While the Agency recognizes that certain crop treatments and various pests may be best treated by broadcast applications, ethoprop is to be immediately incorporated into the soil either during or following application to all crops, thus significantly reducing the potential for ethoprop to remain on the soil surface and be available for runoff. Thus, actual surface water concentrations to which aquatic organisms may be potentially exposed may be lower than those predicted by the water model.

Also, regarding the six reported fish kill incidents associated with ethoprop, three were attributed to the use of ethoprop on golf course turf, and for the remaining three, while the direct cause was not determined, ethoprop use on tobacco in the area may have been a contributing factor. Note that the registrant has since cancelled ethoprop use on golf courses, and the maximum applications rate for use on tobacco is to be reduced from 12 lb ai/A to 6 lb ai/A.

In addition, the Agency has determined that buffer zones will be necessary for applications of the EC formulation of ethoprop to any fields adjacent to surface water bodies. The EC is applied as a liquid, and as such is more readily available for runoff than the granular formulations, due to it being moderately mobile in soil, but with a decreased mobility in soils with increasing organic matter. For granular products, water must be available to dissolve the active ingredient off the granules, and this is anticipated to be a slower process than the immediately mobile liquid active ingredient in the EC product.

Buffer zones are currently specified on the labels for the EC formulation, having been added to these labels in 1982, and include the following restrictions: "Do not apply within 140 feet of inland freshwater habitats," and in addition, specified the following: "Along the Atlantic seaboard, do not apply with [*sic; within*] 800 feet of brackish water habitats." Note that ethoprop is particularly toxic to estuarine and marine organisms, so the buffer zone adjacent to these water bodies is even larger than for freshwater habitats. Based on the toxicity and resultant RQs for freshwater and estuarine/marine species, and the physical properties of the liquid formulation, the current buffer zones specified on the label for the EC formulation are to remain unchanged. The label language for buffer zones is listed in Table 14 in Section V of this IRED document.

In addition, as discussed as part of the risk management decision addressing risk to terrestrial species, the Agency recognizes that there are substantial and unique benefits associated with the use of ethoprop, due to its effectiveness against various pests and its cost-competitiveness in comparison with some less efficacious alternative chemicals.

## E. Labeling

In order to remain eligible for reregistration, other use and safety information needs to be placed on the labeling of all products containing ethoprop. For the specific labeling statements, refer to Table 14 in Section V of this document.

Based on the risk information in Section 3, and the mitigation information in earlier parts of this Section 4, the Agency had concerns regarding various uses of ethoprop. In response to these risks, the technical registrant has agreed to cancel the following uses:

- peanuts;
- citrus seedlings; and
- golf courses.

The technical registrant has agreed to cancel the following use methods:

- all aerial applications;
- slit treatment;
- push-type spreaders;
- hand applications, including direct hand-held equipment, such as spoons;
- liquid low-pressure handwand sprayers;
- liquid backpack sprayers;
- liquids with a sprinkler can;
- mixing/loading/applying liquid concentrate by a handheld measuring container; and
- hand-dipping in liquids.

The technical registrant has agreed to modify the following use practices:

- delete post-plant treatments to corn (current labels permit applications until at-layby);
- delete broadcast applications of the EC to cabbage; only banded treatments are permitted;
- delete broadcast applications to sweet potatoes; only banded treatments are permitted for both the EC and granular formulations;
- drop the following crops from the current EC label: snap and lima beans, field and sweet corn, and sugar cane;
- restrict the maximum number of applications for all uses to one application per year, except for use on bananas, plantains, and pineapples;
- reduce the maximum label rate for tobacco from 12 lb ai/A to 6 lb ai/A;
- reduce the maximum label rate for potatoes to treat nematodes east of the Mississippi River from 12 lb ai/A to 9 lb ai/A;
- reduce the maximum label rate for ornamentals from 6 lb ai/A to 3 lb ai/A;
- reduce the maximum label rate for granular treatments to pineapples (Special Local Needs label) from 12 lb ai/A to 6 lb ai/A; and
- specify immediate soil incorporation by mechanical equipment for all products as they are being applied by ground equipment, or that watering-in is to be conducted immediately following applications (for chemigation methods and for use on bananas, plantains, and pineapples only).

The technical registrant has agreed to cancel the following product registrations to support the reregistration of ethoprop:

- MOCAP 10% Granular Nematicide Insecticide (10% ethoprop; EPA Reg. No. 264-465)
- Gel formulation in water soluble packaging (68.2% ethoprop, EPA Reg. No. 264-541)
- MOCAP Plus Nematicide-Insecticide (granular: 10.0% ethoprop and 5.6% disulfoton, EPA Reg. No. 264-459)
- MOCAP Plus 4-2 EC Nematicide-Insecticide (emulsifiable concentrate: 46.0% ethoprop and 23.0% disulfoton, EPA Reg. No. 264-464)
- MOCAP PCNB 3-10 Granular Nematicide-Insecticide (granular: 3.0% ethoprop and 10.0% pentachloronitrobenezene, EPA Reg. No. 264-475)
- HOLDEM Brand Granular Nematicide Insecticide (granular: 10.0% ethoprop and 8.8% phorate, EPA Reg. No. 264-521)
- CHIPCO MOCAP Brand 10G GC [for golf course use] (granular: 10.0% ethoprop, EPA Reg. No. 432-895).

The only other registrant with a registration of an ethoprop-containing product, Micro-Flo Co., has voluntarily agreed to cancel that end-use product registration, since the only crop listed on that label is peanuts, a crop that the technical registrant is dropping from their technical label. The specific product which Micro-Flo has agreed to voluntarily cancel is as follows:

- PCNB-M 10-3G (granular: 3.0% ethoprop and 10.0% pentachloronitrobenezene, EPA Reg. No. 51036-80).

### 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 address these impacts. The Endangered Species Act requires Federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, the Agency puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this IRED that are being implemented at this time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service, as necessary.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are

available for voluntary use by pesticide applicators on the Agency's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register before the end of 2001.

### 2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a group comprised of 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.

Based on these analyses, the Agency is in the process of developing more appropriate label statements for spray and dust drift control to ensure that public health and the environment is protected from unreasonable adverse effects. In August 2001, the Agency published for public comment draft guidance for label statements ("Draft PR Notice 2001-X" http://www.epa.gov/PR_Notices/#2001) and a Federal Register Notice, August 22, 2001 (http://www.epa.gov/fedrgstr/), announcing the availability of this draft guidance for a 90-day public comment period. After receipt and review of comments, the Agency will publish final guidance (PR Notice) for registrants to use in labeling their products.

In the interim, until the Agency decides upon and publishes the final label guidance for spray drift, registrants may choose to use the proposed statements. Registrants should refer to and read the draft PR Notice to obtain a full understanding of the proposed guidance and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

Registrants may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling for purposes of complying with the deadlines for label submission as outlined in this document. This proposed language is as follows:

For products applied outdoors as liquids (except mosquito adulticides):

> "Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals."
>
> "For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use _____ [*registrant to fill in*

*blank with spray quality, e.g. fine or medium*] or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles."

"For overhead chemigation, apply only when wind speed is 10 mph or less."

"The applicator also must use all other measures necessary to control drift."

The Agency recognizes that the above option does not address all other application types. Registrants may, therefore, wish to choose some variation of the old and proposed new language for their particular products, depending on their application methods. Thus, until the Agency decides upon and publishes the final label guidance for spray/dust drift, registrants may choose to use the above proposed statements.

However, if registrants do not chose to utilize the proposed new language, at a minimum, other language is still necessary. Since the Agency has determined that spray drift related language shall be included on all product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method, the following statement must be added to ethoprop labels:

"Do not allow this product to drift."

To mitigate risk concerns for granular products, the registrant for ethoprop has agreed to delete aerial applications. The current EC label does not permit aerial applications. Thus, any spray drift language to address aerial applications should not be included on any revised labels to be submitted for ethoprop; the granular labels instead need to state:

"Aerial applications not permitted for this product."

In addition, the Agency had previously determined that a "no-spray zone" (buffer zone adjacent to surface waters) is necessary for the EC formulation, due to both the toxicity of ethoprop to aquatic organisms, and the potential mobility of this formulation. When the Draft PR Notice 2001-X is finalized, the label statement may need to be amended. However, in the interim, the EC formulation end-use product needs to include the following no-spray zone statement (see Table 14):

"Do not apply this product within140 feet inland of freshwater habitats, and along the Atlantic seaboard, do not apply within 800 feet of brackish water habitats. Under no circumstances is this product to be applied within 140 feet of people or these surface water bodies."

## V. What Registrants Need to Do

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

For ethoprop technical grade active ingredient products, technical registrants need to submit the following items:

**Within 90 days from receipt of the generic data call-in (DCI):**

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and technical registrant's response form); and
(2) any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:**

(1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

For questions about generic reregistration or the DCI, please contact Anthony Britten at 703-308-8179. Address all materials you submit in response to the DCI as follows:

By US mail:
Document Processing Desk
Anthony Britten
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Or by express or courier service only:
Document Processing Desk
Anthony Britten
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

For products containing the active ingredient ethoprop, registrants need to submit the following items for each product:

**Within 90 days from the receipt of the product-specific data call-in (PDCI):**

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

(2) any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:**

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for registration (EPA Form 8570-1) and indicate on the form that it is an "application for reregistration";

(3) five copies of the draft label incorporating all label amendments outlined in Table 14 of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

(6) the product-specific data responding to the PDCI.

For questions about product reregistration or the PDCI, please contact Karen E. Jones at 703-308-9047. Address all materials you submit in response to the PDCI as follows:

By US mail:
Document Processing Desk
Karen E. Jones
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Or by express or courier service only:
Document Processing Desk
Karen E. Jones
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

## A. Manufacturing-Use Products

### 1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ethoprop for the above eligible uses has been reviewed and determined to be substantially complete, except for the following additional required confirmatory data. The required studies are listed by their new OPPTS guideline numbers. Old guideline numbers, if applicable, are in parentheses.

- OPPTS 830.7050 - UV/Visible absorption with technical grade active ingredient
- OPPTS 835.7100 - Drinking water monitoring from ground water sources
- OPPTS 835.7200 - Drinking water monitoring from surface water sources
- OPPTS 850.1500 - Full fish life cycle testing with marine/estuarine fish (72-5b)

[and full life cycle testing with freshwater fish is reserved (72-5a), pending outcome of testing with marine/estuarine fish]

- OPPTS 850.2300 - Avian reproduction testing with the northern bobwhite quail (71-4a) [and avian reproduction testing with the mallard duck is reserved (71-4b), pending outcome of testing with bobwhite quail]

- OPPTS 860.1340 - Residue analytical method (171-4c)

- OPPTS 860.1380 - Storage stability data (171-4e)

- OPPTS 860.1500 - Crop field trials; beans, cabbage and potatoes (171-4k)

- OPPTS 870.3465 - 90-day inhalation toxicity study [this study is reserved pending review of the Perceived Dust data] (82-4)

- OPPTS 870.6100 - Acute and 28-day delayed neurotoxicity of organophosphorus substances [in hen] (81-7)

- OPPTS 870.6300 - Developmental neurotoxicity study (83-6)

- OPPTS 875.1350-SS, Special Study - Information concerning the granular formulations, including properties of cellulose-based granules themselves; the physical properties of cellulose-based ethoprop granules; methods to collect and analyze the very small dust particles released; determinations of whether these small particles contain ethoprop or are just fractionated cellulose; and additional information on the Perceived Dust method (including quality control data)

- OPPTS 875.1500 - Worker biological monitoring with the EC formulation

- OPPTS 875.2800 - Description of human activity for post-application

The above studies are confirmatory data. If the Agency finds that the results of these studies do not confirm the Agency's expectations, or provide information which identify additional risks of concern, the Agency will reconsider the measures established in this IRED.

Also, a DCI notice was issued on September 10, 1999 to all registrants of OP pesticides currently registered under FIFRA (64 FR 42945-42947, August 6, 1999, and 64 FR 44922-44923, August 18, 1999), including Rhone-Poulenc Ag Company (the corporate predecessor of the technical registrant, Aventis CropScience). The DCI requirements included acute, subchronic, and developmental neurotoxicity (DNT) studies. In response, Aventis cited studies for acute and subchronic neurotoxicity in the rat, and for the DNT data requirement, Aventis submitted a protocol for Agency review. The Agency sent a response letter to Aventis on May 30, 2001 concerning the cited studies and the protocol for these neurotoxicity study requirements. In the letter, the Agency indicated that the acute and subchronic neurotoxicity studies for ethoprop were supplementary, but upgradable to meet the current data requirements; however, data have not yet been submitted. Concerning the requirement for DNT data, Aventis (as well as

other registrants) have not yet submitted a study report. In addition, the Agency had previously determined that additional neurotoxic esterase (NTE) testing is required for the ethoprop IRED, based on results of existing neurotoxicological testing, and has listed this data requirement as confirmatory.

### 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 Table 14 at the end of this section.

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of reregistration 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.

A product-specific data call-in, outlining specific data requirements, accompanies this IRED.

### 2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 14 at the end of this section.

## C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this IRED. 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 the registrant may distribute and sell ethoprop products bearing old labels/labeling for 26 months from the date of issuance of this IRED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this IRED. Registrants and persons other than the registrant remain obligated to meet

pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

### D. Labeling Changes Summary Table

A summary of the required label changes for ethoprop is shown in Table 14.

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| | Manufacturing-Use Products | |
| Required on all MUPs | "Only for formulation into an insecticide/nematicide for the following uses(s) (*fill blank only with those uses that are being supported by MUP registrant*)." | Directions for Use |
| One of these statements may be added to a label to allow reformulation of the product for a specific use, or all additional uses supported by a formulator or user group. | "This product may be used to formulate products for specific use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."<br><br>"This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." | |
| Environmental Hazards Statements | **"Environmental Hazards"**<br><br>"This chemical is toxic to aquatic organisms (fish and invertebrates) and wildlife. 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." | Precautionary Statements under Environmental Hazards<br><br>Buffer zones also must appear in Directions for Use |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| | End-Use Products Intended for Occupational Use (WPS) | |
| Handler PPE for all Formulations | For **sole-active-ingredient** end-use products that contain ethoprop, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control specifications set forth in this section. Any conflicting PPE specified on the current label must be removed.<br><br>For **multiple-active-ingredient** end-use products that contain ethoprop, the handler PPE/engineering control specifications set forth in this section must be compared with the specifications on the current label, and the more protective language must be retained. For guidance on which PPE/engineering control specifications are considered to be more protective, see PR Notice 93-7. | |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Handler PPE Requirements for EC Formulation [2] | **"Personal Protective Equipment (PPE)"**<br><br>"Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical resistant materials following the instructions in Supplement 3 of PR Notice 93-7)*. If you want more options, follow the instructions for category *[insert A, B, C, D, E, F, G, or H]* on an EPA chemical-resistant category selection chart."<br><br>"Mixers, loaders, applicators, and other handlers must wear:<br>-- long-sleeve shirt and long pants, and<br>-- shoes plus socks.<br>In addition, mixers and loaders must wear chemical-resistant gloves and a chemical-resistant apron.<br>See engineering controls for additional requirements."<br><br>"Handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear:<br>-- coveralls over long-sleeve shirt and long pants,<br>-- chemical-resistant gloves,<br>-- chemical-resistant footwear plus socks,<br>-- chemical-resistant apron if exposed to the concentrate,<br>-- chemical-resistant headgear for overhead exposure, and<br>-- a non-powered air purifying respirator equipped with an organic-vapor (OV) removing cartridge or canister, plus an N-*, R-, or P-series prefilter."<br><br>* The registrant must drop the N-series filter from the respirator statement if the pesticide product contains or is used with oil. | Precautionary Statements: Hazards to Humans and Domestic Animals |

[2] PPE that is established on the basis of Acute Toxicity testing with the end-use products (including protective eyewear) must be compared with 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.

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Handler PPE Requirements for Granular Formulations not packaged in a closed loading system (such as the Lock 'n Load, Smart Box, SureFill Container or similar closed transfer system) that meet the specifications of the WPS | **"Personal Protective Equipment (PPE)"**<br><br>"Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical resistant materials following the instructions in Supplement 3 of PR Notice 93-7)*. If you want more options, follow the instructions for category *[insert A, B, C, D, E, F, G, or H]* on an EPA chemical-resistant category selection chart."<br><br>"Applicators using motorized equipment must wear:<br>-- long-sleeve shirt and long pants, and<br>-- shoes plus socks.<br>See engineering controls for additional requirements."<br><br>"Loaders and all other handlers must wear:<br>-- coveralls over long-sleeve shirt and long pants,<br>-- chemical-resistant footwear plus socks,<br>-- chemical-resistant gloves, and<br>-- a non-powered air-purifying respirator equipped with an N-*, R-, or P-series filter."<br><br>* The registrant must drop the N-series filter from the respirator statement if the pesticide product contains or is used with oil. | Precautionary Statements: Hazards to Humans and Domestic Animals |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Handler PPE Requirements for Granular Formulations packaged in a closed loading system (such as Lock 'n Load, Smart Box, SureFill container or similar closed transfer system) that meets the specifications of the WPS [2] | **"Personal Protective Equipment (PPE)"**<br><br>"Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical resistant materials following the instructions in Supplement 3 of PR Notice 93-7)*. If you want more options, follow the instructions for category *[insert A, B, C, D, E, F, G, or H]* on an EPA chemical-resistant category selection chart."<br><br>"Loaders, applicators, and other handlers must wear:<br>-- long-sleeve shirt and long pants, and<br>-- shoes plus socks.<br>In addition, loaders must wear chemical-resistant gloves.<br>See engineering controls for additional requirements."<br><br>"Handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or cleaning or repairing contaminated equipment, must wear:<br>-- coveralls over long-sleeve shirt and long pants,<br>-- chemical-resistant gloves,<br>-- chemical-resistant footwear plus socks,<br>-- chemical-resistant headgear for overhead exposure, and<br>-- a non-powered air-purifying respirator equipped with an N-*, R-, or P-series filter."<br><br>* The registrant must drop the N-series filter from the respirator statement if the pesticide product contains or is used with oil. | Precautionary Statements: Hazards to Humans and Domestic Animals |
| User Safety Requirements for the EC Formulation | "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."<br><br>"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following the PPE Requirements) |
| User Safety Requirements for the Granular Formulations | "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."<br><br>"Discard clothing or other absorbent materials that have been heavily contaminated with this product. Do not reuse them." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following the PPE Requirements) |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Engineering Controls for the EC Formulation | **"Engineering Controls"**<br><br>"Mixers and loaders must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing dermal and inhalation protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 mL. (0.068 oz.) per disconnect point."<br><br>"In addition, mixers and loaders must:<br><br>-- wear the personal protective equipment required in the PPE section of this labeling for mixer/loaders,<br>-- wear protective eyewear if the system operates under pressure,<br>-- be provided and have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible."<br><br>"Applicators using motorized ground-equipment must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:<br>-- wear the personal protective equipment required in the PPE section of this labeling for applicators,<br>-- *either* wear the type of respirator specified in the PPE section of this labeling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,<br>-- be provided and have immediately available for use in case of an emergency when they must exit the cab, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible,<br>-- take off any PPE that was worn in the treated area before reentering the cab, and<br>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements) |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Engineering Controls for Granular Formulations packaged in a closed loading system (such as Lock 'n Load, Smart Box, SureFill container or a similar closed transfer system) that meets the specification of the WPS | **"Engineering Controls"**<br><br>"This product is formulated into a [*insert name of the closed packaging*] system that meets the definition of a closed loading system in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition, loaders must:<br>-- wear PPE specified in the PPE section of this labeling,<br>-- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible."<br><br>"Applicators using motorized ground-equipment must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:<br>-- wear the personal protective equipment required above for applicators,<br>-- *either* wear the type of respirator specified in the PPE section of this labeling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,<br>-- be provided and have immediately available for use in case of an emergency when they must exit the cab, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible,<br>-- take off any PPE that was worn in the treated area before reentering the cab, and<br>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements) |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Engineering Controls for Granular Formulations not packaged in a closed loading system (such as the Lock 'n Load, Smart Box, SureFill Container or similar closed transfer system) that meets the specification of the WPS | **"Engineering Controls"**<br><br>"Applicators using motorized ground-equipment must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:<br>-- wear the personal protective equipment required above for applicators,<br>-- *either* wear the type of respirator specified in the PPE section of this labeling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,<br>-- be provided and have immediately available for use in case of an emergency when they must exit the cab, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible,<br>-- take off any PPE that was worn in the treated area before reentering the cab, and<br>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." | Precautionary Statements: Hazards to Humans and Domestic Animals<br>(Immediately following PPE and User Safety Requirements) |
| User Safety Recommendations | **"User Safety Recommendations"**<br><br>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."<br><br>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."<br><br>"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." | Precautionary Statements: Hazards to Humans and Domestic Animals<br>(Must be placed in a box)<br>(Immediately following Engineering Controls) |
| Environmental Hazards for the EC Formulation | **"Environmental Hazards:**<br><br>"This product is toxic to aquatic organisms (fish and invertebrates) and wildlife and extremely toxic to birds. Birds in treated areas may be killed. For terrestrial uses, do not apply directly to water, or areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. For specific No-Spray Zone requirements, see the Spray Zone Application Restrictions. Cover, incorporate or disc product that is spilled either during loading or application to the soil surface. Do not contaminate water when disposing of equipment wash water."<br><br>"This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area." | Precautionary Statements under Environmental Hazards |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Environmental Hazards for the Granular Formulations | **"Environmental Hazards:**<br><br>"This product is toxic to aquatic organisms (fish and invertebrates) and wildlife and extremely toxic to birds. Birds feeding in treated areas may be killed. For terrestrial uses, do not apply directly to water, or areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover, incorporate or clean up granules that are spilled during loading or are visible on the soil surface in turn areas. Do not contaminate water when disposing of equipment wash water."<br><br>"This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area." | Precautionary Statements under Environmental Hazards |
| Restricted-Entry Interval | "Do not enter or allow workers to enter into treated areas during the restricted-entry interval (REI) of 48 hours. The 48-hour REI is increased to 72 hours in outdoor areas where average rainfall is less than 25 inches a year."<br><br>"EXCEPTION: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated." | Directions for Use, Agricultural Use Requirements Box |
| Early Re-Entry Personal Protective Equipment for products subject to WPS as required by Supplement 3 of PR Notice 93-7 | "PPE required for early re-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:<br>-- coveralls over long-sleeved shirt and long pants,<br>-- chemical-resistant gloves made of any waterproof material,<br>-- chemical-resistant footwear plus socks, and<br>-- protective eyewear."<br><br>"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." | Directions for Use, Agricultural Use Requirements Box |
| General 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. For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation."<br><br>"Do not allow this product to drift." | Directions for Use |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Spray Zone Application Restrictions for the EC Formulation | "Do not apply this product within 140 feet of inland freshwater habitats, and along the Atlantic seaboard, do not apply within 800 feet of brackish water habitats. Under no circumstances is this product to be applied within 140 feet of people or these surface water bodies. "<br><br>"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals."<br><br>"For ground boom applications, apply with nozzle height no more than 4 feet above the ground and only when wind speed is 10 mph or less at the application site as measured by an anemometer. Use medium or coarser spray as described according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles."<br><br>"For overhead chemigation, apply only when wind speed is 10 mph or less and set the nozzle height on the chemigation equipment as close to the ground as is practical and feasible. If end-guns are used, assure that sprays are directed towards the ground."<br><br>"The applicator also must use all other measures necessary to control drift." | Directions for Use |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Other Applications Restrictions | "Not for Household Consumer Use. Do not store or use in or around the home."<br><br>As stated on current product labels, "Do not apply in Long Island, New York."<br><br>For granular products: "For applications only by tractor-drawn spreader; or by backpack granular spreader for only bananas, plantains, and pineapples. Aerial applications are not permitted for this product. Also do not apply by direct hand-held equipment, including measuring containers or spoons."<br><br>For the EC product: "For applications only by motorized ground boom equipment or sprinkler systems including: center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move; or drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system. Do not apply with liquid backpack sprayers, low-pressure handwand liquid equipment, sprinkler cans or hand-held measuring containers, or by hand-dipping of citrus seedlings."<br><br>For the EC product use on ornamentals: only preplant broadcast application to soil for field nursery stock, which may only be mechanically transplanted into the treated area, and not until 72 hours after treatment.<br><br>For applications by ground equipment, the product is to be soil incorporated to a depth of at least 2 to 4 inches, during or immediately following application by mechanical means, including by rotary tiller, rotary hoe, springtooth harrow, of by double-discing. For applications to bananas, plantains, and pineapples, the product is to be incorporated into the soil by hand-raking to a depth of at least 1 inch. | Directions for Use under General Precautions and Restriction or Application Instructions |

| Table 14 : Summary of Labeling Changes for Ethoprop | | |
|---|---|---|
| **Description** | **Amended Labeling Language** | **Placement on Label** |
| Label Amendments to Reflect Risk Mitigation | The labels should be amended to reflect the following:<br>– cancel all uses on peanuts (all formulations);<br>-- cancel all golf course uses (all formulations);<br>-- cancel all uses on citrus seedlings (EC);<br>– reduce the maximum application rate for tobacco to 6 lb ai/A (all formulations);<br>-- reduce the maximum application rate for pineapples to 6 lb ai/A (granular formulation);<br>– reduce the maximum rate for applications to potatoes for the treatment of nematodes for all areas east of the Mississippi River to 9 lb ai/A (all formulations);<br>-- reduce the maximum application rate for ornamentals to 3 lb ai/A (EC);<br>– remove use on snap beans and lima beans (EC only);<br>-- remove use on sugar cane (EC only);<br>-- remove use on sweet corn and field corn (EC only);<br>-- remove post-plant applications to sweet and field corn;<br>– remove broadcast applications to sweet potatoes (all formulations);<br>-- remove broadcast applications to cabbage (EC only); and<br>-- restrict the maximum number of applications to one application per growing season for all field crops, except for bananas, plantains, and pineapples (all formulations). | N/A |

## VI. APPENDICES

This section includes Appendices that provide a listing of all related documents and how to access them, a data call-in (DCI), and other information.

All documents supporting the ethoprop IRED, in hard copy form, may be viewed in the OPP Public Regulatory Docket room or downloaded or viewed via the Internet at the following site: "http://www.epa.gov/pesticides/op". The OPP Public Docket is 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.

## Appendix A. Table of Use Patterns Eligible for Reregistration for Ethoprop

| Site: Application Type / Application Timing / Application Equipment | Formulation [EPA Reg. No./ SLN No.] | Maximum Single Application Rate [a] | Maximum Number of Appls. [b] | Minimum Retreatment Interval | Use Limitations |
|---|---|---|---|---|---|
| **Food/Feed Crop Uses** | | | | | |
| **Bananas/Plantains** | | | | | |
| Application to soil adjacent to stem<br>Growing plants<br>Ground equipment | 15% G<br>[264-457] | 10.6 lb ai/A;<br>rate on a per plant basis: 0.2 oz (6 grams) of ai | 2 per year | 6 months | Treat only the soil within a radius of 30 inches (3/4 meters) of plant stem. |
| Application to soil adjacent to stem<br>Growing plants<br>Drip irrigation system | 6 lb/gal EC<br>[264-458] | 10.6 lb ai/A;<br>rate on a per plant basis: 8 mL of EC (6 grams ai) | | | |
| **Beans (Lima and Snap)** | | | | | |
| Broadcast<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 8.1 lb ai/A | 1 | NA | Use of EC on both lima and snap beans has been voluntarily deleted. |
| Banded<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 3 lb ai/A;<br>0.21 lb ai/1000 ft of row (minimum of 12" band, 36" row spacing) | | | |
| **Cabbage** | | | | | |
| Broadcast<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 5.1 lb ai/A | 1 | NA | |
| Banded<br>At planting<br>Ground equipment | 15% G<br>[264-457] | 1.95 lb ai/A;<br>0.135 lb ai/1000 ft of row (15" band, 36" row spacing) | | | |
| Banded<br>At planting<br>Ground equipment | 6 lb/gal EC<br>[264-458] | 1.65 lb ai/A;<br>2.4 fl oz of EC/1000 ft of row (minimum of 12" band, 36" row spacing) | 1 | NA | Only banded applications to cabbage are allowed for the EC because broadcast applications of EC to cabbage have been voluntarily deleted. |

| Site: Application Type / Application Timing / Application Equipment | Formulation [EPA Reg. No./ SLN No.] | Maximum Single Application Rate [a] | Maximum Number of Appls. [b] | Minimum Retreatment Interval | Use Limitations |
|---|---|---|---|---|---|
| **Corn (Field and Sweet)** | | | | | |
| Broadcast<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 6 lb ai/A | 1 | NA | Use of the EC on both field and sweet corn has been voluntarily deleted. |
| Banded<br>At planting<br>Ground equipment | 15% G<br>[264-457] | 4 lb ai/A;<br>0.15 lb ai/1000 ft of row (minimum of 12" band, 20-40" row spacing) | | | |
| **Cucumbers** | | | | | |
| Banded<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 1.95 lb ai/A;<br>0.315 lb ai/1000 ft of row (minimum of 12" band, 7 ft row spacing) | 1 | NA | |
| | 6 lb/gal EC<br>[264-458] | 1.58 lb ai/A;<br>5.3 fl oz of EC/1000 ft of row (minimum of 12" row, 7 ft row spacing) | | | |
| **Pineapple** | | | | | |
| Chemigation<br>Beginning at planting, and continuing to growing plants<br>Drip irrigation system | 6 lb/gal EC<br>[264-458] | 6 lb ai/A<br>(see Use Limitations for information on maximum application rates for the plant and ratoon crops) | 8 for at planting crop; and 5 for ratoon crop | 2 months | For use only in Hawaii and Puerto Rico.<br>A 120-day PHI is specified.<br>A maximum of 8 applications or 48 lb ai/A can be applied to the at planting crop, and 5 applications or 30 lb ai/A can be applied to the ratoon crop. |
| Banded<br>Preplant application over planting beds, with spot applications allowed 3-6 months after planting<br>Ground equipment | 10% G<br>[PR920002] [c] | 6 lb ai/A | 4 per year | 3 months | A 120-day PHI is specified.<br>For use only in Puerto Rico. |

| Site: Application Type / Application Timing / Application Equipment | Formulation [EPA Reg. No./ SLN No.] | Maximum Single Application Rate [a] | Maximum Number of Appls. [b] | Minimum Retreatment Interval | Use Limitations |
|---|---|---|---|---|---|
| **Potatoes** | | | | | |
| Broadcast<br>Preplant to preemergence<br>Ground equipment | 15% G<br>[264-457]<br>6 lb/gal EC<br>[264-458] | 12 lb ai/A<br>(see Use Limitations for additional information on geographical restrictions) | 1 | NA | The maximum application rate for the treatment of nematodes west of the Mississippi River is 12 lb ai/A. For nematodes east of the Mississippi River, the maximum application rate is 9 lb ai/A. For wireworms, the maximum application rate is 6 lb ai/A nationally. |
| Banded<br>At planting<br>Ground equipment | 15% G<br>[264-457] | 3 lb ai/A;<br>0.21 lb ai/1000 ft of row (12" band, 36" row spacing) | | | |
| | 6 lb/gal EC<br>[264-458] | 3 lb ai/A;<br>4.4 fl oz of EC/1000 ft of row (12" band, 36" row spacing) | | | |
| | 10% G<br>[ME930003] [c] | 3 lb ai/A;<br>0.21 lb ai/1000 ft of row (minimum of 5" band, 36" row spacing) | | | |
| **Sugarcane** | | | | | |
| Broadcast<br>At planting<br>Ground equipment | 10% G<br>[FL850001] [c] | 6 lb ai/A | 1 | NA | Use of the EC product on sugar cane has been voluntarily deleted. |
| Banded<br>At planting<br>Ground equipment | 10G<br>[FL850001] [c]<br>15% G<br>[264-457]<br>20% G<br>[264-469] | 4 lb ai/A;<br>0.56 lb ai/1000 ft of row (minimum of 12" band; 6 ft row spacing) | | | |

| Site: Application Type / Application Timing / Application Equipment | Formulation [EPA Reg. No./ SLN No.] | Maximum Single Application Rate [a] | Maximum Number of Appls. [b] | Minimum Retreatment Interval | Use Limitations |
|---|---|---|---|---|---|
| **Sweet Potatoes** | | | | | |
| Banded<br>Preplant<br>Ground equipment | 15% G<br>[264-457] | 3.9 lb ai/A;<br>0.315 lb ai/1000 ft of row (minimum of 12" band, 42" row spacing) | 1 | NA | Only banded applications to sweet potatoes are allowed, because broadcast applications to sweet potatoes have been voluntarily deleted. |
| | 6 lb/gal EC<br>[264-458] | 3.9 lb ai/A;<br>6.9 fl oz of EC/1000 ft of row (minimum of 12" band, 42" row spacing) | | | |
| **Non Food/Feed Uses** | | | | | |
| **Citrus (Non-bearing trees)** | | | | | |
| Banded application to soil between tree rows<br>Growing plants<br>Ground equipment | 6 lb/gal EC<br>[FL870001] | 5 lb ai/A;<br>3.7 fl oz of EC/1000 sq. ft. | 2 per season | (See Use Limitations) | Only apply to the soil, only to non-bearing trees (i.e., trees that will not produce marketable fruit within 12 months after last application).<br>Application timing should be based on the species of root weevil that is infesting the grove and its life cycle. The treatments should be timed to coincide with either the adult emergence and/or neonate larvae dropping to soil surface. |

| Site: Application Type / Application Timing / Application Equipment | Formulation [EPA Reg. No./ SLN No.] | Maximum Single Application Rate [a] | Maximum Number of Appls. [b] | Minimum Retreatment Interval | Use Limitations |
|---|---|---|---|---|---|
| **Ornamentals (Field nursery stock only)** | | | | | |
| Broadcast only to soil<br>Preplant<br>Ground equipment | 6 lb/gal EC | 3 lb ai/A | 1 | NS | Nursery stock may only be mechanically transplanted into the treated area, and not until 72 hours after treatment. |
| **Tobacco** | | | | | |
| Broadcast<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457]<br>6 lb/gal EC<br>[264-458] | 6 lb ai/A | 1 | NA | |
| Banded<br>Preplant or at planting<br>Ground equipment | 15% G<br>[264-457] | 6 lb ai/A;<br>0.96 lb ai/1000 ft of row (minimum of 18" band, with 42" row spacing) | | | |
| | 6 lb/gal EC<br>[264-458] | 6 lb ai/A;<br>10.3 fl oz of EC/1000 ft of row (minimum of 18" band, with 42" row spacing) | | | |

[a] For banded applications, the maximum rate is expressed both as the maximum rate per acre as lb ai/A, as well as the maximum rate per linear 1000 ft row, as lb ai (for the granular products) or fl. oz. ai (for the EC) per 1000 ft linear row, with the minimum band width and row spacing listed in parentheses.

[b] Maximum number of applications for the growing crop. Note that for tropical crops (bananas, plantains, and pineapples), the at planting and the ratoon crops may take more than a year to mature. In addition, for some agricultural row crops, in some parts of the country, more than one crop per year may be grown, but each growing crop may only be treated one time (i.e., one treatment per crop season).

[c] Each of these granular Special Local Needs (SLN) registered products are based on the 10G formulation. The 10G product registration is to be voluntarily cancelled on December 31, 2001.

**Appendix B.** **Generic Data Requirements and Studies Utilized to Make the IRED for Ethoprop**

## GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the IRED for the active ingredient within Case #0106 (ethoprop). It contains generic data requirements that apply to Ethoprop in all products, including data requirements for which a "typical formulation" is the test substance. The data table is organized as follows:

1. Data Requirement (Columns 1 to 3). The data requirements are listed in the general order in which they appear in 40 CFR part 158, with new OPPTS Guideline Numbers (GLNs) in column 1 and old GLNs in column 2. The name of each GLN Data Requirement is listed in column 3. The GLNs also refer to the Pesticide Assessment Guidance test protocols, 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 each data requirement applies. The following letter designations are used for the 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 lists the identity number for each study, usually the Master Record Identification (MRID) number. Refer to the Bibliography in Appendix D for a complete citation of the study.

**Table of Data Supporting the Guideline Requirements for the IRED for Ethoprop**

| PRODUCT CHEMISTRY | | | | |
|---|---|---|---|---|
| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
| 830.1550 | (61-1) | Product Identity and Composition | All | 00152115, 410044-01, 413044-01, 452063-01, 453885-04 |
| 830.1600 | (61-2(a)) | Starting Materials and Manufacturing Processes | All | 410044-01 |
| 830.1670 | (61-2(b)) | Formation of Impurities | All | 00152115, 410044-01 |
| 830.1700 | (62-1) | Preliminary Analysis | All | 00152115, 412112-03 |
| 830.1750 | (62-2) | Certification of Limits | All | 00152115, 412112-03 |
| 830.1800 | (62-3) | Analytical Method | All | 00152115, 412112-03 |
| 830.6302 | (63-2) | Color | All | 410553-01, 429535-01 |
| 830.6303 | (63-3) | Physical State | All | 410553-01 |
| 830.6304 | (63-4) | Odor | All | 410553-01 |
| 830.7050 | None | UV/Visible Absorption | All | Data Gap |
| 830.7200 | (63-5) | Melting Point | All | Not Applicable: Ethoprop is a liquid at room temperature. |
| 830.7220 | (63-6) | Boiling Point | All | 410553-01 |
| 830.7300 | (63-7) | Density | All | 00142272 |
| 830.7840 830.7860 | (63-8) | Solubility | All | 00142272 |
| 830.7950 | (63-9) | Vapor Pressure | All | 00142272 |
| 830.7370 | (63-10) | Dissociation Constant | All | Waived: Ethoprop does not contain any ionizable functional groups, and does not dissociate in water. |
| 830.7550 | (63-11) | Octanol/Water Partition Coefficient | All | 00142272 |
| 830.7000 | (63-12) | pH | All | 00142272 |
| 830.6313 | (63-13) | Stability | All | 410553-01 |
| 830.6314 | (63-14) | Oxidizing/Reducing Action | All | 00142272 |
| 830.6315 | (63-15) | Flammability | All | 00142272 |
| 830.6316 | (63-16) | Explodability | All | 00142272, 00152115 |
| 830.6317 | (63-17) | Storage Stability | All | 420448-01 |
| 830.7100 | (63-18) | Viscosity | All | 00142272 |
| 830.6319 | (63-19) | Miscibility | All | 00142272, 410553-01 |
| 830.6320 | (63-20) | Corrosion Characteristics | All | 00142272 |

| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
|---|---|---|---|---|
| **ECOLOGICAL EFFECTS** | | | | |
| 850.2100 | (71-1) | Avian Acute Oral Toxicity ($LD_{50}$) | A, B, C | 00078038, 00092147, 00160000, 05008363, 403784-01 (cited as GS0106004) |
| 850.2200 | (71-2(a)) | Avian Dietary Toxicity ($LC_{50}$) - Quail | A, B, C | 00022923 |
| 850.2200 | (71-2(b)) | Avian Dietary Toxicity ($LC_{50}$) - Duck | A, B, C | 00022923 |
| 850.2400 | (71-3) | Wild Mammal Toxicity | A, B, C | 00078035, 419212-01, 429795-02, 444725-01 |
| 850.2300 | (71-4(a)) | Avian Reproduction - Quail | A, B, C | 443127-01 (partially satisfies); Data Gap |
| 850.2300 | (71-4(b)) | Avian Reproduction - Duck | A, B, C | 443127-02 (partially satisfies); Data Gap (Reserved pending results from avian reproduction in the quail) |
| 850.2500 | (71-5) | Field Study | A, B, C | 449895-03, 449895-04, 450641-01, 451844-02 |
| 850.1075 | (72-1(a)) | Freshwater Fish Acute Toxicity - Warm Water Species (Bluegill) | A, B, C | 00078042, 00160187 |
| 850.1075 | (72-1(b)) | Freshwater Fish Acute Toxicity - Cold Water Species (Rainbow Trout) | A, B, C | 00078042, 00106001 |
| 850.1010 | (72-2) | Freshwater Invertebrate Acute Toxicity | A, B, C | 00068325, 00160188, 436863-03 |
| 850.1075 | (72-3(a)) | Estuarine/Marine Acute Toxicity - Fish | A, B, C | 402284-01, 436863-01 |
| 850.1025 | (72-3(b1)) | Estuarine/Marine Invertebrate Acute Toxicity - Oyster (shell deposition) | A, B, C | 00066341, 436863-02 |
| 850.1035 | (72-3(b2)) | Estuarine/Marine Invertebrate Acute Toxicity - Mysid Shrimp | A, B, C | 402284-01, 436863-02 |
| 850.1045 | (72-3(b3)) | Estuarine/Marine Invertebrate Acute Toxicity - Penaeid Shrimp | A, B, C | 00048779, 402284-01 |
| 850.1400 | (72-4(a)) | Fish-Early Life Stage - Freshwater | A, B, C | 406501-02 |
| 850.1300 | (72-4(b)) | Freshwater Invertebrate - Chronic (Full Life Cycle) | A, B, C | 406501-01, 438774-01 |
| 850.1350 | (72-4(c)) | Estuarine/Marine Invertebrate - Chronic (Full Life Cycle) | A, B, C | 00066341, 444575-01 |
| 850.1500 | (72-5(a)) | Freshwater Fish Life Cycle | A, B, C | Data Gap (Reserved pending results from estuarine/marine fish life cycle study) |
| 850.1500 | (72-5(b)) | Estuarine/Marine Fish Life Cycle | A, B, C | 00066341, 444721-01 (partially satisfies); Data Gap |
| 850.3020 | (141-1) | Honey Bee Acute Contact | A, B, C | 00043714, 00066220 |

| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
|---|---|---|---|---|
| 850.5400 | (122-2) | Aquatic Plant Growth | A, B, C | 402284-01 |
| | | **TOXICOLOGY** | | |
| 870.1100 | (81-1) | Acute Oral Toxicity - Rat | All | 00078035, 444725-01 |
| 870.1200 | (81-2) | Acute Dermal Toxicity - Rabbit | All | 00078035, 429795-02 |
| 870.1200 | (81-2) | Acute Dermal Toxicity - Rat | All | 429795-01 |
| 870.1300 | (81-3) | Acute Inhalation Toxicity - Rat | All | 00128218 |
| 870.2400 | (81-4) | Primary Eye Irritation - Rabbit | All | 00078036 |
| 870.2500 | (81-5) | Primary Skin Irritation - Rabbit | All | 00048774 |
| 870.2600 | (81-6) | Dermal Sensitization | All | Waived due to high acute dermal toxicity of technical ethoprop |
| 870.6100 | (81-7) | Acute Delayed Neurotoxicity - Hen | All | 406094-01(partially satisfies); Data Gap: Neurotoxic Esterase test |
| 870.6200 | (81-8) | Acute Neurotoxicity Screen - Rat | All | 434424-02, 431977-01, 441140-0, 449895-01 |
| 870.6300 | (83-6) | Developmental Neurotoxicity | All | Data Gap; DCI on 9/10/99 for all OPs |
| 870.3100 | (82-1(a)) | 90-Day Feeding - Rodent | All | 425302-01 |
| 870.3150 | (82-1(b)) | 90-Day Feeding - Dog | All | 00075240 |
| 870.3200 | (82-2) | 21-Day Dermal - Rabbit | All | 413044-04, 450348-01 |
| 870.3200 | (82-2) | 21-Day Dermal - Rat | All | 450746-01, 450746-02 |
| 870.3465 | (82-4) | 90-Day Inhalation - Rat | All | Data Gap (Reserved pending analyses of dust associated with granular formulations, and refinements of inhalation exposure estimates) |
| 870.6200 | (82-7) | Subchronic Neurotoxicity - Rat | All | 434424-01 |
| 870.4100 | (83-1(a)) | Chronic Feeding Toxicity - Rat | All | 00138636, 402918-01, 425302-01 |
| 870.4100 | (83-1(a)) | Chronic Feeding Toxicity - Mouse | All | 40356301, 433260-01 |
| 870.4100 | (83-1(b)) | Chronic Feeding Toxicity - Dog | All | 00160179, 414986-01 |
| 870.4200 | (83-2(a)) | Oncogenicity - Rat | All | 402918-01, 425301-01 |
| 870.4200 | (83-2(a)) | Oncogenicity - Mouse | All | 403563-01, 433260-01 |
| 870.3700 | (83-3(a)) | Developmental Toxicity - Rat | All | 413044-02 |
| 870.3700 | (83-3(b)) | Developmental Toxicity - Rabbit | All | 413044-03 |
| 870.3800 | (83-4) | 2-Generation Reproduction - Rat | All | 419212-01 |
| 870.4300 | (83-5) | Combined Chronic Toxicity/ Carcinogenicity - Rat | All | 00138636, 402918-01, 425302-01 |
| 870.5140 | (84-2(a)) | Gene Mutation (Ames Test) | All | 00160180, 00160181, 440650-01 |

| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
|---|---|---|---|---|
| 870.5375 | (84-2(b)) | Structural Chromosomal Aberration | All | 00160183, 403869-01, 412112-02 |
| 870.5550 | (84-4) | Other Genotoxic Effects - Unscheduled DNA Synthesis in Mammalian Cells in Culture | All | 00160182, 440387-02 |
| 870.5900 | (84-4) | Other Genotoxic Effects - In Vitro Sister Chromatid Exchange | All | 00160184 |
| 870.7485 | (85-1) | General Metabolism | All | 418043-01 |
| **OCCUPATIONAL/RESIDENTIAL EXPOSURE** | | | | |
| 875.2400 | (133-3) | Dermal Passive Dosimetry Exposure | A, B, C | 449841-01, 451131-02, 451672-01, 452507-02 |
| 875.2500 | (133-4) | Inhalation Passive Dosimetry Exposure | A, B, C | 449841-01, 451131-02, 451672-01, 452507-02 |
| 875.2400 | (133-3) | Transferable Turf Residue | A, B, C | 449722-01,449722-03 |
| 875.2400 | (133-3) | Granular Handler Exposure | A, B, C | 449722-01,449722 -06, 449722-07 |
| 875.1500 | | Worker Biomonitoring with the EC Formulation | A, B, C | Data Gap |
| 875.1350 SS | | Information Concerning the Granular Formulations | A, B, C | 438525-01, 450797-06, 452063-01, 452063-02, 453885-04, 453885-05 (partially satisfies); Data Gap |
| 875.2800 | | Description of Human Activities for Post-Application | A, B, C | Data Gap |
| **ENVIRONMENTAL FATE** | | | | |
| 835.2120 | (161-1) | Hydrolysis | All | 412707-03 |
| 835.2240 | (161-2) | Photodegradation - Water | All | 412707-02, 438335-02 |
| 835.2410 | (161-3) | Photodegradation - Soil | All | 412707-04, 438335-01 |
| 835.4100 | (162-1) | Aerobic Soil Metabolism | All | 00160171 |
| 835.4200 | (162-2) | Anaerobic Soil Metabolism | All | 00160171 |
| 835.4300 | (162-4) | Aerobic Aquatic Metabolism | All | 449895-02 |
| 835.1240 | (163-1) | Leaching/Adsorption/Desorption | All | 437786-01 |
| 835.1410 | (163-2) | Laboratory Volatility | All | 412112-01 |
| 835.6100 | (164-1) | Terrestrial Field Dissipation | All | 417124-01, 443980-01 |
| 860.1850 | (165-1) | Confined Rotational Crop | All | 421976-01 |
| 860.1900 | (165-2) | Field Rotational Crop | All | 443502-01 |
| None | (165-4) | Bioaccumulation in Fish | All | 414256-01, 414256-02, 430384-01, 430384-02 |
| 835.7100 | (166-1) | Ground Water Monitoring Study | All | Data Gap |

| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
|---|---|---|---|---|
| 835.7200 | | Surface Water Monitoring Study | All | Data Gap |
| | | **RESIDUE CHEMISTRY** | | |
| 860.1300 | (171-4(a)) | Nature of Residue - Plants | A, B, C | 00040380, 00075252, 00075253, 00075354, 00075255, 00075256, 00092103, 406532-05, 416910-01, 418140-01, 418408-01, 419460-01, 438364-01, 438687-01 |
| 860.1300 | (171-4(b)) | Nature of Residue - Livestock | A, B, C | 00092070, 429232-01, 429627-01, 432090-01 |
| 860.1340 | (171-4(c)) | Residue Analytical Method - Plants | A, B, C | 00075245, 00075246, 00092079, 00092080, 00125395, 00125397, 00129928, 00145970, 00153065, 00153326, 00154203, 00160441, 422206-01, 432775-02, 433736-01, 443215-01; Data Gap |
| 860.1360 | (171-4(m) | Multiresidue Method | A, B, C | 412707-01, 422421-01 |
| 860.1380 | (171-4(e)) | Storage Stability | A, B | 00160441, 435394-01, 439715-01; Data Gap |
| 860.1480 | (171-4(j)) | Magnitude of Residues - Meat, Milk, Poultry, and Egg | A, B, C | 00092101 |
| 860-1500 | (171-4(k)) | **Magnitude of Residue in Crop Plants - Crop Field Trials** | | |
| 860.1500 | (171-4(k)) | Crop Field Trials (Potatoes) | A | 00153065, 400285-02; Data Gap |
| 860.1500 | (171-4(k)) | Crop Field Trials (Sweet Potatoes) | A | 00075252 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Cabbage) | A | 00092068, 00125397, 435832-01; Data Gap |
| 860.1500 | (171-4(k)) | Crop Field Trials (Beans, Lima) | A | 406532-04, 435396-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Beans, Snap) | A | 406532-04, 435386-01; Data Gap |
| 860.1500 | (171-4(k)) | Crop Field Trials (Soybeans) | A | 00076720, 00092072, 00092074 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Lima and Snap, Forage) | A | 406532-04 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Soybean, Forage and Hay) | B | 00076720, 406532-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Cucumbers) | A | 406532-04, 434840-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Corn, Fresh (inc. Sweet) (K+CWHR)) | A | 00075249, 00075250, 00092108, 00092109, 00092135, 406532-07, 434910-01, 437482-03 |

| New Guideline Number | (Old Guideline Number) | Requirement | Use Pattern | Citation(s) (MRID) |
|---|---|---|---|---|
| 860.1500 | (171-4(k)) | Crop Field Trials (Corn, Grain (inc. pop)) | A | 00075249, 00075250, 00092108, 00092109, 00092135, 406532-07, 435309-01, 437482-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Corn, Forage and Fodder) | B | 00075249, 00075250, 00092108, 00092109, 00092135, 406532-07, 435309-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Banana) | A | 406532-06 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Mushrooms) | A | 00030481, 00030482 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Okra) | A | 00125395 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Peanut) | A | 00092106, 00092116, 00129928, 00141494, 406532-02, 435397-01, 440624-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Peanut Hay) | B | 00092106, 00092116, 00129928, 00141494, 406532-02, 435397-01, 440624-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Pineapple) | A | 00092070, 00154203, 429016-01 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Pineapple, Fodder and Forage) | B | 00092070, 00154203 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Sugarcane) | A | 406532-03 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Sugarcane, Fodder and Forage) | B | 406532-03 |
| 860.1500 | (171-4(k)) | Crop Field Trials (Tobacco) | C | 00145970, 00153065, 418096-01 |
| 860.1520 | (171-4(l)) | **Magnitude of Residues in Processed Food/Feed** | | |
| 860.1520 | (171-4(l)) | Processed Food (Corn) | A | 437482-02 |
| 860.1520 | (171-4(l)) | Processed Food (Peanut) | A | 435398-01, 440033-01 |
| 860.1520 | (171-4(l)) | Processed Food (Pineapple) | A | 429455-01 |
| 860.1520 | (171-4(l)) | Processed Food (Potato) | A | 433736-01 |
| 860.1520 | (171-4(l)) | Processed Food (Soybean) | A | Uses have been deleted from label |
| 860.1520 | (171-4(l)) | Processed Food (Sugarcane) | A | 432775-01, 439715-01 |
| 810.1000 | 90-1 | Use/Usage Data | A, B, C | 449702-01 452859-01 |
| 860.1850 | (165-1) | Confined Accumulation in Rotational Crops | A, B | 421976-01 |
| 860.1900 | (165-2) | Field Accumulation in Rotational Crops | A, B | 443502-01 |

## Appendix C. Technical Support Documents Utilized to Make the IRED for Ethoprop

Additional documentation in support of this IRED 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.

The docket initially contained preliminary human health risk assessment and related documents as of May 21, 1998, and the preliminary environmental risk assessment as of October 5, 1998. Sixty days after each of these documents became available, the first public comment periods closed. The EPA then considered comments, revised the risk assessments, and added the formal "Response to Comments" document and the revised risk assessments to the docket on September 2, 1999.

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/op

These documents include:

Human Health and Effects Documents:

1. Ethoprop - Report of the Cancer Assessment Review Committee. (Jess Rowland, October 2, 1997)
2. Ethoprop - FQPA Requirement - Report of the Hazard Identification Assessment Review Committee. (Jess Rowland, November 10, 1997)
3. Memorandum. HED Metabolism Committee Meeting on 1/27/98. (Kit Farwell, February 6, 1998)
4. Review of Ethoprop Incident Reports. (Jerome Blondell and Monica F. Spann, March 9, 1998)
5. Ethoprop, Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision. (John Abbots, March 27, 1998)
6. Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Ethoprop. (Kathryn Boyle, April 2, 1998)
7. Toxicology Chapter for the Reregistration Eligibility Document for Ethoprop. (Kit Farwell, April 17, 1998)
8. Ethoprop. Anticipated Residues for Acute and Chronic Non-Cancer Dietary Exposure. (Sheila Piper, April 23, 1998)
9. Ethoprop. Anticipated Residues for Chronic (Cancer) Dietary Exposure. (Sheila Piper, April 29, 1998)
10. Ethoprop. Acute and Chronic Dietary Risk Analyses for the HED RED Chapter. (Christina Swartz, May 5, 1998)

11. Organophosphate Pesticides: Ethoprop Human Health Risk Assessment. (Kit Farwell, May 21, 1998)
12. Memo. HED Hazard Identification Assessment Review Committee. (Jess Rowland, June 3, 1998)
13. Ethoprop Revised Human Health Risk Assessment, Attachment 3. Addendum to Toxicology Chapter. Selection of Inhalation Endpoints. Assessment by the Hazard Identification Assessment Review Committee and the FQPA Safety Factor Committee. (Kit Farwell, August 31, 1998)
14. Ethoprop Revised Human Health Risk Assessment, Attachment 4. Response to the USDA Comments to the EPA's Monte Carlo Dietary Exposure estimate for Ethoprop and Further Refinements. (Sheila Piper, July 12, 1999)
15. Ethoprop Revised Human Health Risk Assessment, Attachment 5. Revised Chronic Dietary Exposure Analyses for the HED Risk Assessment. (Christina Swartz, July 21, 1999)
16. Ethoprop Revised Human Health Risk Assessment, Attachment 6. Revised Occupational/Non-Occupational/Residential Exposure Assessment for the Reregistration Eligibility Decision. (Catherine Bodurow Joseph, September 2, 1999)
17. Ethoprop Revised Human Health Risk Assessment. (Kit Farwell, September 2, 1999)
18. Ethoprop - Revised Report of the Hazard Identification Assessment Review Committee. (Kit Farwell, May 15, 2000)
19. Ethoprop: Revised Occupational/Non-Occupational/Residential Exposure Assessment For Reregistration Eligibility Decision (RED) Document. (Jeffrey Dawson, May 18, 2000)
20. Ethoprop - Review of aldicarb (Temik 10G) granular backpack mixer/loader/applicator study (MRID 451672-01) in bananas as a source of surrogate data for ethoprop exposure and assessment. (Jeffrey Dawson, October 17, 2000)
21. Ethoprop - Review of fipronil granular mixer/loader/applicator study (MRID 452501-01) in bananas as a source of surrogate data and accompanying ethoprop risk assessment. (Jeffrey Dawson, January 5, 2001)

Environmental Fate and Effects Documents:

1. Ethoprop Tier II EECs. (Sid Abel, May 26, 1998)
2. Environmental Fate and Effects Division RED Chapter for Ethoprop. (Sid Abel, N.E. Federoff, Dana Spatz, Ann Stavola, October 5, 1998)
3. Errata Sheets. (November 18, 1998; February 18, 1999; August 30, 1999)
4. Review of Aerobic Aquatic Metabolism study (162-4) and updated tier II drinking water EECs for Ethoprop for use in the human health risk assessment. (Dana S. Spatz and Dirk F. Young, April 24, 2000)
5. Revised ethoprop drinking water assessment. (Jim Cowles, March 26, 2001)

Risk Management Documents:

1. Memorandum. Notes on Ethoprop SMART Meeting on 10/30/97. (Judy Loranger, October 31, 1997)

2. Overview of Revised Ethoprop Risk Assessment - prepared for Technical Briefing. (Kathryn Boyle, September 2, 1999)
3. Response to Comments on Preliminary Risk Assessment for the Organophosphate Ethoprop. (Kathryn Boyle, September 2, 1999)

Biological and Economic Analysis Documents

1. EPA's Quantitative Usage Analysis. (John Faulkner, August 1, 1998, revised February 2, 1999)
2. Specific Request Concerning Ethoprop. (John L. Faulkner and William L. Gross, Jr., April 6, 2000)
3. Review of National Potato Council's Response to EPA Questions Regarding Ethoprop. (John L. Faulkner and William L. Gross, Jr., July 5, 2000)

**Appendix D. Citations Supporting the IRED for Ethoprop (Bibliography)**

**GUIDE TO APPENDIX D**

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by the Agency in arriving at the positions and conclusions stated elsewhere in the Interim Reregistration Eligibility Decision (IRED) document. Primary sources for studies in this bibliography have been the body of data submitted to the Agency 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 MRID, each entry consists of a citation containing standard elements followed, in the case of material submitted to the Agency, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1)Submission date. The date of the earliest known submission appears immediately following the word "received."

(2)Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3)Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4)Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA Accession Number of the volume in which the original submission of the study appears. The six-digit Accession Number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

| MRID # | CITATION |
|---|---|
| 00022923 | Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report) |
| 00030481 | Snetsinger, R.; Kanuk, M.J. (1979) Ethoprop Residue Tolerance Petition--Mushrooms: Summary. (Unpublished study including PR No. 908 and Laboratory No. 6E-2554, received Mar 27, 1980 under 0E2341; prepared by New York State Agricultural Experiment Station, Northeast Regional Pesticide Laboratory and Cannon Laboratories, Inc., submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:099351-A) |
| 00030482 | Snetsinger, R.; Chung, S.L.; Kielbasa, R.; et al. (1979) Ethoprop: Sciarid Fly Control in Mushrooms. (Unpublished study including PR No. 908 and published data, received Mar 27, 1980 under 0E2341; prepared in cooperation with Pennsylvania State Univ., Dept. of Entomology, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:099351-C) |
| 00040380 | Menzer, R.E.; Iqbal, Z.M.; Boyd, G.R. (1971) Metabolism of O-Ethyl S,S-dipropyl phosphorodithioate (Mocap) in bean and corn plants. Journal of Agricultural and Food Chemistry 19(2):351-356. (Also in unpublished submission received Sep 2, 1971 under 2F1204; submitted by Mobil Chemical Co., Richmond, Va.; CDL:094057-D) |
| 00048774 | Becker, J. Parke, G.S.E. (1977) Report: A Primary Dermal Irritation Study of Ethoprop 93% Technical Grade on Abraded and Nonabraded Skin of New Zealand Albino Rabbits: Laboratory No. 7E-6084. (Unpublished study received July 15, 1977 under 2224-43; prepared by Cannon Laboratories, Inc., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:230885-C) |
| 00048779 | Vilkas, A.G. (1977) Acute Toxicity of Mocap to the Grass Shrimp, Palaemonetes pugio, and Fiddler Crab, Uca pugilator: UCES Project # 11506-05-04. (Unpublished study received Jul 15, 1977 under 2224-43; prepared by Union Carbide Corp., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:230885-H) |

| MRID # | CITATION |
|---|---|
| 00066341 | U.S. Environmental Protection Agency, Environmental Research Laboratory (1981) Acephate, Aldicarb, Carbophenothion, DEF, EPN, Ethoprop, Methyl Parathion, and Phorate: Their Acute and Chronic Toxicity, Bioconcentration Potential, and Persistence as Related to Marine Environments: EPA-600/4-81-023. (Unpublished study) |
| 00043714 | Atkins, E.; Kellum, D.; Neuman, K.; et al. (1975) Effect of Pesticides on Apiculture: Project No. 1499. 1975 annual rept. (Unpublished study received Mar 8, 1976 under 201-EX-50; prepared by Univ. of California--Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology, submitted by Shell Chemical Co., Washington, DC; CDL:095407-U) (Study is duplicate of MRID# 00111934) |
| 00068325 | Vilkas, A.G. (1977) Acute Toxicity of Ethoprop to the Water Flea, Daphnia magna Straus: UCES Proj. # 1506-05-03. (Unpublished study received Aug 16, 1977 under 2224-44; prepared by Union Carbide Corp., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:231370-B) |
| 00066220 | Atkins, E.; Anderson, L.; Kellum, D.; et al. (1977) Protecting Honey Bees from Pesticides. Riverside, CA: Univ. of California. (Leaflet 2883; also In unpublished submission received Nov 2, 1983 under 239-2507; submitted by Chevron Chemical Co., Richmond, CA; CDL:251760-B) (Study is duplicate of MRID# 00132710) |
| 00075239 | Weir, R.J. (1967) Final Report: Three-month Dietary Administration--Rats: Project No. 230-102. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:091296-C) |
| 00075240 | Weir, R.J.; Kundzins, W. (1967) Final Report: 13-week Dietary Administration -- Dogs: Project No. 230-110. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:091296-D) |
| 00075245 | Mobil Chemical Company (19??) The Determination of Residues of Mocap on Corn Products. Undated method. (Unpublished study received Nov 25, 1968 under 9F0750; CDL:091296-J) |
| 00075246 | Mobil Chemical Company (19??) Analysis of Fortified Samples. (Unpublished study received Nov 25, 1968 under 9F0750; CDL:091296-K) |

| MRID # | CITATION |
|---|---|
| 00075249 | Mobil Chemical Company (1966) Summary--Results of Corn Sample Analyses for Mocap Residues. (Compilation; unpublished study received Nov 25, 1968 under 9F0750; CDL:091296-N) |
| 00075250 | Boyd, G.R. (1968) Residues of Mocap in Corn Plants Treated at Exaggerated Rates: Project No. 532. (Unpublished study received Nov 25, 1968 under 9F0750; submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:091296-O) |
| 00075252 | DuVal, A.F.; Boyd, G.R. (1967) The Persistence of Mocap in Treated Soil: RN 67-3. (Unpublished study received Nov 25, 1968 under9F0750; submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:091296-Q) |
| 00075253 | Menzer, R.E. (1967) Uptake and Metabolism of Mocap by Plants. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Univ. of Maryland, Dept. of Entomology, submitted by Mobil Chemical Co., Industrial Chemical Div., Richmond, Va.; CDL:091296-R) |
| 00075254 | Menzer, R.E.; Iqbal, M.Z. (1968) Metabolism of Mocap in Beans and Corn. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Univ. of Maryland, Dept. of Entomology, submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:091296-S) |
| 00075255 | Mobil Chemical Company (19??) Gas Chromatography of Mocap Metabolites Formed in Bean Plants and Isolated by Column Chromatography. (Unpublished study received Nov 25, 1968 under 9F0750; CDL:091296-T) |
| 00075256 | Mobil Chemical Company (19??) Chemical Studies on the Metabolism of Mocap in Bean Plants. (Unpublished study received Nov 25, 1968 under 9F0750; CDL:091296-U) |
| 00076720 | Mobil Chemical Company (1980) [Residue of Mocap EC on Peanuts, Soybeans and Other Crops]. (Compilation; unpublished study received Mar 19, 1981 under 2224-44; CDL:244800-A) |
| 00078035 | Powers, M.B. (1965) Acute Oral Administration--Rats; Acute Dermal Application--Rabbits. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:091295-C) |

| MRID # | CITATION |
|---|---|
| 00078036 | Weir, R.J. (1965) Acute Eye Application--Rabbits. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:091295-D) |
| 00078038 | Weir, R.J.; Clark, O. (1966) Acute Oral LD50 -- Hens: Project No. 230-108. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:091295-F) |
| 00078042 | Weir, R.J. (1967) Final Report: Acute Aqueous Exposure--Goldfish, Bluegill, and Rainbow Trout: Project No. 230-111. (Unpublished study received Nov 25, 1968 under 9F0750; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Macedon, N.Y.; CDL:091295-J) |
| 00092068 | Mobil Chemical Company (1971) Summary--Cole Crop Residue Analysis. (Unpublished study received Sep 10, 1972 under 2F1250; CDL:091781-A) |
| 00092070 | Mobil Chemical Company (1969) Mocap Residues in Pineapples. (Unpublished study received on unknown date under 0F0959; CDL:091636-B) |
| 00092072 | Mobil Chemical Company (1969) (Residue Study of Mocap on Soybeans). (Compilation; unpublished study received Apr 11, 1970 under 0F0872; CDL:091505-B) |
| 00092074 | Downing, C.R. (1969) Effects of Excess Mocap (Prophos) Rates on Soybeans: Project No. 253. (Unpublished study received Apr 11,1970 under 0F0872; submitted by Mobay Chemical Co., Ashland, Va.; CDL:091505-D) |
| 00092079 | Mobil Chemical Company (19??) The Determination of Residues of Mocap in Animal Tissues. Undated method. (Unpublished study received Apr 24, 1967 under 9F0750; CDL:093062-E) |
| 00092080 | Mobil Chemical Company (1969) The Determination of Residues of Prophos in Plant Materials. Method R-89-A dated Oct 7, 1969. (Unpublished study received on unknown date under 0F0872; CDL: 093170-A) |
| 00092101 | Holsing, G.C. (1968) Final Report: 21-day Oral Administration -- Dogs: Project No. 230-124. (Unpublished study received Jan 20, 1970 under 0F0872; prepared by Hazleton Laboratories, Inc., submitted by Mobil Chemical Co., Ashland, Va.; CDL:094845-A) |

| MRID # | CITATION |
|---|---|
| 00092103 | Mobil Chemical Company (1968) The Fate of Mocap in Soil and Plants. (Unpublished study received on unknown date under 9F0750; CDL:098645-D) |
| 00092106 | Mobil Chemical Company (1972) [Residue Study of Mocap on Peanuts]. Includes method R-89-A dated Oct 7, 1969. (Compilation; unpublished study received Apr 14, 1972 under 2224-37; CDL:119790-A) |
| 00092108 | Mobil Chemical Company (1972) Summary of Residue Analyses: [Mocap]. Includes method R-89-A dated Oct 7, 1969. (Compilation; unpublished study received Mar 9, 1972 under 2224-37; CDL:119792-A) |
| 00092109 | Mobil Chemical Company (1971) Summary of Residue Analyses. Includes Method R-89-A dated Oct 7, 1969. (Compilation; unpublished study received Mar 9, 1972 under 2224-37; CDL:119793-A) |
| 00092116 | Mobil Chemical Company (1974) [Determination of Residues of Ethoprop in Various Crops]. Includes Method R-89-A. (Compilation; unpublished study, including published data, received Dec 17, 1974 under 2224-48; CDL:220399-C) |
| 00092135 | Mobil Chemical Company (1976) Summary of Residue Data: Mocap EC--Corn. (Compilation; unpublished study received Mar 29, 1977 under 2224-44; CDL:229328-A) |
| 00092147 | Fink, R.; Beavers, J.B.; Brown, R. (1978) Final Report: Acute Oral LD50 -- Mallard Duck: Ethoprop Technical: Project No. 155-104. (Unpublished study received Jan 4, 1979 under 2224-54; prepared by Wildlife International, Ltd., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:236710-C) |
| 00125395 | Interregional Research Project No. 4 (1978) The Results of Tests on the Amount of Residues Remaining in or on Okra, Including a Description of the Analytical Method Used: [Ethoprop]. (Compilation; unpublished study received Mar 14, 1983 under 359-703; CDL:071458-A) |
| 00125397 | Interregional Research Project No. 4 (1982) The Results of Tests on the Amount of [Ethoprop] Residues Remaining in or on Broccoli and Cabbage, Including a Description of the Analytical Method Used. (Compilation; unpublished study received Mar 14, 1983 under 3E2852; CDL:071459-A) |

| MRID # | CITATION |
|---|---|
| 00128218 | Duckworth, S.; Rusch, G.; Rinehart, W. (1980) An Acute Inhalation Toxicity Study of MCTR 206-79 in the Rat: Project No. 79-7332. (Unpublished study received May 4, 1981 under 2224-44; prepared by Bio/dynamics, Inc., submitted by Interregional Research Project No. 4, New Brunswick, NJ; CDL:070060-B) |
| 00129928 | Guyton, C. (1983) Ethoprop Residue Data on Peanuts Treated with a Narrow Band Application of Mocap 10G: 1982 Field Program C-7: ASD No. 83/026. (Unpublished study received Jul 26, 1983 under 359-703; prepared by Morse Laboratories, Inc., submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:250798-A) |
| 00138636 | Barnett, J.; Jenkins, L.; Parent, R.; et al. (1983) Evaluation of the Chronic Toxicity and Oncogenic Potential of Ethoprop in Fischer 344 Rats: GSRI Project No. 413-858-41. Final rept. (Unpublished study received Feb 8, 1984 under 359-694; prepared by Gulf South Research Institute, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:252358-A; 252359) |
| 00141494 | Guyton, C. (1984) Ethoprop Residue Data for Peanut Hay, Hulls and Nutmeat Following Two Applications of Mocap 10G: ASD No. 84/082. Unpublished study prepared by Rhone-Poulenc Inc. 48 p. |
| 00142272 | Orth, D. (1984) Product Chemistry Testing for Ethoprop Technical and Granular Formulation (MOCAP 10G): Final Report: Project Number 84-PL-34; 84-PL-28. Unpublished study prepared by Biospherics Inc. 12 p. |
| 00145970 | Guyton, C. (1984) Ethoprop Residue Data on Green and Flue Cured Tobacco: ASD No. 84/085. Unpublished compilation prepared by Rhone-Poulenc, Inc. and Morse Laboratories, Inc. 43 p. |
| 00152115 | Beche, R. (1984) Ethoprop, Technical Grade Analysis and Certification of Product Ingredients. Unpublished study prepared by Rhone-Poulenc Agrochimie. 118 p. |
| 00153065 | Rhone-Poulenc Inc. (1985) Residue Data for Ethoprop. Unpublished compilation. 131 p. |
| 00153326 | Guyton, C. (1985) Ethoprop Residue Data for California Cole Crops Treated with Mocap EC at 12 LB AI/A and Ethoprop Residue Data for Brussels Sprouts Treated with Mocap 5G at 12 LB AI/A . Unpublished compilation prepared by Rhone-Poulenc Inc. 102 p. |

| MRID # | CITATION |
|---|---|
| 00154203 | Yanagihara, K. (1983) Residue Data in/on Pineapple Resulting from Mocap Drip Irrigation Treatments. Unpublished study prepared by University of Hawaii, Dept. of Agricultural Biochemistry. 127 p. |
| 00160000 | Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p. |
| 00160171 | Jordan, E. (1986) Metabolism of Ethoprop (...) in Soil under Aerobic and Anaerobic Conditions: ASD No. 86/199. Unpublished study prepared by Rhone-Poulenc Inc. in cooperation with Mobil Environmental and Science Lab. 147 p. |
| 00160179 | Brown, D. (1986) Ethoprophos: 52 Week Oral (Capsule Administration) Toxicity Study in the Beagle: Rept. No. 4923-198/16. Unpublished study prepared by Hazleton Laboratories Europe Ltd. 248 p. |
| 00160180 | Barfknecht, T. (1985) Ames Salmonella/Microsome Plate Test (EPA/OECD): Ethoprop: Study No. PH 301-RP-001-85. Unpublished study prepared by Pharmakon Research International, Inc. 30 p. |
| 00160181 | Stankowski, L. (1985) CHO/HGPRT Mammalian Cell Forward Gene Mutation Assay: Ethoprop: Study No. PH 314-RP-001-85. Unpublished study prepared by Pharmakon Research International, Inc. 52 p. |
| 00160182 | Barfknecht, T. (1985) Rat Hepatocyte Primary Culture/DNA Repair Test: Ethoprop: Study No. PH 311-RP-001-85. Unpublished study prepared by Pharmakon Research International, Inc. 66 p. |
| 00160183 | SanSebastian, J. (1985) In vitro Chromosome Aberration Analysis in Chinese Hamster Ovary (CHO) Cells: Ethoprop: Study No. PH 320-RP-001-85. Unpublished study prepared by Pharmakon Research International, Inc. 50 p. |
| 00160184 | SanSebastian, J. (1986) In vitro Sister Chromatid Exchange in Chinese Hamster Ovary (CHO) Cells: Ethoprop: Study No. PH-319-RP-001-85. Unpublished study prepared by Pharmakon Research International, Inc. 92 p. |
| 00160441 | Perez, G. (1986) Freezer Storage Stability of Ethoprop in Crops: ASD No. 86/194. Unpublished study prepared by Morse Laboratories, Inc. 81 p. |

| MRID # | CITATION |
|---|---|
| 00160187 | Swigert, J.; Bowman, J. (1986) Acute Toxicity of Ethoprop to Blue-gill Sunfish (Lepomis macrochirus): Static Acute Toxicity Report #34319. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 53 p. |
| 00160188 | Forbis, A.; Frazier, S.; Schoen, L. (1986) Acute Toxicity of Ethoprop Technical to Daphnia magna: Static Acute Toxicity Report #34320. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 38 p. |
| 05008363 | Hudson, R.H.; Haegele, M.A.; Tucker, R.K. (1979) Acute oral and percutaneous toxicity of pesticides to mallards: correlations with mammalian toxicity data. Toxicology and Applied Pharmacology 47(3):451-460. |
| 40028502 | Fronek, F. (1986) Crop Residue Information: UAP 101: Study No. 86-8A. Unpublished compilation prepared by The Industrial Laboratories Co. 59 p. |
| 40228401 | Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p. (Study is duplicate of MRID# 40098001) |
| 40291801 | Spicer, E. (1987) Lifetime Dietary Toxicity and Oncogenicity Study in Rats: IRDC Study No. 347-029. Unpublished study prepared by International Research & Development Corp. 2574 p. |
| 40356301 | Inoue, H. (1984) Chronic Feeding and Oncogenicity Studies in Mice with Ethoprop: Rept. No. 497. Unpublished study prepared by Biosafety Research Center (AN-PYO Center). 2490 p. |
| 40378401 | Schafer, E.W.; Brunton, R.B. 1979. Indicator bird species for toxicity determinations: Is the technique usable in test method development? Vertebrate Pest Control and Management Materials, ASTM STP 680, J.R. Beck, Ed., American Society for Testing and Materials, 1979, pp. 157-168. (cited in the EFED Environmental Risk Assessment as reference GS0106004) |
| 40386901 | Dearlove, G. (1987) Dominant Lethal Study of Ethoprop Technical Administered Orally Via Gavage to Crl:COBS CD (SD)BR Male Rats: Final Rept.: Protocol No. 218-004. Unpublished study prepared by Argus Research Laboratories, Inc. 569 p. |

| MRID # | CITATION |
|---|---|
| 40609401 | Roberts, N.; Phillips, C.; Gopinath, C.; et al. (1986) Acute Delayed Neurotoxicity Study with Ethoprophos in the Domestic Hen: Laboratory Project ID: RNP 244/86198. Unpublished study prepared by Huntingdon Research Center Ltd. 63 p. |
| 40650101 | Surprenant, D. (1988) The Chronic Toxicity of Ethoprop Technical to Daphnia magna under Flow-through Conditions: Report #87-10-2512: Study #10566-0986-6105-130. Unpublished study prepared by Springborn Life Sciences, Inc. 44 p. |
| 40650102 | Surprenant, D. (1987) The Toxicity of Ethoprop Technical to Fathead Minnow (Pimephales promelas) Embryos and Larvae: SLS Report #: BW-87-6-2408; SLS Study # 10566.0986.6105.120. Unpublished study prepared by Springborn Life Sciences, Inc. 41 p. |
| 40653201 | Mobil Chemical Co. (1969) Mocap Residues in Soybeans Forage and Hay. Unpublished study prepared by Mobil Research Center, Ashland, VA. 34 p. |
| 40653202 | Mobil Chemical Co. (1969) Mocap Residues in Peanut Vines. Unpublished study prepared by Mobil Research Center, Ashland, VA. 20 p. |
| 40653203 | Mobil Chemical Co. (1971) Mocap (Prophos) Residues in Sugarcane. Unpublished study prepared by Mobil Research Center, Ashland, VA. 65 p. |
| 40653204 | Mobil Chemical Co. (1974) Mocap (Ethoprop) Residues in Cucumber, Beans and White Potato. Unpublished study prepared by Mobil Research Center, Ashland, VA. 107 p. |
| 40653205 | Mobil Chemical Co. (1968) The Fate of Mocap in Soil and Plants. Unpublished study prepared by Mobil Research Center, Ashland, |
| 40653206 | Mobil Chemical Co. (1970) Mocap in Bananas. Unpublished study prepared by Mobil Research Center, Ashland, VA. 43 p. |
| 40653207 | Mobil Chemical Co. (1968) Mocap in Corn. Unpublished study prepared by Mobil Research Center, Ashland, VA. 27 p. |
| 41004401 | Murayama, S. (1989) Ethoprop Technical: Product Identity and Composition: Proj. ID 783C10. Unpublished study prepared by Rhone-Poulenc Ag Co. 83 p. |

| MRID # | CITATION |
|---|---|
| 41055301 | Murayama, S. (1989) Ethoprop Technical: The Technical Grade of the Active Ingredient and the Manufacturing-Use Product: Physical and Chemical Properties: Project ID; 783C10; File No. 40485. Unpublished study prepared by Battelle, Columbus Div. 74 p. |
| 41211201 | Carpenter, M. (1989) Laboratory Volatility from Soil of Ethoprop: ABC Laboratory Project ID 38001. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 784 p. |
| 41211202 | Ivett, J. (1989) Mutagenicity Test on Ethoprop Technical in the Rat Bone Marrow Cytogenetic Assay: HLA Study No. 10750-0-452. Unpublished study prepared by Hazleton Laboratories America, Inc. 38 p. |
| 41211203 | Murayama, S. (1989) Ethoprop Technical: The Technical Grade of the Active Ingredient and the Manufacturing Use Product: Analysis and Certification of Product Ingredients: Laboratory Project ID 783C10. Unpublished study prepared by Rhone-Poulenc Ag Co. 103 p. |
| 41270701 | Ver Hey, M. (1989) Determination of the Characteristics of Ethoprop when Subjected to Analysis by the United States Food and Drug Administration (FDA) Multiresidue Protocol IV (40 CFR 158.125): Project ID: Rhone-Poulenc 1087. Unpublished study prepared by Colorado Analytical Research & Development Corp. 81 p. |
| 41270702 | Carpenter, M. (1989) "Photodegradation of [Carbon 14]-Ethoprop in pH 7 Buffered Solution": Project ID: ABC Final Report No. 38139. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 45 p. |
| 41270703 | Das, Y. (1989) Hydrolysis of [1-Ethyl-[carbon 14]]Ethoprop in Aqueous Solutions Buffered at pH 5, 7, and 9: Project No. ISSI No. 89140. Unpublished study prepared by Innovative Scientific Services, Inc., (ISSI). 76 p. |
| 41270704 | Carpenter, M. (1989) "Determination of the Photolysis Rate of [carbon 14]-Ethoprop on the Surface of Soil": ABC Final Report No. 38140. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 47 p. |
| 41304401 | Murayama, S. (1989) Ethoprop Technical: Physical and Chemical Characteristics: Lab Project Number: 783C10. Unpublished study prepared by Battelle. 85 p. |

| MRID # | CITATION |
|---|---|
| 41304402 | Rodwell, D. (1989) Teratology Study in Rats with Ethoprop: Final Report: Lab Project Number: 3147.39. Unpublished study prepared by Springborn Life Sciences, Inc. 241 p. |
| 41304403 | Rodwell, D. (1989) Teratology Study in Rabbits with Ethoprop: Final Report: Lab Project Number: 3147.41. Unpublished study prepared by Springborn Life Sciences, Inc. 250 p. |
| 41304404 | Henwood, S. (1989) 3-Week Dermal Toxicity Study with Ethoprop Technical in Rabbits: Final Report: Project HLA 6224-152. Unpublished study prepared by Hazleton Laboratories America, Inc. 252 p. |
| 41425601 | Burgess, D. (1990) Uptake, Depuration and Bioconcentration of [Carbon 14]-Ethoprop by Bluegill Sunfish (Lepomis macrochirus). Project Number: 38161. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 41 p. |
| 41425602 | Heitkamp, J. (1990) Characterization of [Carbon 14]-Ethoprop Residues in Bluegill (Lepomis macrochirus) Water and Tissues: Lab Project Number: 38162. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 61 p. |
| 41498601 | Hamada, N. (1990) A Five-month Oral Toxicity Study with One-month Recovery in Beagle Dogs with Ethoprop Technical: Final Report: Lab Project I.D.: 656-143. Unpublished study prepared by Hazleton Laboratories America, Inc. 445 p. |
| 41691001 | Johnson, T. (1990) Metabolic Fate and Distribution of [Carbon 14]-Ethoprop in Cabbage under Field Conditions: Lab Project Nos.: 1302; 337. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 337 p. |
| 41712401 | Norris, F. (1990) A Terrestrial Field Soil Dissipation Study with Ethoprop in Washington and North Carolina: Final Report. Lab Project Numbers 40641; EC/P-89-0012: R109-082/087;R122-009/011: ML 89-0095-RHP. Unpublished study prepared by Rhone-Poulenc Ag Co. in coop with A & L Eastern Ag Labs, Inc. and Morse Labs, Inc. 164 p. |
| 41804301 | Yenne, S. (1990) Ethoprop [carbon 14]: Absorption, Distribution, Metabolism, and Excretion in the Rat: Lab Project Number: 68/102; RP P89/367. Unpublished study prepared by Hazleton, UK and Rhone-Poulenc Ag. 944 p. |

| MRID # | CITATION |
|---|---|
| 41809601 | Johnson, T. (1991) Identification of Pyrolysis Products of [Carbon 14]-Ethoprop in Cigarette Smoke: Lab Project Number: 1316: 369. Unpublished study prepared by PTRL East, Inc. 76 p. |
| 41814001 | Johnson, T. (1991) Metabolic Fate and Distribution of [Carbon 14] Ethoprop in Potatoes Under Field Conditions: Lab Project Number: 1322: 335. Unpublished study prepared by PTRL East, Inc. 73 p. |
| 41840801 | Johnson, T. (1991) Metabolic Fate and Distribution of [Carbon 14]-Ethoprop in Corn under Field Conditions: Lab Project Number: 1325: 336. Unpublished study prepared by PTRL East, Inc. 76 p. |
| 41921201 | Neeper-Bradley, T. (1991) Two-Generation Reproduction Study of Ethoprop Technical Administered in the Diet to CD (Sprague-Dawley) Rats: Lab Project Number: 53-598. Unpublished study prepared by Bushy Run Research Center (Union Carbide). 913 p. |
| 41946001 | Wootton, M.; Johnson, T. (1991) Metabolic Fate and Distribution of Carbon 14 Ethoprop in Cabbage Under Field Conditions: Addendum I: Characterization of Bound Residues: Lab Project Number: 337: 1371. Unpublished study prepared by PTRL East, Inc. 26 p. |
| 42044801 | Eubanks, M. (1991) Ethoprop Technical: Storage Stability Study: Lab Project Number: AC-90-016: 41033. Unpublished study prepared by Rhone-Poulenc Ag Co. 54 p. |
| 42197601 | Wootton, M.; Johnson, T. (1992) A Confined Rotational Crop Study with [carbon 14]-Ethoprop Using Radishes (Raphanus sativus), Spinach (Spinacia oleracrea) and Wheat (Triticum aestivium): Lab Project Number: 1386: 346/189W. Unpublished study prepared by PTRL East, Inc. 229 p. |
| 42220601 | Eng, S. (1992) Ethoprop Method Validation: Determination of Ethoprop and its Metabolite in/on Cabbage: Lab Project Number: EC-91-171: 41071. Unpublished study prepared by Rhone-Poulenc Ag Co. 73 p. |
| 42242101 | Ver Hey, M. (1991) Food and Drug Administration Pesticide Analytical Manual, Volume 1, Testing of O-Ethyl-S-propylphosphorothioate: Lab Project Number: 1164. Unpublished study prepared by Colorado Analytical Research & Development Corp. 101 p. |

| MRID # | CITATION |
|---|---|
| 42530201 | Williams, K. (1992) 104-Week Combined Chronic Toxicity and Carcinogenicity Study with Ethoprop in Rats: Lab Project Number: HLA 6224-151. Unpublished study prepared by Hazleton Labs America, Inc. 3720 p. |
| 42901601 | Mede, K. (1993) Mocap EC/Pineapple/Magnitude of Residue/Raw Agricultural Commodity: Final Study Report: Lab Project Number: USA90M86. Unpublished study prepared by Hawaiian Sugar Planters' Assoc. 262 p. |
| 42923201 | Byrd, J. (1993) A Nature of the Residue Study with (Carbon 14)-Ethoprop in Dairy Goats: Lab Project Number: 9150G: EC91-162: EC91-162/SBL. Unpublished study prepared by Southwest Bio-Labs, Inc. 315 p. |
| 42945501 | Mede, K. (1993) MOCAP EC/Pineapple/Magnitude of Residue/Processed Fractions: Final Study Report: Lab Project Number: USA90M87: 44145: EC-91-171. Unpublished study prepared by Hawaiian Sugar Planters' Association. 133 p. |
| 429535-01 | Helfant, L. (1993) Ethoprop Technical: Product Chemistry Physical and Chemical Properties Series 63, Guideline 63-2 (Color): Lab Project Number: 44206: 93010LJH. Unpublished study prepared by Rhone-Poulenc Ag Co. 9 p. |
| 42962701 | Bates, N.; Byrd, J. (1993) A Nature of the Residue Study with (Carbon 14)-Ethoprop in Laying Hens: Lab Project Number: 9151C. Unpublished study prepared by Southwest Bio-Labs, Inc. 319 p. |
| 42979501 | Siglin, J. (1987) Acute Dermal LD50 Study with Ethoprop (Technical) in Sprague-Dawley Rats: Lab Project Number: 3147.5. Unpublished study prepared by Springborn Institute for Bioresearch, Inc. 67 p. |
| 42979502 | Siglin, J. (1987) Acute Dermal LD50 Study with Ethoprop (Technical) in New Zealand White Rabbits: Lab Project Number: 3147.2. Unpublished study prepared by Springborn Institute for Bioresearch, Inc. 50 p. |
| 43038401 | Heintzelman, R. (1993) Selected Raw Data Submission Pertaining to Uptake, Depuration and Bioconcentration of (carbon 14)-Ethoprop by Bluegill Sunfish (Lepomis macrochirus): Lab Project Number: 38161. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 136 p. |

| MRID # | CITATION |
|---|---|
| 43038402 | Heintzelman, R. (1993) Selected Raw Data Submission Pertaining to Characterization of (carbon 14)-Ethoprop Residues in Bluegill Sunfish (Lepomis macrochirus) Water and Tissues: Lab Project Number: 38162. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 181 p. |
| 43197701 | Weiler, M. (1994) Acute Neurotoxicity Study with Ethoprop in Rats: Final Report: Lab Project Number: HWI 6224-200. Unpublished study prepared by Hazleton Wisconsin, Inc. 1577 p. |
| 43209001 | Byrd, J. (1994) Amended Supplemental Report to Final Report, Entitled A Nature of the Residue Study with (carbon 14)-Ethoprop in Dairy Goats: Lab Project Number: 9150G: EC 91-162. Unpublished study prepared by Southwest Bio-Labs, Inc. 58 p. |
| 43277501 | Kowite, W. (1994) Mocap 20G: Sugarcane Processing Study for Registration Standard: Lab Project Number: USA90M88: 10031: 44312. Unpublished study prepared by Rhone-Poulenc Ag Co. 451 p. |
| 43277502 | Thiem, D. (1994) MOCAP Independent Laboratory Method Validation: Final Report: Lab Project Number: 1198: 44329. Unpublished study prepared by Colorado Analytical Research & Development Corp. 111 p. |
| 43326001 | Rhone-Poulenc Ag Co (1994) Chronic Feeding and Oncogenicity Studies in Mice with Ethoprop: Supplement: Lab Project Number: 497: 0094/025/002. Unpublished study. 1712 p. |
| 43373601 | Kowite, W. (1994) Ethoprop: Magnitude of Residues in Potato Processed Fractions Resulting from Ground Application of MOCAP EC (1992): Final Report: Lab Project Number: USA92M56: 44374. Unpublished study prepared by Rhone-Poulenc Ag Co., Wm. J. Englar & Associates, and Horizon Labs., Inc. 441 p. |
| 43442401 | Weiler, M. (1994) 13-Week Dietary Neurotoxicity Study with Ethoprop in Rats: Final Report: Lab Project Number: HWI 6224-199. Unpublished study prepared by Hazleton Wisconsin, Inc. 644 p. |
| 43442402 | Weiler, M. (1994) Acute Oral Gavage Study with Ethoprop in Rats: Time-Related Effects of Ethoprop on Brain, Plasma, and Red Blood Cell Cholinesterase Activities: Final Report: Lab Project Number: HWI 6224-209. Unpublished study prepared by Hazleton Wisconsin, Inc. 106 p. |

| MRID # | CITATION |
|---|---|
| 43484001 | Kowite, W. (1994) Ethoprop: Magnitude of Ethoprop Residue in Cucumber RAC Resulting From Ground Application of MOCAP EC (1993): Final Study Report: Lab Project Numbers: US93M02R: 44588: 93-0085. Unpublished study prepared by Horizon Labs, Inc. 421 p. |
| 43491001 | Kowite, W. (1994) Ethoprop: Magnitude of Residues in Sweet Corn RAC Resulting from Ground Application of MOCAP 10G (1993): Final Study Report: Lab Project Number: US93M05R: 44597: 93-0095. Unpublished study prepared by Horizon Labs, Inc. 383 p. |
| 43530901 | Kowite, W. (1995) ETHOPROP: Magnitude of Residues in Field Corn RAC Resulting From Ground Application of MOCAP 10G (1993): Final Study Report: Lab Project Numbers: 44616: US93M06R: 10059. Unpublished study prepared by Horizon Labs, Inc. 880 p. |
| 43538601 | Lee, R. (1995) Magnitude of Ethoprop Residues in/on Snap Bean Pods, Vines, and Hay Resulting from a Single Preplant/Incorporated Ground Application of MOCAP Brand EC Nematicide/Insecticide at an 8.0 lb ai/A Rate: 1993: Final Study Report: Lab Project Number: US93M04R: 44601: 93-0065. Unpublished study prepared by Rhone-Poulenc Ag Co. 523 p. |
| 43539401 | Ibrahim, A. (1995) Stability of Ethoprop and o-Ethyl-s-propylphosphorothioate in Frozen Raw Agricultural Commodities and Processed Fractions: Lab Project Number: EC-92-215: 44589: EC-50-374-P1. Unpublished study prepared by Rhone-Poulenc Ag Co. 450 p. |
| 43539601 | Lee, R. (1995) Magnitude of Ethoprop Residues in/on Lima Bean Pods, Vines, and Hay Resulting from a Single Preplant/Incorporated Ground Application of MOCAP 6EC at 8.0 lb ai/A Rate: Final Study Report: Lab Project Number: US93M03R: 44611: 93-0055. Unpublished study prepared by Rhone Poulenc Ag Co. 488 p. |
| 43539701 | Cappy, J. (1995) Magnitude of Ethoprop Residues in/on Peanuts after Soil Application with MOCAP Brand Nematicide-Insecticide: Final Study Report: Lab Project Number: US93M08R: 44632: 93-0075. Unpublished study prepared by Rhone Poulenc Ag Co. 570 p. |
| 43539801 | Cappy, J. (1995) Magnitude of Ethoprop Residues in Peanut Processing Fractions: Final Study Report: Lab Project Numbers: US93M09R: 44633: 93-0126. Unpublished study prepared by Rhone-Poulenc Ag Co.; Horizon Lab, Inc.; and Midwest Labs. 300 p. |

| MRID # | CITATION |
|---|---|
| 43583201 | Lee, R. (1995) Magnitude of Ethoprop Residues in/on Cabbage Resulting from a Single Preplant Incorporated Ground Application of Mocap at a 12.0 lb ai/A Rate, 1993: Final Study Report: Lab Project Number: US93M01R: 44622: 93-0045. Unpublished study prepared by Rhone-Poulenc Ag Co. 388 p. |
| 43686301 | Machado, M. (1995) Ethoprop Technical--Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5811: 10566.1294.6348.505. Unpublished study prepared by Springborn Labs, Inc. 71 p. |
| 43686302 | Dionne, E. (1995) Ethoprop Technical--Acute Toxicity to Eastern Oyster (Crassostrea virginica) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-5-5839: 10566.1294.6350.504. Unpublished study prepared by Springborn Labs, Inc. 71 p. |
| 43686303 | Machado, M. (1995) Ethoprop Technical--Acute Toxicity to Mysids (Mysidopsis bahia) Under Flow-Through Conditions: Final Report: Lab Project Number: 95-4-5802:10566.1294.6349.515. Unpublished study prepared by Springborn Labs, Inc. 71 p. |
| 43748201 | Kowite, W. (1995) Ethoprop: Magnitude of Residues in Field Corn RAC (Grain) Resulting from Ground Application of Mocap 10G (1994): Final Report: Lab Project Number: US94M01R: 44755: 94-0384. Unpublished study prepared by Horizon Labs, Inc. 285 p. |
| 43748202 | Kowite, W. (1995) Ethoprop: Magnitude of Residues in Field Corn Processing Fractions Resulting from Ground Application of Mocap 10G (1994): Final Report: Lab Project Number: US94M03R: 44757: 94-0390. Unpublished study prepared by Horizon Labs, Inc. and Texas A&M University. 374 p. |
| 43748203 | Kowite, W. (1995) Ethoprop: Magnitude of Residues in Sweet Corn RAC Resulting from Ground Application of Mocap 10G (1994): Final Report: Lab Project Number: US94M02R: 44756: 94-0388. Unpublished study prepared by Horizon Labs, Inc. 238 p. |
| 43778601 | Feung, C.; Stillwell, D. (1995) O-Ethyl-S-Propyl Phosphorothioic Acid (Ethoprop Metabolite) Adsorption/Desorption Study: Lab Project Number: EC-94-291. Unpublished study prepared by Rhone-Poulenc Ag Co. and A & L Great Lakes Lab., Inc. 126 p. |

| MRID # | CITATION |
|---|---|
| 43833501 | Gorman, M. (1995) Determination of the Photolysis Rate of (carbon 14)-Ethoprop on the Surface of Soil--Supplemental Study: Amended Final Report: Lab Project Number: 38140-1: EC-95-316: 38140. Unpublished study prepared by ABC Labs, Inc. 117 p. |
| 43833502 | Gorman, M. (1995) Photodegradation of (carbon 14)-Ethoprop in pH 7 Buffered Solution--Supplemental Study: Final Report: Lab Project Number: 38139-1: EC-95-316: 38139. Unpublished study prepared by ABC Labs, Inc. 137 p. |
| 43836401 | O'Neal, S.; Johnson, T. (1995) Characterization of (carbon 14)-Ethoprop Bound Residue in Potatoes: (Final Report): Lab Project Number: 849: 1830: PTRL 849. Unpublished study prepared by PTRL East, Inc. 94 p. |
| 43852501 | Rosenheck, L.; Schuster, L. (1995) Worker Loader and Applicator Exposure to Temik 15G: Lab Project Number: 94388. Unpublished study prepared by ABC Labs, Inc., Pan-Ag Div. 344 p. |
| 43868701 | O'Neal, S. (1995) Characterization of (carbon 14)-Ethoprop Bound Residue in Corn: Lab Project Number: 860: 1861. Unpublished study prepared by PTRL East, Inc. 100 p. |
| 43877401 | Putt, A. (1995) Ethoprop Technical--The Chronic Toxicity to Daphnia magna Under Flow-Through Conditions: Final Report: Lab Project Number: 95-5-5857: 10566.1294.6351.130. Unpublished study prepared by Springborn Labs, Inc. 115 p. |
| 43971501 | Eng, S. (1996) Storage Stability of Ethoprop and Its Metabolite M1 in Sugarcane Substrates and the Processed Fractions: Lab Project Number: EC-94-271: 44954. Unpublished study prepared by Rhone-Poulenc Ag Co. 244 p. |
| 44003301 | Macy, L. (1996) MOCAP 10G: Magnitude of Ethoprop Residues in Peanut Processing Fractions: Final Study Report: Lab Project Number: US95M06R: 45056: 95-0240. Unpublished study prepared by Horizon Laboratories, Inc. 325 p. |
| 44038701 | Putnam, D. (1981) Activity of T1688 in the Dominant Lethal Assay in Rodents: Lab Project Number: T1688.116: 1688. Unpublished study prepared by Microbiological Associates. 119 p. |

| MRID # | CITATION |
|---|---|
| 44038702 | Myhr, B. (1981) Evaluation of #01238101 in the Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay: Lab Project Number: 20991: 447. Unpublished study prepared by Litton Bionetics, Inc. 69 p. |
| 44062401 | Chancey, E. (1996) Magnitude of Ethoprop Residues in/on Peanuts after Soil Application with MOCAP Brand Nematicide/Insecticide: Final Study Report: Lab Project Number: US95M03R: 45069: 95-0137. Unpublished study prepared by Horizon Laboratories, Inc. 386 p. |
| 44065001 | Blackburn, G. (1981) A Murine Lymphoma Mutagenesis Assay, Heterozygous at the Thymidine Kinase Locus for the Determination of the Potential Mutagenicity of Ethoprop: Lab Project Number: 2474-80. Unpublished study prepared by Mobil Environmental and Health Science Lab. 52 p. |
| 44114001 | Klonne, D. (1996) Summary of Acute Toxicity and Cholinesterase-Inhibiting Potential for Several Possible Ethoprop Plant Metabolites: 1) O-Ethyl-S-propylphosphorothioate ("M1" Metabolite), 2) Ethyl Phosphate, 3) O-Ethyl-O-methyl-S-propylphosphorothioate, 4) O-Ethyl-S-methyl-S-propylphosphorodithioate: Lab Project Number: ETP-M1-96-002: 53-537: 90-85-11194. Unpublished study prepared by Rhone-Poulenc Ag Co. 70 p. |
| 44312701 | Taliaferro, M.; Miller, V. (1997) Reproduction Study with Ethoprop in the Northern Bobwhite (Colinus virginianus): Lab Project Number: 029516: EBA-029516. Unpublished study prepared by EBA, Inc. 319 p. |
| 44312702 | Taliaferro, M.; Miller, V. (1997) Reproduction Study with Ethoprop in the Mallard Duck (Anas platyrhynchos): Lab Project Number: 029515: EBA-029515. Unpublished study prepared by EBA, Inc. 313 p. |
| 44321501 | Lalko, M. (1997) Independent Laboratory Method Validation of MOCAP-Related Residues in/on Lima Beans: Final Report: Lab Project Number: EC-97-341: MK03-97: 10070. Unpublished study prepared by McKenzie Labs., Inc. 170 p. |
| 44350201 | Norris, F. (1997) Ethoprop: Determination of the Magnitude of Residues in/on Rotational Crops Resulting from a Pre-Plant Incorporated Application of MOCAP EC Brand Nematicide-Insecticide: Final Study Report: Lab Project Number: US95M04R: 45326: 95-0187. Unpublished study prepared by Horizon Labs. and American Agricultural Services, Inc. 484 p. |

| MRID # | CITATION |
|---|---|
| 44398001 | Norris, F. (1997) Ethoprop: Terrestrial Soil Dissipation after Application to Turf: Final Report: Lab Project Number: 96M08726: 45369: 10159. Unpublished study prepared by American Agricultural Services, Inc. 923 p. |
| 44457501 | Sousa, J. (1997) Ethoprop Technical: Chronic Toxicity to Mysids (Mysidopsis bahia) under Flow-Through Conditions: Lab Project Number: 97-10-7128: 10566.0497.6418.530. Unpublished study prepared by Springborn Laboratories, Inc. 98 p. |
| 44472101 | Sousa, J. (1997) Ethoprop Technical--Early Life-Stage Toxicity Test with Sheepshead Minnow (Cyprinodon variegatus): Final Report: Lab Project Number: 97-10-7127: 10566.0497.6419.520: 021797/FIFRA/520. Unpublished study prepared by Springborn Labs., Inc. 91 p. |
| 44472501 | Weiler, M. (1998) Acute Oral Toxicity Study with Ethoprop and Three Ethoprop Metabolites (O-ethyl-S-methyl-S-propylphosphorodithioate, O-ethyl-O-methyl- S-propylphosphorothioate, and O-ethyl-S-propylphosphorothioate) in Rats with Determination of Effects on Cholinesterase Activity: Lab Project Number: COVANCE 6224-246. Unpublished study prepared by Covance Labs., Inc. 203 p. |
| 44972201 | Klonne, D. (1999) Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns: Lab Project Number: OMAOO5: OMAOO1: OMAOO2. Unpublished study prepared by Ricerca, Inc., and Morse Laboratories. 2213 p. |
| 44972203 | Cowell, J.; Johnson, D. (1999) Evaluation of Transferable Turf Residue Techniques: Evaluation Study of Transferable Residue Techniques (OMDOO1) and Transferable Residue Technique Modification Study: An Evaluation of Three Turf Sampling Techniques (OMDOO2): Lab Project Number: OMDOO1: OMDOO2: 44047. Unpublished study prepared by Monsanto Integrative Technologies, and ABC Laboratories. 563 p. |
| 44972206 | Vargyas, L. (1996) Characterization of DCPA Formulations: Lab Project Number: 4618-96-0155-AS-001. Unpublished study prepared by Ricerca, Inc. 58 p. |
| 44972207 | Formanik, J. (1997) Validation of Method for the Analysis of Worker Exposure and Reentry Matrices for Dacthal: Lab Project Number: OMVOO1: 6884-96-0159-CR-001: 6884-96-0159. Unpublished study prepared by Ricerca, Inc. 215 p. |

| MRID # | CITATION |
|---|---|
| 44989501 | Weiler, M. (1999) Acute Oral Toxicity Study with Ethoprop Metabolite O-ethyl-S-propylphosphorothioate (M1) in Rats with Determination of Effects on Cholinesterase Activity: Final Report: Lab Project Number: COVANCE 6224-250: PROPOSAL 23237A. Unpublished study prepared by Covance Laboratories Inc. 77 p. |
| 44989502 | Lewis, C. (1993) (14-carbon)-Ethoprophos: Degradation and Retention in Water/Sediment Systems: Final Report: Lab Project Number: 68/135-1015: P6875D. Unpublished study prepared by Hazleton UK. 172 p. |
| 44989503 | Temple, D.; Lee, T.; Palmer, D. (1999) MOCAP EC: An Evaluation of its Effects Upon Avian Species on and around Potato Fields in the Columbia Basin of Washington State: Lab Project Number: 171-132: ML92-0302-RHP: 171/022692/MPWA/CYP6. Unpublished study prepared by Wildlife International, Ltd. and Morse Laboratories, Inc. 423 p. |
| 44989504 | Temple, D.; Lee, T.; Palmer, D. (1999) MOCAP 10G: An Evaluation of its Effects Upon Avian Species on and around Potato Fields in the Columbia Basin of Washington State: Lab Project Number: 171-128: ML91-0236-RHP: 171/092590/10G/CYP6. Unpublished study prepared by Wildlife International, Ltd. and Morse Laboratories, Inc. 422 p. |
| 45034801 | Austin, E. (2000) 4-Week Repeated Dose Dermal Toxicity Study with Mocap 20G in Rats: Lab Project Number: 6224-263. Unpublished study prepared by Covance Labs. 141 p. |
| 45064101 | Temple, D.; Lee, T.; Palmer, D. (2000) Mocap EC: An Evaluation of its Effects Upon Avian Species and Other Wildlife on and Around Tobacco Fields in North Carolina: Lab Project Number: 171-127. Unpublished study prepared by Wildlife International, Ltd. 499 p. |
| 45074601 | Henwood, S. (1990) 3-Week Dermal Toxicity Range-Finding Study with Ethoprop Technical in Rats: Final Report: Lab Project Number: HLA 6224-160: TP9279. Unpublished study prepared by Hazleton Laboratories America, Inc. 181 p. |
| 45074602 | Henwood, S. (1990) 3-Week Dermal Toxicity Study with Ethoprop Technical in Rats: Final Report: Lab Project Number: HLA 6224-162: ETP-TP-90-1014: TP9328. Unpublished study prepared by Hazleton Laboratories America, Inc. 274 p. |

| MRID # | CITATION |
|---|---|
| 45079706 | Linchick, C.; Powell, G. (2000) Temik Brand 15G-Quality Control Data on Dust Control of Gypsum and Grit Formulations: Lab Project Number: 02ALD00/AVENTIS. Unpublished study prepared by Aventis CropScience. 101 p. Temik dust data |
| 45113102 | Wilson, A. (1999) ETHOPROPHOS Biomonitoring Exposure to Applicators and Loaders During Typical Application Activities with MOCAP 10G Applied to Potatoes in the United Kingdom: Lab Project Number: RNP 617: RNP 617/993560. Unpublished study prepared by Huntingdon Life Sciences Ltd. 71 p. |
| 45167201 | Urtizberea, M. (1999) Worker Exposure Study During Application in Banana Plantation with Temik 10G: Lab Project Number: SA 98337: RPS/ALD/98072. Unpublished study prepared by ADME Bioanalyses. 156 p. |
| 45184402 | Temple, D.; Lee, T.; Palmer, D. (2000) MOCAP 10G: An Evaluation of Its Effects Upon Avian Species on and Around Potato Fields in Maine: Lab Project Number: 171-131. Unpublished study prepared by Wildlife International, Ltd. 445 p. |
| 45206301 | Ligon, R. (2000) Perceived Dust Evaluation of MOCAP Granulars: Lab Project Number: WOODBINE 08180. Unpublished study prepared by Aventis CropScience. 11 p. |
| 45206302 | Lunchick, C. (2000) Aventis CropScience Comments and Revisions Pertaining to the U.S. EPA Re-Assessment of the Occupational Exposure and Risk of Ethoprop for the Reregistration Eligibility Document Dated 18 May 2000. Unpublished study prepared by Aventis CropScience. 14 p. |
| 45250702 | Pontal, P. (1996) Fipronil: Worker Exposure Study During Application of Regent 20GR in Banana Plantation: Lab Project Number: 338/95/0072: 94/136: 94002 HI. Unpublished study prepared by Rhone-Poulenc Agrochemie. 196 p. |
| 45285901 | Carringer, R. (2000) The Benefits of Mocap EC Fôrmulation of Ethoprop for the Minor Crops of Tobacco, Sweet Potato, Cabbage, and Cucumber. Unpublished study prepared by The Carringers, Inc. 23 p. |
| 45388504 | Lignon, R. (2001) Perceived Dust Evaluation of MOCAP Granulars: Lab Project Number: WOODBINE 03231. Unpublished study prepared by Aventis CropScience. 22 p. |

45388505 Hou, A. (2001) Particle Size of Biodac Through Light Scattering-Camsizer. Unpublished study prepared by Horiba Instruments Incorporated. 17 p.

45535501 Anderson, C.; Wood, T.; Morace, J. (1997) Distribution of Dissolved Pesticides and Other Water Quality Constituents in Small Streams, and their Relation to Land Use, in the Willamette River Basin, Oregon, 1996. U.S. Geological Survey Water-Resources Investigations Report. 87 p.

## Appendix E. Generic Data Call-In

See the attached table for a listing of the generic data requirements. Note that a complete Generic Data Call-In (DCI), with all pertinent instructions, is being sent to each registrant under separate cover.

United States Environmental Protection Agency
Washington, D.C. 20460

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 000264
AVENTIS CROPSCIENCE USA LP
2 T.W. ALEXANDER DRIVE BOX 12014
RESEARCH TRIANGLE PARK NC 27709

2. Case # and Name
0106 Ethoprop
Chemical # and Name 041101
Ethoprop

3. Date and Type of DCI
GENERIC

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 830.7050 * | U/V Visible Absorption | | | | | ABC | | 12 mos. | |
| 875.1350 * | Perceived Dust of Granular Formulatio | | | | | | | 12 mos. | |
| 875.1500 * | Biological Monitoring Study | | | | | ABC | | 12 mos. | |
| 835.7100 * | Groundwater Monitoring Study | | | | | ABC | | 12 mos. | |
| 835.7200 * | Surface Drinking Water Monitoring Stu | | Y | | | ABC | | 22 mos. | |
| 850.1500 * | Fish Life Cycle | | | | | ABC | | 12 mos. | |
| 850.2300 * | Avian Reproduction Studies | | Y | | | ABC | | 24 mos. | |
| 860.1340 * | Residue Analytical Method-Animal | | | | | ABC | | 12 mos. | |
| 860.1380 * | Storage Stability Data | | Y | | | | | 24 mos. | |
| 860.1500 * | Cropfield trials | | Y | | | AB | | 24 mos. | |
| 870.3465 * | 90-day Inhalation Toxicity | | Y | | | | | 24 mos. | |
| 870.6100 * | Acute and 28-day Neurotoxicity of Org | | Y | | | | | 24 mos. | |
| 875.2800 * | Description of Human Activity for Pos | | | | | ABC | | 12 mos. | |

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0106 Ethoprop
Chemical # and Name
041101 Ethoprop

| GUIDELINE | COMMENT |
|---|---|
| 830.7050 | UV/Visibile Absorption with Technical Grade Active Ingredient<br>This guideline must be performed with the technical grade active ingredient. |
| 875.1350 | Perceived Dust of Granular Formulation<br>The registrant must submit information about the granular formulations, including the properties of the cellulose-based granules themselves, the physical properties of the cellulose-based ethoprop granules, methods to collect and analyze the very small dust particles released, determinations of whether these small particles released contain ethoprop or just fractionated cellulose, and additional information about the Perceived Dust method (including Quality Control data). |
| 875.1500 | Biological Monitoring Study<br>The registrant must submit a final report of their biomonitoring study to EPA by March 31, 2002. Pending review of this study, EPA may need additional information about the pharmacokinetics (PK) of ethoprop in humans, including human PK testing, to document the worker dose levels. |
| 835.7100 | Groundwater Monitoring Study<br>As confirmatory data and to refine the risks from drinking water from ground water sources, the registrant must conduct a groundwater monitoring program. The registrant must conduct one of the following three monitoring programs: 1) a prospective ground water program consisting of studies in three different regions and soil types around the country to represent the full usage patterns of ethoprop; 2) a retrospective monitoring program at various sites involving multiple fields with observation wells installed downgradient from previously treated fields; or 3) a sampling program to monitor the ground water from existing private and Community Water Systems (CWS) wells in high use ethoprop areas from regions with vulnerable soil conditions.<br>Irrespective of the option chosen, the registrant must: a) locate all wells in Hydrologic Group A soils; b) monitor near areas where ethoprop is used, and document |

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0106 Ethoprop
Chemical # and Name
041101 Ethoprop

| GUIDELINE | COMMENT |
|---|---|
| | current and historical ethoprop use; c) establish a direct hydraulic connection between the ethoprop application area and the aquifer volume which provides water to the monitoring wells (if a connection cannot be established, the results of monitoring concentration in the wells will be ambiguous); d) provide the characteristics of the existing wells (e.g., screened interval, well diameter, depth to ground water); e) submit a monitoring protocol for approval. If selecting option 2 or 3, the registrant must discuss the statistical significance of the sampled wells in relation to the population consuming groundwater within the entire ethoprop use area. The registrant must determine the concentrations of parent ethoprop and the four metabolites/residues of toxicological concern, specifically SME, OME, M1, and M2. The registrant must also submit quarterly reports to the Agency to document the ground water analyses conducted. |
| 835.7200 | Surface Drinking Water Monitoring Study<br>The registrant must conduct a 3-year monitoring program at selected surface drinking water sources. The registrant has submitted a site selection proposal (MRID 454708-01) that has identified five (5) surface water intakes for monitoring. The Agency has accepted this site selection proposal as being representative of the geographical distribution of ethoprop usage, and of drinking water treatment systems downstream from areas where ethoprop is likely to be used.<br>The sampling program must continue at each site for three (3) years, and reports must be submitted quarterly. The registrant must also conform to their sampling and analytical protocol, submitted to the Agency on August 8, 2000, titled Surface Water Monitoring for residues of Ethoprop in High Use Areas in the United States. The analyses of water samples are to specifically include ethoprop, SME, OME, M1, and M2. |
| 850.1500 | Fish Life Cycle Toxicity<br>An estuarine/marine fish life-cycle toxicity test using the TGAI is required for ethoporp. The preferred test species is the shepshead minnow. |

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0106 Ethoprop
Chemical # and Name
041101 Ethoprop

| GUIDELINE | COMMENT |
|---|---|
| | RESERVED: There is also a data gap for freshwater fish life cycle toxicity testing, but the requirement is reserved pending the outcome of the life-cycle toxicity testing in estuarine/marine fish. |
| 850.2300 | Avian Reproduction Testing with the northern bobwhite quail.<br>A study has been submitted, but the test data do not support the determination of a no observed effects concentration (NOEC), because there were observed effects even at the lowest concentration tested. To fulfill this study guideline, the registrant must submit another avian reproduction study in the bobwhite quail.<br><br>RESERVED: There is a similar data gap for avian reproduction in the mallard duck, but the Agency is reserving this requirement, pending the outcome of the avian reproduction testing in the bobwhite quail. |
| 860.1340 | Residue Analytical Method - Plants<br>A residue analytical method is needed to determine all the residues in or on each commodity for which EPA is reassessing a tolerance. EPA has determined that the residues of tolicological concern for ethoprop include the parent, as well as the following metabolites: SME, OME and M1. The registrant is required to develop, evaluate, and validate a new method which determines the parent and each metabolite/residue of tolxicological concern. The registrant must then submit this method to EPA for independent method validation. |
| 860.1380 | Storage Stability<br>The registrant is required to submit storage stability data for all samples collected and analyzed as part of the field crop trial studies, based on data developed using the new analytical method which determines all residues of toxicological concern. |

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0106 Ethoprop
Chemical # and Name
041101 Ethoprop

| GUIDELINE | COMMENT |
|---|---|
| 860.1500 | Crop Field Trials: Snap Beans, Cabbage, and Potato<br>Crop field trials must be conducted for each of the above commodities. Each crop trial take place at two representative geographical locations to assess the residues of parent ethoprop and all the metabolites of toxicological concern in/on the raw agricultural commodity, following application of ethoprop according to a registered use pattern. The reguistrant must submit a protocol to EPA before starting field crop trial studies. Once acceptable data on the field crop trials have been submitted and evaluated, the registrant must propose a tolerances for each commodity. |
| 870.3465 | 90-Day Inhalation Toxicity<br>RESERVED: The data requirement for a subchronic inhalation toxicity study in the rat to refine the risks for the granular products is reserved pending both EPA's review of the data available to characterize the amount of dust released from the granular ethoprop forumulations and EPA's determination of estimates of the inhalation exposures associated with these granular formulations. |
| 870.6100 | Acute and 28-day Delayed Neurotoxicity of Organophosphorus Substances<br>This newest guideline revised and expanded the previous guideline 81-7. The guideline assays for organophosphorus induced delayed neurotoxicity (OPIDN). The guideline also added an assay for Neurotoxic Esterase (NTE), and anzyme whose inhibition is highly correlated with OPIDN. This data requirement is limited to the NTE portion of the new guideline. Two groups of 3-5 hens must be tested, one being the control group and the other is tobe treated with technical ethoprop at the LD50 (the dose lethal to approximately 50% of the hens). The assay is to be conducted at 48 hours after dosing, with analyses performed on brain and spinal cord NTE. EPA has determnined that the histopathological findings from the existing acute neurotoxicity study in the hen are indicative of a potential for lesions in the brains of treated birds, even having considered results in the control group and the historical controls. EPA has determined that these NTE data are confirmatory. |

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0106 Ethoprop
Chemical # and Name
041101 Ethoprop

| GUIDELINE | COMMENT |
|---|---|
| 875.2800 | Description of Human Activity for Post-Application<br>The registrant must submit information on post-application activities and techniques, such as transplanting of tobacco plants, as well as cultural and harvesting activities for pineapples, bananas, and plantains. |

## Appendix F. Product Specific Data Call-In

See the attached table for a listing of the product-specific data requirements. Note that a complete Product Specific Data Call-In (DCI), with all the pertinent instructions, is being sent to each registrant under separate cover.

United States Environmental Protection Agency
Washington, D. C. 20460

**DATA CALL-IN RESPONSE**

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

| 1. Company name and Address | 2. Case # and Name | 3. Date and Type of DCI |
|---|---|---|
| SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 | 0106 Ethoprop | PRODUCT SPECIFIC |

| 4. EPA Product Registration | 5. I wish to cancel this product registration voluntarily. | 6. Generic Data | | 7. Product Specific Data | |
|---|---|---|---|---|---|
| | | 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below. | 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." | 7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response." | 7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response." |
| NNNNNN-NNNNN | | N.A. | N.A. | | |

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0106 Ethoprop

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| | Prod Chem - Regular Chemical | | | | | | | | |
| 830.1550 | Product identity & composition (1) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1600 | Description of materials used (1,2) to produce the product | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1620 | Description of production (1,2) process | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1650 | Description of formulation (1,2) process | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1670 | Discussion of formation of (1,3) impurities | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1700 | Preliminary analysis (1,4) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1750 | Certified limits (1,5) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.1800 | Enforcement analytical method (1) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6302 | Color (17) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6303 | Physical state | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6304 | Odor (17) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved
OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0106 Ethoprop

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 830.7000 | pH (9) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.7050 | UV/Visible absorption | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.7100 | Viscosity (13) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.7300 | Density | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6314 | Oxidation/reduction: chemical incompatability (10) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6315 | Flammability (11) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6316 | Explodability (12) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6317 | Storage stability | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6319 | Miscibility (14) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6320 | Corrosion characteristics | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 830.6321 | Dielectric breakdown voltage (15) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| | | | | | | | | | |
| | Acute Toxic - Regular Chemical | | | | | | | | |
| | | | | | | | | | |
| 870.1100 | Acute oral toxicity (1,37) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 870.1200 | Acute dermal toxicity (1,2,37) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 870.1300 | Acute inhalation toxicity (3) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 870.2400 | Acute eye irritation (2) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 870.2500 | Acute dermal irritation (1,2) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |
| 870.2600 | Skin sensitization (4) | | | | | ABCDEFGHIJKLMNO | MP/EP | 8 mos. | |

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

# FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

## Case # and Name: 0106 Ethoprop

**Key:** MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product;TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

**Use Categories Key:**

| | | | | |
|---|---|---|---|---|
| A - Terrestrial food crop | B - Terrestrial food feed crop | C - Terrestrial nonfood crop | D - Aquatic food crop | E - Aquatic nonfood outdoor |
| F - Aquatic nonfood Industrial | G - Aquatic nonfood residential | H - Greenhouse food crop | I - Greenhouse nonfood crop | J - Forestry |
| K - Residential outdoor | L - Indoor food | M - Indoor nonfood | N - Indoor Medical | O - Indoor residential |

**Footnotes:** [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

**Prod Chem - Regular Chemical**

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
17 Not required unless efficacy data are required.

**Acute Toxic - Regular Chemical**

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

**FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS**

**Case # and Name: 0106 Ethoprop**

**Footnotes (cont.):**

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

## Appendix G. Batching of Ethoprop 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 ethoprop as an active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition, and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note 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. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If the registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If the registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by todays standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data are generated or existing data are referenced, the registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the IRED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5), or Citing an Existing Study (Option 6). If a registrant depends on another registrant's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5, or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

With the voluntary cancellation of various products by the various registrants, there are five remaining products which contain ethoprop as the active ingredient. These products have been placed into 4 batches in accordance with the active and inert ingredients and type of formulation. Please note that this batching scheme may not apply to products with CSFs that have been revised after generation of this document.

| Batch 1 | EPA Reg. No. | Percent Active Ingredient | Formulation Type |
|---|---|---|---|
| | 264-456 | 95.9 | Technical; Solid |
| | 264-599 | 94.4 | Technical; Solid |

| Batch 2 | EPA Reg. No. | Percent Active Ingredient | Formulation Type |
|---|---|---|---|
| | 264-458 | 69.6 | Emulsifiable Concentrate; Liquid |

| Batch 3 | EPA Reg. No. | Percent Active Ingredient | Formulation Type |
|---|---|---|---|
| | 264-469 | 20.0 | Solid; clay-based |

| Batch 4 | EPA Reg. No. | Percent Active Ingredient | Formulation Type |
|---|---|---|---|
| | 264-457 | 15.0 | Solid; cellulose-based |

## Appendix H. List of Registrants Sent this Data Call-In

United States Environmental Protection Agency
Washington, D. C. 20460

**LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE**

**Case # and Name: 0106 Ethoprop**

| Co. Nr. | Company Name | Additional Name | Address | City & State | Zip |
|---|---|---|---|---|---|
| 000264 | AVENTIS CROPSCIENCE USA LP | | 2 T.W. ALEXANDER DRIVE BOX 12014 | RESEARCH TRIANGLE PARK | 27709 |
| 000432 | AVENTIS ENVIRONMENTAL SCIENCE USA | | 95 CHESTNUT RIDGE ROAD | MONTVALE NJ | 07645 |
| 051036 | MICRO-FLO COMPANY LLC | | BOX 772099 | MEMPHIS TN | 38117 |
| 066300 | HIRAM MERCADO PEREZ | | BOX 1157 | CAYEY PR | 00737 |

## Appendix I. 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 hard-copy 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@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 FR 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 FR 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

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

3. The National Pesticides 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. http://ceris.purdue.edu/npirs/npirs.html

4. The National Pesticides Information Center (NPIC), formerly 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: www.npic.orst.edu/index.html

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.