

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 15, 2005

Dear Reader:

The Reregistration Eligibility Decision (RED) document for was signed on September 28, 2001. A post-signature comment period opened April 18, 2002 and closed June 17, 2002. The risk assessments, benefit assessments, and public comments can be found on the FDMS docket system, available at <http://www.regulations.gov> (docket # OPP-2002-0009). The Environmental Protection Agency has reviewed and responded to the public comments. These responses are also available for viewing in the FDMS docket. As a result of its review of the public comments, the Agency revised the Propargite RED, where appropriate. The following changes were made to the September 28, 2001 version of the RED; these changes are incorporated in this December 15, 2005 version.

- (1) Walnut: 21-day restricted-entry interval (REI) exemption granted for tree shaking;
- (2) Citrus (bearing): REI for all activities changed to 20 days;
- (3) Mint: REIs for all activities reduced to 7 days;
- (4) Potato: maximum per season use rate increased from 3.7 to 4.1 pounds active ingredient per acre ("lbs. a.i./A") acre per season;
- (5) Potato: spray interval reduced from 21 days to 14 days for Washington State;
- (6) Mint: spray interval reduced from 21 days to 14 days.

In addition to the substantive changes listed above, the Agency has also reformatted Appendix B, Appendix D and Appendix I for clarity, and has made technical changes to Table 15 to conform to current labeling language.

The revised document attached to this letter represents the EPA's reregistration decision for propargite. If you have questions on this RED or any of the revisions listed above, please contact the Chemical Review Manager, Dayton Eckerson, at (703) 308-8038. For questions about product reregistration, please contact Bonnie Adler (703) 308-8523.

Sincerely,

Debra Edwards, Ph.D.
Director, Special Review and Reregistration Division

Attachment



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

September 28, 2001

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessment for the miticide propargite. The Agency has revised the human health and environmental effects risk assessments based on the comments received during the public comment period and additional data received from the registrant. Based on the EPA's revised risk assessments for propargite, 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 propargite. EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of propargite, and its associated human health and environmental risks. The Agency's decision on the individual chemical propargite can be found in the attached document entitled, "Reregistration Eligibility Decision for Propargite" which was approved on September 28, 2001.

A Notice of Availability for the Reregistration Eligibility Decision for Propargite is being published in the *Federal Register*. To obtain copies of the RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), USEPA, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/reregistration/status.htm>

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. In cooperation with the U.S. Department of Agriculture, the Agency held a teleconference on July 19, 2000, during which the results of the human health and environmental effects risk assessments were presented to interested stakeholders. Information discussed during the call, such as propargite usage and occupational practices, are reflected in this RED. Also, a close-out conference call was conducted on September 25, 2001 with many of the same participants from the July 19 conference call, to discuss the risk management decisions and resultant changes to the propargite labels.

A risk mitigation proposal for propargite was submitted by Uniroyal Chemical, the technical registrant. During the public comment period provided for the preliminary risk assessment, EPA also received comments from the Almond Hullers and Processors Association and the National Agricultural Aviation Association (NAAA). Subsequent to the comment period for the propargite preliminary risk assessment, EPA also received a series of letters and e-mails from several growers groups and extension services attesting to the benefits of propargite. These comments can also be found in the public docket for propargite.

Please note that the propargite risk assessment and the attached RED concern only this particular pesticide. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." At this time, the Agency does not believe that propargite shares a common mechanism of toxicity with other pesticides. Therefore, propargite is not subject to any cumulative risk assessment as required by the Food Quality Protection Act (FQPA).

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that registrants of propargite must respond to DCIs issued by the Agency within 90 days of receipt of this letter. This RED also contains labeling requirements for propargite products. End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

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 propargite. 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.

There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Dayton Eckerson at (703) 308-8038. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

**Reregistration Eligibility Decision
(RED)
for
Propargite
Case No. 0243**

Effective: September 28, 2001

Amended: December 15, 2005_____

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GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|--------|--|
| AE | Acid Equivalent |
| a.i. | Active Ingredient |
| AGDCI | Agricultural Data Call-In |
| ai | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| AR | Anticipated Residue |
| ARC | Anticipated Residue Contribution |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| CI | Cation |
| CNS | Central Nervous System |
| cPAD | Chronic Population Adjusted Dose |
| CSF | Confidential Statement of Formula |
| CFR | Code of Federal Regulations |
| CSFII | USDA Continuing Surveys for Food Intake by Individuals |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| DFR | Dislodgeable Foliar Residue |
| DRES | Dietary Risk Evaluation System |
| DWEL | Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur. |
| DWLOC | Drinking Water Level of Comparison. |
| EC | Emulsifiable Concentrate Formulation |
| EEC | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem. |
| EP | End-Use Product |
| EPA | U.S. Environmental Protection Agency |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| G | Granular Formulation |
| GENEEC | Tier I Surface Water Computer Model |
| GLC | Gas Liquid Chromatography |
| GLN | Guideline Number |
| GM | Geometric Mean |
| GRAS | Generally Recognized as Safe as Designated by FDA |
| HA | Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination |

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| | situations occur. |
| HAFT | Highest Average Field Trial |
| HDT | Highest Dose Tested |
| IR | Index Reservoir |
| LC ₅₀ | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. |
| LD ₅₀ | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LEL | Lowest Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOAEL | Lowest Observed Adverse Effect Level |
| MATC | Maximum Acceptable Toxicant Concentration |
| MCLG | Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act. |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MP | Manufacturing-Use Product |
| MPI | Maximum Permissible Intake |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| NA | Not Applicable |
| N/A | Not Applicable |
| NAWQA | USGS National Water Quality Assessment |
| NOEC | No Observable Effect Concentration |
| NOEL | No Observed Effect Level |
| NOAEL | No Observed Adverse Effect Level |
| NPDES | National Pollutant Discharge Elimination System |
| NR | Not Required |
| OP | Organophosphate |
| OPP | EPA Office of Pesticide Programs |
| OPPTS | EPA Office of Prevention, Pesticides and Toxic Substances |
| Pa | pascal, the pressure exerted by a force of one newton acting on an area of one square meter. |
| PAD | Population Adjusted Dose |
| PADI | Provisional Acceptable Daily Intake |
| PAG | Pesticide Assessment Guideline |
| PAM | Pesticide Analytical Method |
| PCA | Percent Crop Area |

| | |
|------------------|---|
| PDP | USDA Pesticide Data Program |
| PHED | Pesticide Handler's Exposure Data |
| PHI | Preharvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| ppm | Parts Per Million |
| PRN | Pesticide Registration Notice |
| PRZM/ | |
| EXAMS | Tier II Surface Water Computer Model |
| Q ₁ * | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |
| RAC | Raw Agriculture Commodity |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RQ | Risk Quotient |
| RS | Registration Standard |
| RUP | Restricted Use Pesticide |
| SAP | Science Advisory Panel |
| SCI-GROW | Tier I Ground Water Computer Model |
| SF | Safety Factor |
| SLC | Single Layer Clothing |
| SLN | Special Local Need (Registrations Under Section 24(c) of FIFRA) |
| TC | Toxic Concentration. The concentration at which a substance produces a toxic effect. |
| TD | Toxic Dose. The dose at which a substance produces a toxic effect. |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TLC | Thin Layer Chromatography |
| TMRC | Theoretical Maximum Residue Contribution |
| torr | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions. |
| TRR | Total Radioactive Residue |
| UF | Uncertainty Factor |
| µg/g | Micrograms Per Gram |
| µg/L | Micrograms Per Liter |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| UV | Ultraviolet |
| WHO | World Health Organization |
| WP | Wettable Powder |
| WPS | Worker Protection Standard |

Executive Summary

EPA has completed its review of public comments on the preliminary risk assessments and is issuing its risk management decision for propargite. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on propargite. After considering the risks identified in the revised risk assessment, mitigation measures proposed by Uniroyal Chemical Company, the technical registrant of propargite, and comments and mitigation suggestions from other interested parties, EPA developed its risk management decision for uses of propargite that pose risks of concern. This decision is discussed fully in this document.

Propargite is an organosulfur miticide/acaricide used on a variety of bearing and non-bearing agricultural food crops, as well as non-food agricultural sites. It was first registered in 1969. Approximately 2 million pounds of propargite active ingredient are applied annually. Sites on which propargite has the highest percent of crop treated include grapes, walnuts, almonds, nectarines, and mint.

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency does not believe that propargite shares a common mechanism of toxicity with other chemicals. Although chemical class is not necessarily synonymous with a common mechanism of toxicity, structurally similar chemical substances do frequently exhibit common modes of toxicity and may be considered together by EPA for purposes of cumulative risk assessment. Propargite is the only organosulfur chemical that is subject to reregistration under FIFRA and tolerance reassessment under the FQPA. Therefore, propargite is not subject to any cumulative risk assessment as required by the Food Quality Protection Act (FQPA).

Overall Risk Summary

EPA's human health risk assessment for propargite indicates that food risk, both acute and chronic, are not a concern (2% of aPAD and <1% of cPAD). The drinking water risk estimates for acute and chronic exposures, based on screening models and USGS monitoring data, are also not of concern for either ground or surface waters. Propargite is classified as a B2 chemical carcinogen based on the appearance of intestinal tumors in test animals. The cancer dietary risk from food alone is 1.8×10^{-7} for the general U.S. population, and is not a concern for the Agency. However, the cancer drinking water risk from surface water alone may be of concern, based on the screening models and USGS/NAWQA monitoring data. There are also concerns for workers who mix, load, and apply propargite to agricultural sites. Finally, EPA has identified a chronic reproductive risk of concern to birds and mammals, and some risk to aquatic species.

To mitigate risks of concern posed by the uses of propargite, EPA considered the mitigation

proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the worker, and ecological concerns. Results of the risk assessments, and required label amendments to mitigate those risks, are presented in this RED.

Dietary Risk – Food

EPA's dietary risk analysis consists of three parts: acute dietary risk, chronic (non-cancer) dietary risk, and chronic cancer risk. The acute dietary exposure analysis was performed using a refined Tier 3 approach based on the Dietary Exposure Evaluation Model (DEEMTM). The DEEMTM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Under this analysis, a risk estimate that is less than 100% of the acute Population Adjusted Dose ("aPAD") (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's level of concern. Based on the estimates for acute exposure to propargite, the percentage of aPAD utilized is 2 percent; therefore the acute dietary (food) risk estimate for propargite is not of concern.

For the chronic (non-cancer) dietary risk assessment, an average of consumption values for each sub-population is combined with average residue values in/on commodities over a 70-year lifetime to determine average exposure. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern.

The chronic dietary analysis utilized USDA Pesticide Data Program (PDP) monitoring data, field trial data, calculated livestock anticipated residues, and percent crop treated information. Based on that analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic dietary (food) risk estimate is also not of concern.

Chronic (cancer) dietary risk is also calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is combined with a linear low-dose risk model (" Q_1^* ") to determine the lifetime (cancer) risk estimate. The Agency generally considers risks greater than 1×10^{-6} (1 in 1 million) to exceed its level of concern for cancer dietary exposure. Propargite is classified as a B2 chemical carcinogen (likely human carcinogen), based on the appearance of intestinal tumors in rats. The results of the Q_1^* model indicate that the cancer dietary risk from food alone is 1.8×10^{-7} for the general U.S. population. Therefore, the cancer dietary risk from food alone is not a concern.

Dietary Risk – Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the

maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC) to determine whether modeled or monitoring estimated environmental concentration (EEC) levels exceed this level. EECs that are above the corresponding DWLOC exceed the Agency’s level of concern. Modeling is generally considered to be an unrefined assessment and provides high-end estimates.

Based on modeling data, the acute drinking water exposures for females 13-50 years old for surface water and groundwater were less than the acute DWLOC of 2400 ppb. Since the EEC of 34 ppb for surface water and 0.006 for groundwater is less than the DWLOC, the acute dietary risk from food and drinking water are not a concern. Similarly, modeling data for chronic drinking water concentrations for surface water and groundwater exposures also indicated that chronic dietary risk from food and drinking water are not of concern. The DWLOCs were 1400 ppb for the U.S. population and 400 ppb for infants and children compared to a chronic EEC of 8.7 for surface water and 0.006 for groundwater. However, modeling data does indicate a concern for cancer. The EECs for surface water of 4.8 ppb exceed the cancer DWLOC of 0.71 ppb.

Although the cancer drinking water risk estimates from surface water is above the Agency’s level of concern, the Agency believes the modeling estimates and monitoring data upon which the assessment is based are conservative. Actual drinking water exposure to propargite from surface water sources is expected to be less. Moreover, the registrant has agreed to add label statements prohibiting application of propargite by ground within 50 feet or by air within 75 feet of aquatic areas to mitigate the drinking water (and ecological) risk concerns. The registrant has also agreed to conduct a drinking water monitoring study to confirm the Agency’s belief that drinking water exposures will not exceed the level of concern.

Residential Risk

Use of propargite in residential settings is not permitted. Therefore, the Agency does not expect residential exposures to propargite.

Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) as well as exposures from non-occupational sources (e.g., residential uses). Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency. Because there are no residential uses of propargite, the aggregate risks are limited to dietary (food and water) exposure. The risks from those combined exposures are discussed above in the preceding “Dietary Risk - Drinking Water” section.

Occupational Risk

Occupational exposure to propargite is of concern to the Agency, and it has been determined

that a number of mitigation measures are required. For the agricultural uses of propargite, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern (i.e., dermal MOEs are less than 100) at baseline level of protection (shoes, socks, long-sleeved shirts and long pants, and no gloves) for acute and chronic health effects. Also, mixer and loader cancer risks, when calculated without personal protective equipment or engineering controls, can range up to 1×10^{-3} . That estimate also exceeds the Agency's level of concern. EPA believes these risks can be mitigated to an acceptable level with the following label restrictions: (1) requiring use of personal protective equipment for certain scenarios; (2) requiring engineering controls for certain scenarios; (3) increasing restricted entry intervals for certain uses, and (4) reclassifying propargite as a restricted use pesticide.

Ecological Risk

Ecological risks are of concern to the Agency. Based on toxicity studies submitted by the Registrant, propargite poses a potential for adverse effects on reproduction in birds and mammals. Risk to aquatic organisms and plants is generally lower than the risk for birds and mammals; however, the chronic risk concern levels for freshwater invertebrates and freshwater fish are either approached or exceeded for over 60 days from multiple propargite applications. Propargite is also expected to be highly toxic to amphibians. To address these ecological risks, the registrant has agreed to:

- Decrease seasonal maximum rates for several high use crops. See Table 11.
- Add spray intervals of 21 days for most food crops (28 days for citrus). See Table 12.
- Decrease the number of annual applications for cotton.
- Add label statements prohibiting application of propargite by ground within 50 feet or by air within 75 feet of aquatic areas.
- Add label requirements to minimize spray drift exposures.
- Conduct testing to better characterize exposure and risk to birds.

The reclassification of propargite to restricted use may also help address the concerns related to runoff to aquatic areas. Additionally, as noted in the drinking water description above, the registrant will be conducting a surface water monitoring study to address drinking water concerns. Although that study will not be directed specifically at ecological risk, it is expected to produce data useful to assessing ecological risks as well.

Conclusions

The Agency is issuing this Reregistration Eligibility Document (RED) for Propargite, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing propargite. With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that all currently registered uses of propargite are eligible for reregistration.

There is a 60-day public comment period for this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require 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, which was August 3, 1996. 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. Propargite is an organosulfur chemical, and is the only chemical in this class that is subject to tolerance assessment under FQPA. Although chemical class is not necessarily equivalent to a common mechanism of action, in some cases, chemicals within the same class have been shown to share a common mechanism of action and are being considered together for purposes of a cumulative assessment (e.g., the organophosphates). For propargite, there are no other organosulfur chemicals being reviewed under FQPA, and the Agency does not believe that propargite shares a common mechanism of toxicity with other chemicals. Therefore, propargite is not subject to any cumulative risk assessment as required by the FQPA.

This document presents the Agency’s revised human health and ecological risk assessments; the tolerance reassessment; and the reregistration eligibility decision for propargite.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-fold safety factor
- Whether and how to use probabilistic analyses in dietary exposure assessments
- How to interpret “no detectable residues” in dietary exposure assessments
- Refining dietary (food) exposure estimates
- Refining dietary (drinking water) exposure estimates
- Assessing residential exposure
- Aggregating exposure from all non-occupational sources

- How to conduct a cumulative risk assessment for organophosphate or other pesticides with a common mechanism of toxicity
- Selection of appropriate toxicity endpoints for risk assessments of organophosphates
- Whether and how to use data derived from human studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes required label changes based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

II. Chemical Overview

A. Regulatory History

Propargite was first registered in the United States in 1969 for control of mites on a variety of field, fruit, and vegetable crops, as well as ornamentals. It is manufactured by Uniroyal Chemical, the sole propargite registrant, under the trade names Omite and Comite. EPA issued a Registration Standard for Propargite on September 30, 1986 (PB 87-139358). A data call-in was issued on October 13, 1995. In April 5, 1996, the Agency and the registrant signed an agreement under which the registrant voluntarily canceled certain uses of the pesticide. The uses canceled under the agreement included those for apricots, apples, peaches, pears, plums, figs, cranberries, strawberries, green beans, and lima beans. Based on Agency analysis of submitted residue monitoring data, those uses were believed to pose an unacceptable carcinogenicity dietary risk. Tolerances for these 10 uses were subsequently revoked (64 FR 39068; July 21, 1999).

In an effort to promote transparency of the reregistration process and public understanding of regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA) modified the reregistration and tolerance reassessment process in 1998. This modified process provides opportunities for stakeholders to ask questions about and provide input to the risk assessment and risk mitigation strategies, via conference calls and other formats. Consistent with this process, a conference call was conducted on July 19, 2000 with EPA, USDA, the registrant, and other stakeholders (i.e., growers, commodity groups, and others) to discuss the basis of the calculated risks of propargite, and the Agency's resultant risk concerns. Information discussed during the call, such as propargite usage and occupational practices, are reflected in this RED. The August 2, 2000

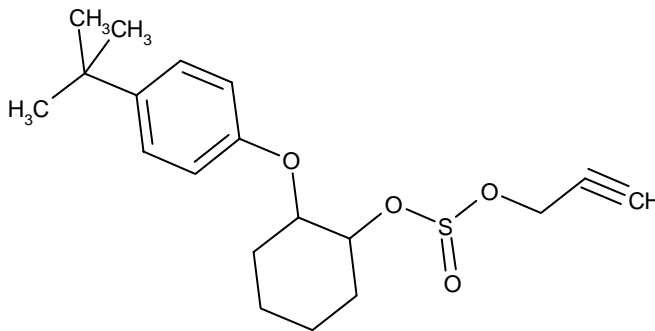
risk assessments were made publically available. Also, a close-out conference call was conducted on September 25, 2001 with many of the same participants from the July 19, 2000 conference call, to discuss the risk management decisions and resultant changes to the propargite labels.

This RED was signed on September 28, 2001. A post-signature comment period opened April 18, 2002 and closed June 17, 2002. The Environmental Protection Agency has reviewed and responded to the public comments. As a result of its review of the public comments, the Agency revised this Propargite RED, where appropriate. The comments and the Agency's responses are available for viewing on the FDMS docket system, available at <http://www.regulations.gov> (docket # OPP-2002-0009). The following changes were made to the September 28, 2001 version of the RED; these changes are incorporated in this December 15, 2005 version.

- (1) Walnut: 21-day restricted-entry interval (REI) exemption granted for tree shaking;
- (2) Citrus: REI for all activities changed to 20 days;
- (3) Mint: REIs for all activities reduced to 7 days;
- (4) Potato: maximum per season use rate increased from 3.7 to 4.1 pounds of active ingredient per acre ("lbs. a.i./A") per season;
- (5) Potato: spray interval reduced from 21 days to 14 days for Washington State;
- (6) Mint: spray interval reduced from 21 days to 14 days.

In addition to the substantive changes listed above, the Agency has also reformatted Appendix B, Appendix D and Appendix I for clarity.

B. Chemical Identification



- **Common Name:** Propargite
- **Chemical Name:** 2-(p-tert-butylphenoxy)cyclohexyl-2-propynyl sulfite
- **Chemical family:** Organosulphite

- **Case number:** 0243
- **CAS registry number:** 2312-35-8
- **OPP chemical code:** 097601
- **Empirical formula:** $C_{19}H_{26}O_4S$
- **Molecular weight:** 350.5 g/mole
- **Trade and other names:** Omite, Comite
- **Basic manufacturer:** Uniroyal Chemical

Propargite technical is a light to dark brown viscous liquid which decomposes ($\sim 200^\circ\text{C}$) before boiling, has a specific gravity of 1.10 at 20°C , octanol/water partition coefficient ($\log K_{ow}$) of 5.8 at 25°C , and vapor pressure of 4.49×10^{-9} mm Hg at 25°C . Propargite is only slightly soluble in water (1.9 ppm at 25°C), but is soluble in most organic solvents (>200 g/L in acetone, dichloromethane, hexane, methanol, and toluene).

C. Use Profile

The following information is based on the currently registered uses of propargite:

Type of Pesticide: Miticide/Acaricide

Summary of Use Sites:

Food: The use sites for propargite include alfalfa, almond, avocado, beans (dry, including dry lima beans), boysenberry, carrot, cherry, corn (field, pop, sweet), currant, date, filbert, grapefruit, jojoba, grapes, hazel nut, hops, lemon, lime, macadamia nut, mint, nectarine, orange, peanuts, pecan, persimmon, pistachio, potato (white, Irish), quince, raspberry, sorghum, sugar beets, tangerines, and walnut.

Other agricultural sites: Christmas tree plantations, clover, conifers, cotton, and ornamental (shade trees, herbaceous plants, woody shrubs and vines).

Residential: None.

Public Health: None.

Target Pests: The common mites controlled by propargite include among others *panonychus*, *tetranychus*, *eotetranychus*, *bryobia*, *oligonychus*, and *typhlodromus*.

Formulation Types Registered: Propargite is formulated as an emulsifiable concentrate liquid and as a wettable powder.

Application Methods and Equipment

Aerial (spray) Equipment: Foliar applications to fruit/nut trees, field crops (e.g., alfalfa, sorghum, corn), cotton, vegetable crops, specialty crops (e.g., Christmas trees, mint, peanuts), roots and tuber vegetable (e.g., carrot, sugar beet).

Chemigation Equipment: Roots and vegetable (e.g., potatoes) and field crops.

Groundboom Equipment: Fruit/nut orchard floors, field crops, cotton, and vegetable crops.

Airblast Equipment: Fruit/nut/ornamental tree foliage.

High Pressure Handwand Equipment: Non-bearing nursery stock.

Application Rates and Frequency: 0.5 to 4.8 lbs active ingredient/acre ; 2 to 3 times per year

Use Classification: Not classified.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of propargite, based on available pesticide usage information for a 10 year period. A full listing of all uses of propargite, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Analysis" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 2 million lbs. a.i. of propargite are used annually, according to Agency and registrant estimates.

Table 1. Propargite Estimated Usage for Representative Sites¹

| Crop | Lbs. Active Ingredient Applied (Wt. Avg.) ² | Percent Crop Treated (Likely Maximum) | Percent Crop Treated (Wt. Avg.) |
|------------|--|---------------------------------------|---------------------------------|
| Alfalfa | 54,900 | 0.3 % | 0.1 % |
| Almonds | 320,000 | 58.9% | 34.5% |
| Beans, Dry | 50,400 | 4.0 % | 2.0 % |
| Corn | 460,000 | 0.7 % | 0.4 % |
| Cotton | 360,000 | 2.9 % | 1.6 % |
| Grapes | 350,000 | 30.1% | 21.7% |
| Mint | Not Available | 34.0% | 22.0% |
| Nectarines | 20,000 | 44.4% | 22.2% |
| Oranges | 43,400 | 1.4 % | 0.7 % |

| | | | |
|-------------|---------|-------|--------|
| Peanuts | 22,500 | 2.9 % | 0.78 % |
| Potatoes | 43,000 | 5.9 % | 2.1 % |
| Sorghum | 2,800 | 0.4 % | 0.2 % |
| Sugar Beets | 5,000 | 0.2 % | 0.1 % |
| Walnuts | 120,000 | 46.3% | 25.3% |

¹ Uses with more than 1,000,000 acres grown or over 20% crop treated were selected as representative sites.

² Weighted Average is based on data for 1988 through 1998; the most recent years and more reliable data are weighted more heavily.

III. Summary of Propargite Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organosulfite pesticide propargite, as fully presented in the documents, "Propargite; Chemical No. 097601. Revised Human Health Risk Assessment for Propargite," dated June 6, 2000, as amended by the "Revised Human Health Risk Assessment for Propargite", dated September 13, 2001, and "Environmental Fate and Effects Division Science Chapter for Reregistration Eligibility Document for Propargite," dated June 7, 2000. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

The original risk assessments for propargite were made available in the public docket and on the internet on August 2, 2000. The Agency reviewed and addressed all comments on the risk assessment documents. There is a discussion of these comments in Section IV, later in this document.

A. Human Health Risk Assessment

In response to comments and studies submitted, the risk assessments were updated and refined. The conclusions of the risk assessment are summarized below.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is sufficiently complete, and that it supports a reregistration eligibility determination for all currently registered uses.

Propargite is classified as a B2 chemical carcinogen based on the appearance of intestinal tumors in test animals. The cancer concern was based on a 2-year cancer bioassay conducted on Sprague Dawley ("SD") rats. In that study, propargite caused fatal tumors of the intestine in both male and female rats. In other studies on mice and Wistar rats, propargite did not exhibit carcinogenicity or mutagenicity. In the SD rat study, there was a greater response in males and therefore, intestinal tumors in male rats were selected for dose-response modeling. Statistical analysis conducted on the survival data indicated that there was a dose-related increase in mortality. The usual Agency practice in such instances is to use the Weibull time-to-tumor model which takes into account both time and dose in estimating probability of tumor occurrence to calculate the cancer risk in humans. After discussions with the Registrant and Agency experts on alternative approaches to statistical cancer modeling, the Agency concluded that its initial analysis, based on the time-to-tumor model, had not correctly accounted for the survival data and that the simpler Quantal model, which estimates tumor incidence only as a function of dose, should be used instead.

A time-to-tumor model is appropriate when there is dose-related mortality in test animals from

non-cancer toxicity. When such dose-related responses occur, animals dying early from non-cancer causes would presumably not be at risk for developing a tumor. In the present case, however, the Agency realized that the early deaths occurring in the study were explained by animals dying from the intestinal tumors before the end of the study, and therefore, those animals were clearly at risk for developing tumors. Thus, the more complex time-to-tumor model was not appropriate. Additionally, further statistical analysis performed by the registrant clearly demonstrated that the Quantal model fit the data from the study very well, while the fit of the time-to-tumor was poor. The net effect of the use of the Quantal Model for propargite is that the estimated cancer potency of propargite is approximately 6 times lower than that presented in the preliminary risk assessment of June 6, 2000.

Further details on the toxicity of propargite can be found in the September 13, 2001 Human Health Risk Assessment, and the August 14, 2001 Memorandum "Recommendation for Selection of Cancer Dose-Response Model and Q_1^* for Propargite". A brief overview of the studies used for the dietary risk assessment and other relevant information is outlined in Table 2 .

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X based on the following factors: first, the toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute in utero exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. Although propargite produced developmental effects in the rabbit, these effects were observed at the maternally toxic dose. Second, the Agency believes that its exposure assessments will not underestimate the potential dietary exposures for infants and children from the use of propargite. Third, there are currently no approved residential uses of propargite. Based on these factors, the additional 10X factor as required by FQPA was reduced to 1X.

c. Population Adjusted Dose (PAD)

The PAD is a risk expression describing the dietary risk of a chemical, and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., $RfD/FQPA$ safety factor). In the case of propargite, the FQPA safety factor is 1; therefore, the acute RfD equals the acute PAD and the chronic RfD equals the chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern. The Agency's acute assessment concerns women of child-bearing age only, since the toxicological endpoint relates to developmental toxicity. No suitable acute toxicological endpoint was identified for the general population.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Propargite

| Assessment | Dose (mg/kg/day) | Endpoint | Study/MRID | Uncertainty Factor | FQPA Safety Factor | PAD (mg/kg/day) |
|----------------------------------|------------------|--|---|---|--------------------|-----------------|
| Acute Dietary-females 13-50 | NOAEL= 8 | Increased incidence of fused sternebrae in fetuses at 10 mg/kg/day (LOAEL). | Developmental Toxicity in Rabbits 41336301 | 100 | 1 | aPAD = 0.08 |
| Acute Dietary-general population | NOAEL= N/A | No relevant single exposure endpoint was identified. | N/A | N/A | 1 | N/A |
| Chronic Dietary | NOAEL = 4 | Decreased body weight/body weight gain and increased mortality at 19 mg/kg/day(LOAEL) for males. | Chronic Feeding and Carcinogenicity in Rats 41750901 & 42837201 | 100 | 1 | cPAD = 0.04 |
| Cancer Risk | | Jejunal Tumors in Sprague-Dawley rat | [Same as above] | $Q_1^* = 0.033 \times 10^{-1} \text{ (mg/kg/day)}^{-1}$ | | |

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for propargite were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91. For the acute dietary risk assessment, the entire distribution of single day food consumption events was combined with a distribution of residues. This is known as a probabilistic analysis. Risk is reported at the 99.9th percentile of exposure to obtain a distribution of exposure in mg/kg/day. For the chronic dietary risk assessment, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

In the case of propargite, a probabilistic acute dietary analysis was conducted utilizing USDA Pesticide Data Program (PDP) monitoring data, field trial data, calculated livestock anticipated residues, and percent crop treated information.

e. Food Risk Characterization

Because no relevant effects following a single dose of propargite were identified for the U.S. general population, an acute dietary risk assessment for the entire U.S. population was not conducted. However, an assessment was conducted for the subpopulation of women of childbearing age ("females 13-50 years old") because developmental effects (birth defects) in rats were noted in one developmental rat toxicity study. The effects, skeletal malformations, are presumed to occur after a single exposure (dose), and thus, are appropriate for the acute risk assessment. There was no increased susceptibility to infants or children. Estimated acute dietary exposure is below EPA's level of concern at the 99.9th percentile (the maximum dietary risk estimate of 2 percent of the aPAD).

Estimated chronic dietary risk estimate is also below EPA's level of concern. Less than 1 percent of the chronic PAD for the U.S. general population and all population subgroups is estimated.

The maximum lifetime cancer dietary risk is estimated to be 1.8×10^{-7} for the general U.S. population. Therefore, the cancer risk from food is also not a concern since the risk is less than 1×10^{-6} .

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or, if available, actual monitoring data to estimate those risks. Modeling is generally considered to be an unrefined assessment and provides a high-end estimate of risk.

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. Both of these models are considered to be screening tools, with the PRZM-EXAMS model being somewhat more refined than the other two. In addition, the Agency used time-weighted annual mean for propargite concentrations in surface water samples from the United States Geologic Survey National Water Quality Assessment ("USGS /NAWQA") (Oristimba Creek Watershed) for the years 1992 and 1993.

Propargite is moderately persistent (metabolism half-lives = 38-168 days) and immobile (K_d s ranged from 60 to 218 mL/g, while K_{oc} s ranged from 2963 to 57966 mL/g). It degrades rapidly under alkaline hydrolytic conditions (half-life = 2.2 days) and is moderately persistent to persistent under neutral (half-lives = 75 days) and acid (pH 5; half-life = 120 days) hydrolytic conditions. Soil and aquatic photolysis and aerobic and anaerobic metabolism occur at moderate rates (half-lives = 39-168 days). Because of its high affinity for soil and sediment, propargite has the potential to move off the site of application during rainfall, irrigation, erosion, runoff on soil particles and by drift. Given the moderate to slow degradation rates for metabolism and photolysis, and the high K_{oc} values, propargite will probably be adsorbed to sediments and organic material if transported to surface waters. The Agency Metabolism Assessment Review Committee has concluded that the residue of concern in plants and animals is propargite *per se* and not its metabolites or degradate products.

a. Surface Water

PRZM-EXAMS (“Tier II”) modeling was conducted as a refinement to the drinking water exposure assessment because the GENEEC (“Tier I”) surface water modeling predicted that the 56-day average propargite concentrations in surface water were likely to exceed the cancer drinking water level of comparison (DWLOC).

The Tier II modeling simulated average propargite a peak residue of 34 ppb for the acute value, and average residues of 8.7 ppb for the chronic value, and 4.8 for the cancer value. Since the cancer value exceeded the cancer DWLOC of 0.71, EPA investigated the United States Geologic Survey (“USGS”) National Water Quality Assessment (“NAWQA”) monitoring data further to evaluate how it compared to the modeling results. In that monitoring program, propargite was detected in 175 of 5196 samples for the period 1991 to 1995, with a maximum concentration of 20.0 ppb. The next highest concentration was 3.7 ppb. Out of the total 5196 samples, propargite was detected in 53 of 1000 samples taken from agricultural streams. Propargite was detected in 1 of 327 samples taken from urban streams, at a concentration of 0.015 ppb. Propargite was detected in 8 of 245 samples taken from 14 integrator sites on large streams and rivers, with a maximum concentration of 2.0 ppb.

Propargite detections in the NAWQA study were predominantly associated with the San Joaquin-Tulare study unit at intensive-fixed monitoring sites. This region corresponds with high propargite use (> 1.526 lb propargite/mile²/year) in the San Joaquin region and is associated primarily with beans, cotton, and almond production.

Although the cancer drinking water risk estimates from surface water is above the Agency’s level of concern, the Agency believes, in the case of propargite, the modeling and monitoring data upon which the estimates are based are conservative and overestimates of actual exposure to propargite in drinking water from surface water sources. The reasons for this are described in the next section under “DWLOCs for Cancer.”

b. Ground Water

A Tier I screening model, SCI-GROW, was used to provide an upper-end estimate of drinking water concentrations derived from ground water. The Agency’s default body weights and water consumption values used to calculate drinking water exposures are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). The predicted groundwater concentration is 0.006 ppb. Fate studies also suggest that propargite has a low potential to reach groundwater. Therefore, the Agency does not have a concern for human exposure to propargite for drinking water from ground water sources.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a “drinking water level of comparison”(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern. In the case of propargite, there are no residential uses, therefore, only food and drinking water contributions were considered.

The results of the Agency’s drinking water analysis are summarized here. Details of this analysis, which used screening models and actual monitoring data, are found in the Revised Human Health Risk Assessment for Propargite, dated September 13, 2001.

i. DWLOCs for Acute Exposure

The DWLOC for acute exposure is 2400 ppb. Table 3 below presents the calculations for the acute drinking water assessment.

Table 3. Drinking Water Levels of Comparison for Acute Dietary Exposure.

| Population Subgroup | Acute PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Max. Water Exposure (mg/kg/day) | DWLOC _{acute} (ppb) | Surface Water EEC (ppb) (PRZM-EXAMS) | Groundwater EEC (ppb) (SCI-GROW) |
|---------------------|-----------------------|---------------------------|---------------------------------|------------------------------|--------------------------------------|----------------------------------|
| Females 13-50 yrs. | 0.08 | 0.001 | 0.08 | 2400 | 34 | 0.006 |

ii. DWLOCs for Chronic Exposure

The DWLOC for chronic exposures are 400 ppb for infants and children and 1400 ppb for the general U.S. population. Table 4 below presents the calculations for the chronic drinking water assessment.

Table 4. Drinking Water Levels of Comparison for Chronic (Non-Cancer) Dietary Exposure.

| Population Subgroup | Chronic PAD (mg/kg/day) | Food Exposure (mg/kg/day) | Max. Water Exposure (mg/kg/day) | DWLOC _{chronic} (ppb) | Surface Water EEC (ppb) (PRZM-EXAMS) | Groundwater EEC (ppb) (SCI-GROW) |
|---------------------|-------------------------|---------------------------|---------------------------------|--------------------------------|--------------------------------------|----------------------------------|
| US Population | 0.04 | 0.00001 | 0.04 | 1400 | 8.7 | 0.006 |
| All Infants | 0.04 | 0.00001 | 0.04 | 400 | 8.7 | 0.006 |
| Children 1-6 | 0.04 | 0.00001 | 0.04 | 400 | 8.7 | 0.006 |
| Children 7-12 | 0.04 | 0.00001 | 0.04 | 400 | 8.7 | 0.006 |
| Females 13-50 yrs. | 0.04 | 0.00001 | 0.04 | 1200 | 8.7 | 0.006 |
| Males 20+ yrs | 0.04 | 0.00001 | 0.04 | 1400 | 8.7 | 0.006 |

iii. DWLOCs for Cancer

The cancer DWLOC is the concentration of a pesticide in drinking water as a part of the aggregate chronic exposure that results in a negligible cancer risk (1×10^{-6} or less). The surface water EECs are 4.8 ppb based on PRZM-EXAMS modeling and the groundwater EECs are 0.006 ppb based on SCI-GROW. The Cancer DWLOC is 0.71.

Table 5. Propargite Cancer Dietary Exposure/Risk.

| Population Subgroup | Lifetime Risk ($Q_1^* = .033$) | Target Max Exposure ² mg.kg.day | Chronic Food Exposure mg/kg/day | Max Water Exposure ³ mg/kg/day | Exposure (mg/kg/day) | Groundwater EEC (ppb) (SCI-GROW) | Surface Water EEC (ppb) (PRZM-EXAMS) | DWLOC _{cancer} (ppb) |
|---------------------|----------------------------------|--|---------------------------------|---|----------------------|----------------------------------|--------------------------------------|-------------------------------|
| U.S. Population | 1.8×10^{-7} | 0.0000303 | 0.00001 | 0.0000203 | 0.000006 | 0.006 | 4.8 | 0.71 |

¹DWLOC_{cancer} was calculated for US population only. Default body weight and consumption value for calculation of the DWLOC were: 2L/70 kg.

²Target Maximum Exposure (mg/kg/day) = [negligible risk/ Q^*]

³Maximum Water Exposure (mg/kg/day) = [Target Maximum Exposure - (Chronic Food Exposure + Residential Exposure (Lifetime Average Daily Dose))]

⁴Cancer DWLOC 9ppb = $\frac{\text{maximum water exposure (mg/kg/day)} \times \text{body weight (kg)}}{[\text{water consumption (L)} \times 10^{-3} \text{mg}/\mu\text{g}]^2}$

3. Aggregate Risks (Food and Water)

An aggregate risk assessment considers the combined risk from dietary exposure (food and drinking water) and residential risk or other non-occupational exposures, when appropriate. The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require that for establishing a pesticide tolerance “that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.” Aggregate exposure will typically include exposures from food, drinking water, and residential uses of a pesticide, and other non-occupational sources of exposure. When appropriate, aggregate risk assessments are conducted for acute (one day), short-term (one to seven days), intermediate-term (seven days to several months), and chronic (lifetime) exposure. Occupational exposure is not considered in any aggregate exposure assessment.

a. Acute Aggregate Risk

The acute aggregate risk estimates for propargite address exposure from food and drinking water. There are no residential uses of propargite. Acute exposure is considered to occur in a one-day time frame via the oral route of exposure. Acute dietary risks are below the Agency’s level of concern if less than 100 % of the aPAD. The estimated concentrations of propargite in drinking water, which are 34 ppb for surface water and 0.006 ppb for groundwater, are below the Agency’s level of concern for all subpopulations including children 1-6 years (DWLOC = 2400 ppb). The Agency is, therefore, not concerned with aggregate risks associated with propargite use.

b. Chronic (Non-Cancer) Aggregate Risk

A chronic aggregate assessment estimates risk from long term exposure to food and water. There are no residential uses of propargite. The chronic DWLOC for infants and Children is 400 ppb and 1400 ppb for the general population, while the EEC in surface water is 8.7 ppb and ground water is 0.006 ppb. The chronic EECs are less than the chronic DWLOCs. The Agency is, therefore, not concerned with aggregate risks associated with propargite use.

c. Aggregate Risk for Cancer

The EECs for surface water (4.8 ppb) were greater than the cancer DWLOC (0.71 ppb), indicating that the chronic exposure to propargite in food and water is greater than the Agency’s level of concern. Surface water concentrations below 1.0 ppb would result in cancer risks below 1×10^{-6} for drinking water alone when back calculated. Based on monitoring data, the time weighted average propargite concentration in ambient surface water samples from the USGS/NAWQA (Oristimba Creek Watershed) for the years 1992 and 1993 were 0.30 and 1.24 ppb, respectively. Therefore, there is a potential cancer risk of concern when ambient monitoring data are used to estimate drinking water exposure to propargite from surface water sources.

The EECs for groundwater were less than the cancer DWLOC, and therefore not a concern.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of propargite include: individual farmers or growers who mix, load, and/or apply pesticides, and professional or custom agricultural applicators. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). In the case of propargite, MOEs greater than 100 for dermal and 1000 for inhalation do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of propargite is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for propargite. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for propargite are listed below in table 6.

Table 6. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Assessments for Propargite

| Assessment | Dose (mg/kg/day) | Endpoint | Study/ MRID |
|--|--|--|--|
| Short-Term ¹ (Dermal) | NOAEL= 6 MOE = 100 | Decreased maternal body weight gain at 8 mg/kg/day (LOAEL). | Developmental Toxicity in Rabbits 41336301 |
| Intermediate-Term ¹ (Dermal) | NOAEL= 4 MOE = 100 | Reduction in body weight gain and food consumption at 20 mg/kg/day (parental LOAEL). | Reproductive Toxicity in Rats 41352401 |
| Short Term ² (Inhalation) | LOAEL= 0.31mg/L or 50 mg/kg MOE = 1000 | Increased mortality at 0.31 mg/L (LOAEL) in males. | Acute Inhalation in Rats 42857003 |
| Intermediate Term ² (Inhalation) | | | |
| Cancer Q ₁ ^{*1} | 0.033x10 ⁻¹ (mg/kg/day) | Jejunal (intestinal) tumors at 400 and 800 ppm dose levels. | Mouse - 18 month Rat - 24 month 42837201 |

¹ A 14% dermal absorption factor was used for risk assessment based on highest absorption/elimination noted in submitted studies. Dermal MOE used for risk assessment of 100 based on use of animal toxicity studies.

² Separate MOEs for dermal and inhalation were used because of different endpoints. An MOE of 1000 was selected for inhalation, including a 10X factor due to lack of a NOAEL, severity of effects at the lowest dose tested, and 4 hour duration. A 100% inhalation absorption factor was used.

Propargite is considered corrosive and has been placed in Category I for both eye and dermal irritation in rabbits. There have also been documented reports of dermal and eye irritation developing in workers exposed to propargite in the field. Evidence for its dermal sensitization potential have been noted; a study that provides conclusive results of this effect has not been possible due to the irritating properties of this chemical.

Table 7: Acute Toxicity of Propargite.

| Guideline No. | Study Type | MRID #(S). | Results | Toxicity Category |
|---------------|---------------------------------|------------|--|-------------------|
| 870.1100 | Acute Oral-Rat | 42857001 | LD ₅₀ = 2639 mg/kg for males 2947 mg/kg for females 2800 mg/kg combined | III |
| 870.1200 | Acute Dermal-Rabbit | 42857002 | LD ₅₀ > 2000 mg/kg | III |
| 870.1300 | Acute Inhalation-Rat | 42857003 | LC ₅₀ = 0.95 mg/L for males 0.95 mg/L for females 0.89 mg/L combined | III |
| 870.1400 | Primary Eye Irritation-Rabbit | 42857004 | Corrosive | I |
| 870.1500 | Primary Skin Irritation-Rabbit | 42857005 | Corrosive | I |
| 870.1600 | Dermal Sensitization-Guinea Pig | 42857006 | Sensitizer | N/A |

b. Exposure

Uniroyal submitted applicator exposure studies in support of the reregistration process for propargite. These studies include:

- Airblast applicator exposure studies (MRID Nos. 418486-05 and 420997-02)
- Groundboom applicator exposure study (MRID No. 418486-05)

It is EPA's policy to combine chemical specific studies with similar surrogate data from the Pesticide Handlers Exposure Database (PHED) to assess handler exposures for regulatory actions. This policy is in effect because individual chemical-specific studies do not necessarily encompass the variety of equipment in use throughout the country and the large variability of exposures among handlers. While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. PHED was designed by a Task Force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from propargite labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the September 13, 2001, Revised Human Health Assessment document for Propargite, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount of acres treated were derived from current product labeling. Application rates specified on propargite labels range from 0.5 to 4.5 pounds of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent 8 hours of application work for specific types of application equipment.

EPA calculated the baseline MOE (short-term and intermediate-term) and cancer risk for each of the exposure scenarios using the following **baseline** PPE assumptions: Long-sleeved shirt, long pants, shoes (or boots) and socks (no gloves).

If the short-term or intermediate-term MOE calculated using this baseline PPE was 100 or greater for an exposure scenario, then no further calculations were made. If the baseline short-term or intermediate-term MOE was less than 100 for any exposure scenario, an additional short-term or intermediate-term MOE was calculated based on increasing the levels of protection (additional PPE). EPA calculated a short-term and/or intermediate-term MOE using additional PPE for each occupational exposure scenario that had baseline total MOE of less than 100, using the following additional **PPE** assumptions:

- Baseline PPE + chemical resistant gloves.
- Coveralls over long sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear plus socks, and chemical resistant headgear for over head exposures (such as airblast applications).

If the short-term or intermediate-term MOE calculated using this additional-PPE was 100 or greater for an exposure scenario, then no further calculations were made. If MOE remained less than 100 for any occupational exposure scenario, a short-term or intermediate-term MOE was calculated based on the mandatory use of engineering controls, where feasible. Engineering controls needed to address identified risks are noted in the final column of Table 8. EPA calculated the engineering-control short-term or intermediate-term MOE for each occupational exposure scenario with an additional-PPE short-term or intermediate-term MOE of less than 100, using the following **engineering control** assumptions:

- Occupational mixers and loaders handling liquid formulations using a closed system are wearing baseline PPE, chemical resistant gloves and chemical resistant apron.

- Occupational mixers and loaders handling wettable powders using a closed system (water-soluble packages) are wearing baseline PPE, chemical resistant gloves and chemical resistant apron.
- Occupational applicators who use aerial, airblast, or tractor-driven application equipment and handlers flagging for aerial applications are located in enclosed cabs or cockpits and wearing baseline PPE.

Finally, exposure to workers through post-application entry into agricultural fields treated with propargite, were also assessed. The assumptions used in that analysis are described under section 3.c.ii. below.

c. Occupational Handler Risk Summary

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with propargite. Based on the use patterns and potential exposures described above, 14 major agricultural exposure scenarios are identified in this document to represent the extent of propargite uses.

Agricultural exposure scenarios include: (1a) mixing/loading liquids for aerial application, (1b) mixing/loading liquids for chemigation, (1c) mixing/loading liquids for groundboom application, (1d) mixing/loading liquids for orchard airblast sprayer application, (1e) mixing/loading liquids for application of high pressure handwand, (2a) mixing/loading wettable powder for aerial application, (2b) mixing/loading wettable powder for groundboom application, (2c) mixing/loading wettable powder for orchard airblast sprayer application, (2d) mixing/loading wettable powder for application of high pressure handwand, (3) applying sprays with fixed-wing aircraft, (4) applying sprays using a groundboom sprayer, (5) applying sprays with an airblast sprayer, (6) applying liquids with a high pressure handwand and (7) flagging during aerial spray application.

In most cases, EPA assesses the exposure and risk to mixer/loaders and applicators separately for tractor drawn applications (i.e., airblast, groundboom, and granular spreaders). This practice has evolved, not because it is believed that there are always separate job functions, but rather because of the limited amount of information regarding these practices along with limited exposure data.

EPA has adopted a methodology to present the risks separately for some scenarios and combine others. Most of the hand-held equipment such as backpack sprayers, and push type granular spreaders are assessed as a combined function. With these types of small operations the mixing, loading, and applying are almost always carried out by the same individual and there are data available to estimate exposure from these activities. For equipment such as fixed-wing-aircraft, groundboom tractors, and airblast sprayers the applications are assessed separately from the individual who mixes and loads the formulated product. EPA assumes that the pilots are rarely involved in the mixing/loading. By separating the two job functions, EPA can determine the most appropriate PPE

or engineering control without requiring the handler to wear PPE throughout the entire workday or engineering controls that are not needed.

The potential handler exposures are assessed using the toxicological endpoints and uncertainty factors associated with the active ingredient. Therefore, the PPE and engineering controls are determined by the assessment of the active ingredient and not the currently required risk mitigation measures on propargite labels. This distinction of determining risk mitigation measures based on the active ingredient instead of the label required PPE is also important because of the nature of the end-use products. For example, some end-use products require additional PPE that are not necessary for the active ingredient but rather because of the end-use product's potential for eye and/or skin irritation based on other ingredients of the formulation. Conversely, the Agency does not want to mandate additional PPE (e.g., heat stress issues) if the PPE ensemble is not required based on the endpoint and uncertainty factors.

i. Agricultural Handler Risk

Table 8 below summarizes the numeric MOE values for both the short and intermediate-term exposure durations as well as cancer risk estimates. In the majority of cases, dermal exposure rather than inhalation exposure contributes relatively more exposure (dermal and inhalation exposures were not combined in this assessment for the short and intermediate-term MOEs. However, dermal and inhalation exposures were added for the cancer risk estimates). The MOEs are presented for baseline, PPE and engineering controls. Cancer risk estimates are also summarized at different levels of mitigation. MOEs 100 or above are not a concern for dermal exposure, while MOEs 1000 or above are required to be above the Agency's level of concern for inhalation exposure (and extra 10X factor is included due to lack of a NOAEL, severity of effects at the lowest dose tested, and 4 hour duration). The target for cancer risk is 1×10^{-6} , however, the Agency will not accept risks above 1×10^{-4} . For risks between 1×10^{-6} and 1×10^{-4} , the Agency will pursue risk mitigation where feasible.

Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite

| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^c | | | Cancer ^d | | |
|--|------------------------------|--|--------------------------------------|---------------------------|--|-----|----------------|---|-----|-----------------|------------------------------|------|-------------------|---------------------|-------------------|-------------------|
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control |
| Mixer/Loader Exposure | | | | | | | | | | | | | | | | |
| Mixing/Loading Liquids for Aerial Application (1a) | Roots and Tuber Vegetable | carrot, sugar beet, potatoes, dry beans, mint | Min 2.0 | 350 | 1 | 160 | NA | <1 | 125 | NA | 4135 | NA | NA | 1.3E-3/ 2.7E-3 | 1.4E-5/ 2.8E-5 | 4.0E-6/ 8.0E-6 |
| | Legume Vegetable | | Max 2.5 | | 1 | 130 | NA | <1 | 100 | NA | 3305 | NA | NA | 1.6E-3/ 3.2E-3 | 1.7E-5/ 3.5E-5 | 5.0E-6/ 9.9E-6 |
| | Herbs & Spices | hops | Max 2.5 | 80 | 4 | 560 | NA | 3 | 435 | NA | 14465 | NA | NA | 3.6E-4/ 7.3E-4 | 4.0E-6/ 7.9E-5 | 1.2E-6/ 2.3E-6 |
| | Citrus Fruits | grapefruit, orange | Max 2.5 | 125 | 3 | 360 | NA | 2 | 280 | NA | 9260 | NA | NA | 5.6E-4/ 1.1E-3 | 6.3E-6/ 1.3E-5 | 1.8E-6/ 3.6E-6 |
| | Tree Nuts | almond, walnut | Min 2.5 | 125 | 3 | 360 | NA | 2 | 280 | NA | 9260 | NA | NA | 5.6E-4/ 1.1E-3 | 6.3E-6/ 1.3E-5 | 1.8E-6/ 3.6E-6 |
| | | | Max 4.5 | | 2 | 200 | NA | 1 | 155 | NA | 5145 | NA | NA | 1.0E-3/ 2.0E-3 | 1.1E-5/ 2.2E-5 | 3.3E-6/ 6.5E-6 |
| | Cereal Grains | corn (field, pop, sweet), sorghum grain, alfalfa, clover | Min 1.5 | 350 | 2 | 215 | NA | 1 | 165 | NA | 5510 | NA | NA | 9.6E-4/ 1.9E-3 | 1.1E-5/ 2.1E-5 | 3.1E-6/ 6.1E-6 |
| | | | | | 1200 | <1 | 60 | 170 | <1 | 50 | 130 | 1600 | NA | NA | 3.3E-3/ 6.6E-3 | 3.8E-5/ 7.5E-5 |
| | Non-grass Animal Feed | | Max 2.5 | 350 | 1 | 130 | NA | <1 | 100 | NA | 3305 | NA | NA | 1.6E-3/ 3.2E-3 | 1.7E-5/ 3.5E-5 | 5.0E-6/ 9.9E-6 |
| | | | | | 1200 | <1 | 35 | 100 | <1 | 30 | 80 | 960 | 1400 | NA | 5.5E-3/ 1.1E-2 | 5.8E-5/ 1.2E-4 |
| | Oil Seed | cotton | Max 1.6 | 350 | 2 | 200 | NA | 1 | 155 | NA | 5165 | NA | NA | 1.0E-3/ 2.0E-3 | 1.1E-5/ 2.2E-5 | 3.3E-6/ 6.5E-6 |
| | | | | | 1200 | <1 | 60 | 155 | <1 | 45 | 120 | 1505 | NA | NA | 3.6E-4/ 7.3E-4 | 4.0E-5/ 7.9E-5 |
| | | peanut, jojoba | Min 1.5 | 350 | 2 | 215 | NA | 1 | 165 | NA | 5510 | NA | NA | 9.6E-4/ 1.9E-3 | 1.1E-5/ 2.1E-5 | 3.1E-6/ 6.1E-6 |
| | | | | | Max 2.5 | 1 | 130 | NA | <1 | 100 | NA | 3305 | NA | NA | 1.6E-3/ 3.2E-3 | 1.7E-5/ 3.5E-5 |
| | Ornamental plants | Christmas Tree conifer seed | Max 2.5 | 125 | 3 | 360 | NA | 2 | 280 | NA | 9260 | NA | NA | 5.6E-4/ 1.1E-3 | 6.3E-6/ 1.3E-5 | 1.8E-6/ 3.6E-6 |
| Mixing/Loading Liquids for Chemigation (1b) | Roots and vegetable | potatoes, corn (sweet) | Min 2.0 | 350 | 1 | 160 | NA | 1 | 125 | NA | 4135 | NA | NA | 1.3E-3/ 2.6E-3 | 1.4E-5/ 2.8E-5 | 4.0E-6/ 7.9E-6 |
| | Cereal Grains | Max 2.5 | 1 | | 130 | NA | <1 | 100 | NA | 3305 | NA | NA | 1.6E-3/ 3.2E-3 | 1.7E-5/ 3.5E-5 | 5.0E-6/ 9.9E-6 | |

Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite

| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^e | | | Cancer ^f | | |
|---|---------------------------------------|--|--------------------------------------|---------------------------|--|------|----------------|---|-------|-----------------|------------------------------|------|-----------------|---------------------|-------------------|-------------------|
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control |
| Mixing/Loading Liquids for Groundboom Application (1c) | Roots and Vegetable | potatoes, corn (field, | Min 1.5 | 80 | 7 | 930 | NA | 6 | 725 | NA | 24110 | NA | NA | 2.2E-4/ 4.4E-4 | 2.4E-6/ 4.8E-6 | 6.9E-7/ 1.4E-6 |
| | Cereal Grains | pop, sweet) | | | | | | | | | | | | | | |
| | Non-grass Animal Feed | sorghum grain, alfalfa, clover, cotton, peanut, jojoba and mint | | | | | | | | | | | | | | |
| | Oil Seed | | Max 2.5 | | 4 | 560 | NA | 3 | 435 | NA | 14465 | NA | NA | 3.6E-4/ 7.3E-4 | 4.0E-6/ 7.9E-6 | 1.2E-6/ 2.3E-6 |
| | Herbs and Spices | | | | | | | | | | | | | | | |
| Mixing/Loading Liquids for Airblast Sprayer Application (1d) | Pome Fruits | quince, cherry, | 1.5 | 40 | 15 | 1865 | NA | 10 | 1450 | NA | 48220 | NA | NA | 1.1E-4/ 2.2E-4 | 1.2E-6/ 2.4E-6 | 3.6E-7/ 7.3E-7 |
| | Stone fruits | prunes, orange, | | | | | | | | | | | | | | |
| | Citrus Fruits | grapefruit lemon, lime, tangerine, | | | | | | | | | | | | | | |
| | Berries | boysenberry, current, date | | | | | | | | | | | | | | |
| | Herbs and Spices | raspberry, hops, persimmons, | | | | | | | | | | | | | | |
| | Tropical and Subtropical Fruits | | | | | | | | | | | | | | | |
| | Tree Nuts | almond, filbert, | Min 1.5 | | 15 | 1865 | NA | 10 | 1450 | NA | 48220 | NA | NA | 1.1E-4/ 2.2E-4 | 1.2E-6/ 2.4E-6 | 3.6E-7/ 7.3E-7 |
| | | macadamia nut, pecan, pistachio | Max 3.0 | | 7 | 930 | NA | 6 | 725 | NA | 24110 | NA | NA | 2.2E-4/ 4.4E-4 | 2.4E-6/ 4.8E-6 | 6.9E-7/ 1.4E-6 |
| | | walnut | Max 4.5 | | 5 | 620 | NA | 4 | 485 | NA | 16075 | NA | NA | 3.3E-4/ 6.6E-4 | 3.6E-6/ 7.3E-6 | 1.1E-6/ 2.1E-6 |
| | Ornamental plants | Christmas Tree plantation, conifers, shade trees | Max 2.5 | | 9 | 1120 | NA | 7 | 870 | NA | 28935 | NA | NA | 1.9E-4/ 3.7E-4 | 2.0E-6/ 4.0E-6 | 5.9E-7/ 1.2E-6 |
| Mixing/Loading Liquids for Application of High Pressure Handwand (1e) | Non-bearing nursery stock | all crops | Max 1.5 | 5 | 120 | NA | NA | 90 | 11595 | NA | 385780 | NA | NA | 1.4E-5/ 2.8E-5 | 5.0E-6/ 9.9E-6 | 6.9E-8/ 1.4E-7 |
| Mixing/Loading Wettable Powder for Aerial Application (2a) | Stone fruits | nectarine | Max 3.0 | 125 | 2 | 40 | 325 | 1 | 30 | 255 | 215 | 2155 | NA | 9.6E-4/ 1.9E-3 | 1.0E-4/ 2.0E-4 | 5.3E-6/ 1.1E-5 |
| | Tree Nuts | walnut | Max 4.0 | | 1 | 30 | 245 | 1 | 25 | 190 | 160 | 1615 | NA | 1.3E-3/ 2.6E-3 | 1.4E-4/ 2.8E-4 | 7.9E-6/ 1.6E-5 |
| | Ornamental plants | Christmas Tree | Max 2.5 | 125 | 2 | 50 | 390 | 2 | 40 | 305 | 255 | 2585 | NA | 7.9E-4/ 1.6E-3 | 8.6E-5/ 1.7E-4 | 4.6E-6/ 9.2E-6 |

Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite

| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^e | | | Cancer ^f | | |
|--|--|---|--------------------------------------|---------------------------|--|-----|----------------|---|-----|-----------------|------------------------------|-------|-------------------|---------------------|-------------------|-------------------|
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control |
| Mixing/Loading Wettable Powder for Groundboom Application (2b) | Oil Seed | peanut | Max 1.6 | 80 | 5 | 120 | NA | 4 | 90 | 745 | 625 | 6310 | NA | 3.2E-6/ 6.5E-4 | 4.0E-5/ 7.9E-5 | 1.8E-6/ 3.6E-6 |
| Mixing/ Loading Wettable Powder for Airblast Sprayer Application (2c) | Citrus fruits | grapefruit, orange, lemon, avocado | Min 3.0 | 40 | 6 | 125 | NA | 5 | 100 | NA | 665 | 6730 | NA | 3.0E-4/ 6.0E-4 | 3.6E-5/ 7.3E-5 | 1.7E-6/ 3.4E-6 |
| | Tropical and subtropical fruits | | Max 4.5 | | 4 | 85 | 680 | 3 | 65 | 530 | 445 | 4485 | NA | 4.6E-4/ 9.2E-4 | 5.3E-5/ 1.1E-4 | 2.6E-6/ 5.1E-6 |
| | Herbs & spices | hops | Min 2.0 | | 9 | 190 | NA | 7 | 145 | NA | 1000 | NA | NA | 2.0E-4/ 4.0E-4 | 2.4E-5/ 4.8E-5 | 1.2E-6/ 2.3E-6 |
| | | | Max 2.5 | | 7 | 150 | NA | 5 | 120 | NA | 800 | 8075 | NA | 2.5E-4/ 5.0E-4 | 3.0E-5/ 5.9E-5 | 1.5E-6/ 2.9E-6 |
| | Small Fruits | grapes | Max 3.0 | | 6 | 125 | NA | 5 | 100 | NA | 665 | 6730 | NA | 3.0E-4/ 6.0E-4 | 3.6E-5/ 7.3E-5 | 1.7E-6/ 3.4E-6 |
| Mixing/ Loading Wettable Powder for Application of High Pressure Handwand (2d) | Non- bearing Nursery Stock | all crops | Min 0.5 | 5 | 280 | NA | NA | 215 | NA | NA | 32000 | NA | NA | 6.6E-6/ 1.3E-5 | 2.7E-7/ 5.3E-7 | NA |
| | | | Max 2.5 | 55 | 1210 | NA | 45 | 940 | NA | 6400 | NA | NA | 3.2E-5/ 6.3E-5 | 1.4E-6/ 2.7E-6 | NA | |
| Applicator Exposure | | | | | | | | | | | | | | | | |
| Applying Sprays with Fixed-Wing Aircraft–Enclosed Cockpit (3) | Roots and Tuber Vegetable | carrot, sugar beet, potatoes, dry beans, mint | Min 2.0 | 350 | NA | NA | 735 | NA | NA | 570 | NA | NA | 72940 | NA | NA | 2.4E-6/ 4.9E-6 |
| | | | Max 2.5 | | NA | NA | 585 | NA | NA | 455 | NA | NA | 58355 | NA | NA | 3.0E-5/ 6.1E-5 |
| | Legume Vegetable | | | | | | | | | | | | | | | |
| | Herbs and Spices | hops | Max 2.5 | 80 | NA | NA | 2570 | NA | NA | 2000 | NA | NA | 255295 | NA | NA | 6.9E-7/ 1.4E-6 |
| | Citrus fruits | grapefruit, orange | Max 2.5 | 125 | NA | NA | 1645 | NA | NA | 1280 | NA | NA | 163390 | NA | NA | 1.1E-6/ 2.2E-6 |
| | Tree Nuts | almond, walnut | Min 2.5 | | NA | NA | 1645 | NA | NA | 1280 | NA | NA | 163390 | NA | NA | 1.1E-6/ 2.2E-6 |
| | | | Max 4.5 | | NA | NA | 915 | NA | NA | 710 | NA | NA | 90770 | NA | NA | 1.9E-6/ 3.9E-6 |
| Cereal Grains | corn (field, pop, sweet), sorghum grain, alfalfa, clover | Min 1.5 | 350 | NA | NA | 980 | NA | NA | 760 | NA | NA | 97255 | NA | NA | 1.8E-6/ 3.6E-6 | |

Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite

| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^e | | | Cancer ^f | | |
|-----------------------------------|--|---------------------------------|---|---------------------------|--|------|----------------|---|------|-----------------|------------------------------|-------|-----------------|---------------------|-------------------|-------------------|
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control |
| | | | | 1200 | NA | NA | 290 | NA | NA | 220 | NA | NA | 28000 | NA | NA | 6.2E-6/ 1.3E-5 |
| | Non-Grass animal Feed | | Max 2.5 | 350 | NA | NA | 590 | NA | NA | 455 | NA | NA | 58355 | NA | NA | 3.0E-6/ 6.1E-6 |
| | | | | 1200 | NA | NA | 170 | NA | NA | 130 | NA | NA | 17000 | NA | NA | 1.1E-5/ 2.2E-5 |
| | Oil Seed | peanut, jojoba | Min 1.5 | 350 | NA | NA | 980 | NA | NA | 760 | NA | NA | 97255 | NA | NA | 1.9E-6/ 3.9E-6 |
| | | | Max 2.5 | | NA | NA | 590 | NA | NA | 455 | NA | NA | 583550 | NA | NA | 6.6E-6/ 1.3E-5 |
| | | cotton | Max 1.6 | 350 | NA | NA | 920 | NA | NA | 715 | NA | NA | 91175 | NA | NA | 1.8E-6/ 3.6E-6 |
| | | | 1200 | NA | NA | 270 | NA | NA | 210 | NA | NA | 26595 | NA | NA | 3.0E-6/ 6.1E-6 | |
| | Stone fruit | nectarine | Max 3.0 | 125 | NA | NA | 1370 | NA | NA | 1065 | NA | NA | 136155 | NA | NA | 1.3E-6/ 2.6E-6 |
| | Ornamental plants | Christmas tree, conifer seed | Max 2.5 | 125 | NA | NA | 1645 | NA | NA | 1280 | NA | NA | 163390 | NA | NA | 1.1E-6/ 2.2E-6 |
| | Applying Sprays with a Groundboom Sprayer (4) | Roots and Vegetable | potatoes, corn (field, pop, sweet) sorghum grain, alfalfa, clover, cotton, peanut, jojoba and mint | Min 1.5 | 80 | 1530 | NA | NA | 1190 | NA | NA | 39100 | NA | NA | 1.4E-6/ 2.7E-6 | 1.2E-6/ 2.4E-6 |
| Cereal Grain | | Max 2.5 | | 920 | | NA | NA | 715 | NA | NA | 23460 | NA | NA | 2.4E-6/ 4.9E-6 | 2.0E-6/ 4.1E-6 | 6.9E-7/ 1.4E-6 |
| Non-grass animal feed | | | | | | | | | | | | | | | | |
| oil seed | | | | | | | | | | | | | | | | |
| herbs and spices | | | | | | | | | | | | | | | | |

Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite

| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^e | | | Cancer ^f | | |
|---|----------------------------------|--|--------------------------------------|---------------------------|--|-----|----------------|---|-----|-----------------|------------------------------|-----|-----------------|---------------------|-------------------|-------------------|
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control |
| Applying Sprays with an Airblast Sprayer (5) | pome fruits | quince, cherry, prunes, orange, grapefruit, lemon, lime, tangerine, boysenberry, current, hops, raspberry, date, | Min 1.5 | 40 | 120 | NA | NA | 95 | 140 | NA | 12860 | NA | NA | 1.5E-5/ 3.0E-5 | 1.1E-5/ 2.1E-5 | 2.0E-6/ 4.0E-6 |
| | stone fruits | | | | | | | | | | | | | | | |
| | citrus fruits | | | | | | | | | | | | | | | |
| | berries | | | | | | | | | | | | | | | |
| | tropical & subtropical fruits | persimmons, almond, filbert, macadamia nut, pecan, pistachio, walnut, Christmas Tree plantation, conifers, shade trees | Max 4.5 | | 40 | 120 | 750 | 30 | 90 | 570 | 4285 | NA | NA | 4.6E-5/ 9.2E-5 | 3.1E-5/ 6.2E-5 | 6.9E-6/ 1.4E-5 |
| | small fruits | | | | | | | | | | | | | | | |
| | tree nuts | | | | | | | | | | | | | | | |
| | ornamental plants | | | | | | | | | | | | | | | |
| Applying Liquids with a High Pressure Handwand (6) | non-bearing nursery stock | all crops | Min 0.5 | 5 | 570 | NA | NA | 445 | NA | NA | 17580 | NA | NA | 3.6E-6/ 7.3E-6 | 1.9E-6/ 3.8E-6 | NA |
| | | | Max 2.5 | | 115 | NA | NA | 90 | 250 | NA | 3515 | NA | NA | 1.9E-5/ 3.8E-5 | 9.6E-6/ 1.9E-5 | NA |

| Table 8: Exposure Variables, MOEs and Cancer for Agricultural uses of Propargite | | | | | | | | | | | | | | | | | |
|--|----------------------------|---|--------------------------------------|---------------------------|--|-----|----------------|---|-----|-----------------|------------------------------|-------|-----------------|---------------------|-------------------|-------------------|-------------------|
| Exposure Scenario (Scenario #) | Crop Group | Crop | Application Rates (lb ai/acre) | Daily Acres Treated | Short-Term Dermal MOEs ^b | | | Intermediate-Term Dermal MOEs ^c | | | Inhalation MOEs ^e | | | Cancer ^f | | | |
| | | | | | Base line ^a | PPE | Eng Control | Base line ^a | PPE | Eng. Control | Base line ^d | PPE | Eng. Control | Base line | PPE | Eng. control | |
| Flagger Exposure | | | | | | | | | | | | | | | | | |
| Flagging During Aerial Spray Application (7) | Roots & tuber Vegetable | carrot, sugar beet, potatoes, dry beans, | Min 2.0 | 350 | 335 | NA | NA | 260 | NA | NA | 14170 | NA | NA | 5.9E-6/ 1.2E-5 | 4.6E-6/ 9.1E-6 | 1.2E-7/ 2.4E-7 | |
| | legume vegetable | mint | Max 2.5 | | 265 | NA | NA | 210 | NA | NA | 11335 | NA | NA | 7.6E-6/ 1.5E-5 | 5.7E-6/ 1.1E-5 | 1.5E-7/ 3.0E-7 | |
| | herbs and spices | hops | Ma 2.5 | 80 | 1170 | NA | NA | 910 | NA | NA | 49600 | NA | NA | 1.7E-6/ 3.4E-6 | 1.3E-6/ 2.6E-6 | 3.4E-8/ 6.9E-8 | |
| | Citrus fruits | grapefruit, orange | Max 2.5 | 125 | 750 | NA | NA | 580 | NA | NA | 31745 | NA | NA | 2.7E-6/ 5.4E-6 | 2.0E-6/ 4.1E-6 | 5.3E-8/ 1.1E-7 | |
| | Tree Nut | almond, walnut | Min 2.5 | 125 | 750 | NA | NA | 580 | NA | NA | 31745 | NA | NA | 2.7E-6/ 5.4E-6 | 2.0E-6/ 4.1E-6 | 5.3E-8/ 1.1E-7 | |
| | | | Max 4.5 | | 415 | NA | NA | 325 | NA | NA | 17635 | NA | NA | 5.0E-6/ 9.9E-6 | 3.7E-6/ 7.3E-6 | 9.6E-8/ 1.9E-7 | |
| | cereal grain | (field, pop, sweet), sorghum grain, | Min 1.5 | 350 | 445 | NA | NA | 345 | NA | NA | 18895 | NA | NA | 4.6E-6/ 9.2E-6 | 3.4E-6/ 6.8E-6 | 9.0E-8/ 1.8E-7 | |
| | non-grass animal feed | alfalfa, clover | Max 2.5 | | 265 | NA | NA | 210 | NA | NA | 11335 | NA | NA | 7.6E-6/ 1.5E-5 | 5.7E-6/ 1.1E-5 | 1.5E-7/ 3.0E-7 | |
| | oil seed | cotton | | Max 1.6 | 350 | 415 | NA | NA | 325 | NA | NA | 17715 | NA | NA | 5.0E-6/ 9.9E-6 | 3.6E-6/ 7.3E-6 | 9.6E-8/ 1.9E-7 |
| | | | | 1200 | 120 | NA | NA | 100 | NF | NA | 5165 | NA | NA | 1.7E-5/ 3.3E-5 | 1.2E-5/ 2.5E-5 | 3.3E-7/ 6.6E-7 | |
| | | Peanut, jojoba | | Min 1.5 | 350 | 445 | NA | NA | 345 | NA | NA | 18895 | NA | NA | 4.6E-6/ 9.2E-6 | 3.4E-6/ 6.8E-6 | 9.0E-8/ 1.8E-7 |
| | | | | Max 2.5 | | 265 | NA | NA | 210 | NA | NA | 11335 | NA | NA | 7.6E-6/ 1.5E-5 | 5.7E-6/ 1.1E-5 | 1.5E-7/ 3.0E-7 |
| | Stone fruits | nectarine | | Max 3.0 | 125 | 625 | NA | NA | 485 | NA | NA | 26455 | NA | NA | 3.2E-6/ 6.4E-6 | 1.1E-6/ 2.2E-6 | 6.4E-8/ 1.3E-7 |
| | Ornamental plants | Christmas tree conifer seed | | Max 2.5 | 125 | 750 | NA | NA | 580 | NA | NA | 31745 | NA | NA | 2.7E-5/ 5.4E-5 | 2.0E-6/ 4.1E-6 | 5.3E-8/ 1.1E-7 |

- a Baseline dermal unit exposure represents long pants, long sleeved shirt, **no gloves**, open mixing/loading, open cab tractor.
- b Short-term Dermal MOE = NOAEL (6 mg/kg/day)/Short-term Daily Dermal Dose (mg/kg/day).
- c Intermediate-term MOE = NOAEL (4 mg/kg/day)/Intermediate-term Daily Dermal Dose (mg/kg/day)
- d Baseline inhalation unit exposure represents no respirator
- e Inhalation MOE = LOAEL (49.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
- f the lower end of the range represents 7 days of exposure for a private applicator. The higher end of the range represents 14 days of exposure for a commercial applicator.

ii. Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites. EPA has determined that there are potentially significant short and intermediate-term post-application exposures to workers entering treated fields for post-treatment activities, e.g., weeding, pruning, irrigating, harvesting.

Table 9 below summarizes the Agency's risk assessment for workers, based on various activities and application rates for each crop. This table shows the number of days that must pass after propargite is applied before the risk is above the Agency's level of concern ($\text{MOE} \geq 100$ for intermediate-term dermal exposure). The table also shows the life-time cancer risk that would result if workers were to re-enter a propargite treated field on the first day the $\text{MOE} \geq 100$ for 35 years.

The re-entry interval (REI) is the period of time after propargite application (expressed in days) that must elapse before an unprotected worker may re-enter the field to perform a given operation. The REI is established for a crop by considering the worker activities associated with the crop and determining the number of days after treatment must elapse before a the risk is no longer a concern. Typically, the activity with the highest risk will drive the selection of the appropriate REI for the crop. All of the post-application risk calculations for handlers completed in this assessment are included in the July 31, 2001 document entitled, "Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Propargite."

| Table 9. Occupational Postapplication Risk from Propargite; Days After Treatment at Which the MOE is ≥ 100 | | | | | | |
|---|----------------------------|--|--------------------------------------|---------------|--|---------------|
| Crop grouping | Crop | Activity | Intermediate -Term (days) | | Cancer Risk at First Day $\text{MOE} \geq 100$ | |
| Roots and Tuber Vegetable | Crop | | 1.5 lb ai/A | 2.5 lb ai/A | 1.5 lb ai/A | 2.5 lb ai/A |
| | Potato | Hand Harvesting | Not available | Not available | Not available | Not available |
| | Carrot, Sugar beet | Hand Harvesting | 9 | 13 | 5.28E-5 | 5.51E-5 |
| | Potato, Carrot, Sugar beet | all other activities | 0 | 0 | 1.81E-5 | 3.01E-5 |
| Legume Vegetables | Dry beans | Weeding and Hoeing | 0 | 0 | 3.60E-5 | 5.91E-6 |
| | | Irrigation, Scouting | 5 | 9 | 5.05E-5 | 5.18E-5 |
| | | Hand Harvesting | 9 | 13 | 5.28E-5 | 5.41E-5 |
| Non-grass Animal Feed | Alfalfa, Clover | Hand Harvesting, Mechanized harvesting | Not available | Not available | Not available | Not available |
| | | Irrigation, Scouting | 5 | 9 | 5.05E-5 | 5.28E-5 |

| Crop grouping | Crop | Activity | Intermediate -Term (days) | | | | Cancer Risk at First Day MOE ≥ 100 | | | | |
|------------------------------------|--|---------------------------------------|------------------------------|-----------------|-------------------|-------------------|---------------------------------------|--|----------------|----------------|----------------|
| Citrus Fruits | Crop | | 2.5 lb ai/A | 3.15 lb ai/A | 4.5 lb ai/A | | 2.5 lb ai/A | | 3.15 lb ai/A | 4.5 lb ai/A | |
| | Orange, Lemon, Lime, Tangerine, Grapefruit | Irrigation, Scouting, Hand weeding | 0 | 2 | 8 | | 4.82E-5 | | 5.35E-5 | 5.28E-5 | |
| | | Pruning | 16 | 20 | 26 | | 5.35E-5 | | 5.28E-5 | 5.18E-5 | |
| | | Harvesting | 32 | 36 | 42 | | 5.31E-5 | | 5.21E-5 | 5.15E-5 | |
| Pome Fruits | Crop | | 0.5 lb ai/A | 1.5lb ai/A | 2.5 lb ai/A | 4.5 lb ai/A | 0.5 lb ai/A | | 1.5 lb ai/A | 2.5 lb ai/A | 4.5 lb ai/A |
| | Quince, Cherry, Nectarine, Prune, Avocado, Date, Persimmons, X mas Tree, Ornamental and/or shade trees Ornamental, Herbaceous Plants | Irrigation, Scouting, Hand weeding | 0 | 0 | 0 | 0 | 5.97 E-6 | | 1.97 E-5 | 2.98 E-5 | 5.38 E-5 |
| Stone Fruits | | Pruning | 0 | 0 | 5 | 11 | 1.97 E-5 | | 5.38 E-5 | 5.28 E-5 | 5.05 E-5 |
| Tropical and Subtropical Fruits | | Harvesting | 0 | 9 | 14 | 20 | 4.75 E-5 | | 5.54 E-5 | 5.45 E-5 | 5.21 E-5 |
| Ornamental Plants | | | | | | | | | | | |
| Berries | Crop | | 2.0 lb ai/A | | | | 2.0 lb ai/A | | | | |
| | Boysenberry, Currant, Raspberry | Irrigation, Hand weeding | 0 | | | | 9.74E-6 | | | | |
| | | Scouting | 0 | | | | 1.95E-5 | | | | |
| | | Harvesting, Pruning, tying | 10 | | | | 5.25E-5 | | | | |
| Small fruits | Crop | | 3.0 lb ai/acre | | | | 3.0 ai/A | | | | |
| | Grape | Irrigation, Hand weeding | 0 | | | | 1.46E-5 | | | | |
| | | Scouting | 0 | | | | 2.92E-5 | | | | |
| | | Harvesting, Pruning ,tying | 16 | | | | 5.41E-5 | | | | |
| | | Cane turning | 27 | | | | 5.48E-5 | | | | |
| | | | | | | | | | | | |
| Tree Nuts | Crop | | 3.0 lb ai/A | | 4.5 lb ai/A | | 3.0 lb ai/A | | 4.5 ai/A | | |
| | Almond, Filbert, Macadamia ,Pecan Pistachio, Walnut | Sweeping and blowing the nuts | Not available | | Not available | | Not available | | Not available | | |
| | | Tree shakers | 0 | | 0 | | 3.12E-6 | | 4.69E-6 | | |
| | | Scouting, Weeding, Irrigation | 0 | | 0 | | 3.33E-5 | | 4.98E-5 | | |
| | | Pruning, Hand harvesting | 22 | | 30 | | 5.38E-5 | | 5.35E-5 | | |
| Cereal grains | Crop | | 2.5 lb ai/A | | | | 2.5 lb ai/A | | | | |
| | Corn (unspecified), Corn, field, Corn, Pop Corn, Sweet, Sorghum, grain | Irrigation, Scouting | 0 | | | | 3.83E-5 | | | | |

| Crop grouping | Crop | Activity | Intermediate -Term (days) | Cancer Risk at First Day MOE ≥ 100 |
|------------------|---|---------------------------------------|------------------------------|--|
| | Corn (unspecified), Corn, field, Corn, Pop Corn, Sweet | Hand harvesting, Detasseling | 13 | 4.95E-5 |
| Herbs and Spices | Crop | | 2.5 lb ai/A | 2.5 lb ai/A |
| | Mint | Irrigation, Scouting, Hand weeding | 9 | 5.28E-5 |
| | Hops | Irrigation, Hand weeding, Scouting | 0 | 1.06E-5 |
| | | Harvesting, Training | 33 | 5.51E-5 |
| Oil seed | Crop | | 1.5 lb ai/A | |
| | Cotton | Weeding and hoeing | 0 | 2.53E-6 |
| | | Harvesting | 6 | 4.98E-5 |
| | Cotton Peanut, Jojoba | Irrigation, Scouting | 1 | 5.35E-5 |

5. Human Incident Data

The Agency consulted and reviewed several sources of information on health incidents involving human exposure, finding a history of propargite cases mostly related to handler and worker exposure. The general incident trend, however, appears to be downward. The four sources of information are OPP's Incident Data System (IDS), American Association of Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Pesticides Telecommunication Network. CDPR and OPP data tend to provide the most insight into propargite's association with human health incidents. Detailed descriptions of the above sources and the cases involving propargite are provided in the human health risk assessment.

The incident data contain cases showing propargite poses skin illness and eye irritation concerns for handlers and post-application workers. From CDPR data, field residue exposure was associated with the majority (66%) of the exposures cases in California. A large proportion of cases resulted from field reentry and worker activities involving extensive contact with treated foliage such as turning cane for grapes and harvesting citrus. Applicators and other handlers accounted for the bulk of the balance (28%). These data illustrate that human incidents have historically occurred mostly among workers and handlers.

Propargite usually effects the skin in human exposure cases. Of the confirmed propargite cases reported to the CDPR between 1982 and 1996, 79% of the individuals developed skin illnesses as a result of exposure (528 of 671 persons). Data covering the years 1982-1989 found that propargite was the leading cause of skin-related injuries among all pesticides in California. For the years 1990-1994, propargite dropped to seventh place among pesticides. The drop in the frequency

of illnesses in the early 1990's is apparently attributable to increasing restricted entry intervals (REI), which were put into place in 1989. Depending on the crop, REIs were extended from 2-7 days to 14-42 days. Promulgation of the final Worker Protection Standard regulations in the 1990's may have also contributed to the reduction of incidents. In addition, the registrant fielded a voluntary product stewardship program during this same time frame, presumably facilitating greater compliance with labels by educating handlers and workers.

Notwithstanding the number and types of exposure cases, both PCC and CDPR data indicate that incidents rarely result in hospitalization or long, prolonged absences from work. In some cases, the skin effects may be severe and absences from work are significant. Nonetheless, compared to all other pesticides, propargite has a favorable profile suggesting low risk of moderate or serious effects. Despite the downward trend in exposure cases, incidents still occur on a regular basis involving field workers, suggesting additional mitigation may be warranted on certain crops.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division Science Chapter for Reregistration Eligibility Document for Propargite, dated June 7, 2000, available in the public docket.

1. Environmental Fate and Transport

Propargite is moderately persistent (metabolism half-lives = 38-168 days) and immobile (K_d s ranged from 60 to 218 mL/g, while K_{oc} s ranged from 2963 to 57966 mL/g). It degrades rapidly under alkaline hydrolytic conditions (half-life = 2.2 days) and is moderately persistent to persistent under neutral (half-lives = 75 days) and acid (pH 5 half-life = 120 days) hydrolytic conditions. Soil and aquatic photolysis and aerobic and anaerobic metabolism occur at moderate rates (half-lives = 39-168 days). Degradates are carbon dioxide, propargite glycol ether (TBPC, 2-[4-(1,1-dimethylethyl) phenoxy] cyclohexane-1-ol, also identified as 2-(p-tertiarybutyl phenoxy)cyclohexanol and PTBP (p-tertiary butylphenoxy cyclohexanol). However, the Agency Metabolism Assessment Review Committee has concluded that the residue of concern in plants and animals is propargite *per se* and not its metabolites or degradate products. Because of its high affinity for soil and sediment, propargite has the potential to move off the site of application during rainfall/irrigation by erosion/runoff on soil particles and by drift. Given the moderate to slow degradation rates for metabolism and photolysis, and the high K_{oc} values, propargite will probably be adsorbed to sediments and organic material if transported to surface waters.

2. Ecological Toxicity

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of propargite products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as the LC_{50} (the median concentration of a substance which causes death to 50% of the test animals). The RQ is simply a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), which provide an indication of the relative risk the particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, additional refinements or mitigation may be necessary. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported aquatic or terrestrial incidents to nontarget organisms in the field (e.g., fish or bird kills).

Based on toxicity studies submitted by the Registrant, propargite poses a potential for adverse effects on reproduction in birds and mammals. Risk to aquatic organisms and plants is generally lower than the risk for birds and mammals; however, the chronic risk concern levels for freshwater invertebrates and freshwater fish are either approached or exceeded for over 60 days from multiple propargite applications.

a. Risk to Birds and Mammals

EPA's assessment suggests that the most significant ecological risk posed by the use of propargite is the potential for adverse effects on reproduction in birds and mammals. The assessment indicates that reproduction risk to birds may occur where propargite is applied a single time at 0.5 lb active ingredient per acre or greater. Concerns for reproduction risk to mammals are triggered at application rates of 1.6 lb ai/A or greater. These concerns are heightened when multiple applications of propargite are factored into the assessment. Multiple applications of a pesticide may raise the risk to an organism by increasing the concentration of residues on food items and by extending the period during which these residues may be present. EPA's conclusions for propargite's potential effects to birds and mammals are based on the following labeled use rates and numbers of applications: 2 applications at 4.5 lb ai/A; 2 applications at 3 lb ai/A; 2 applications at 2 lb ai/A; and 2 or 3 applications at 1.6 lb ai/A.

The timing of propargite applications to control target pests coincides with breeding seasons of some birds common to the labeled crop areas. This could expose nesting birds and their developing young to residues which could negatively impact their reproductive success. The chronic effects to birds reported in registrant-submitted studies included reductions in mean numbers of eggs laid/female (mallard and bobwhite), viable embryos (mallard), live 3-week embryos (mallard), hatch success (mallard), hatchling survival and weight (mallard and bobwhite), and adult body weight

change (mallard) at dietary concentration of 288 ppm. At a dietary concentration of 84.7 ppm, slight reductions were also observed in adult body weight change (bobwhite and mallard), eggs laid/female, live embryos, and hatchling survival.

With the exception of multiple applications at 4.5 lb ai/A ($RQ = 0.59$ for species expected to ingest high amounts of short grass or foliage), avian acute risk assessment scenarios for propargite did not exceed acute risk level of concern ($LOC = 3401$ ppm) for birds. LOCs for acute risk are approached, but not exceeded for multiple applications at 3 lb ai/A. Shorter application intervals could increase exposure and risk for these scenarios. A number of application scenarios triggered the restricted use criteria at rates of 1.6 lb ai/A and above ($RQ > 0.2$). For acute toxicity to endangered avian species, all multiple application scenarios assessed exceeded the LOC ($RQ > 0.1$) for short and tall grass and broadleaf plants. RQs for acute effects to birds ingesting primarily fruits and seeds were below levels of concern for acute risk, restricted use, and endangered species.

The assessment suggests the potential for acute effects to mammals for multiple applications at the highest labeled rate of ~4.5 lb ai/A (walnut, and avocado). Levels of concern for acute risk are approached but not exceeded for multiple applications at 3 lb ai/A. Mammalian chronic levels of concern (400 ppm exposure levels) may be exceeded at single application rates over 1.6 lb ai/A (which is allowed for many crop uses of propargite) and at multiple application rates above 0.75 lb ai/A which are allowed for all crop uses. However, there were a number of LOCs for the acute restricted use that were exceeded for herbivorous or herbivorous/insectivorous mammals ($RQs > 0.2$) based on terrestrial exposure scenarios. There are acute endangered species risk concerns for herbivorous or herbivorous/insectivorous mammals ($RQs > 0.1$) for many uses. Granivorous mammals are not predicted to be exposed to residues that could result in acute effects.

The lack of data on propargite persistence on foliage and other avian and mammalian food items is a source of uncertainty in the terrestrial risk assessment. Because no data were available, a default foliar half-life of 30 days was assumed. Foliar dissipation is not expected to be rapid, however, because of propargite's photolytic stability, slow hydrolysis at neutral pH values, and low vapor pressure. Rainfall could result in residue washoff thereby reducing terrestrial exposure. Re-application could result in repeated exposure of terrestrial organisms to propargite residues.

b. Risk to Aquatic Species

The standard method for assessing aquatic risk results in concern for potential chronic effects to freshwater fish and invertebrates. Although EPA's criteria for acute risk to freshwater invertebrates and estuarine fish were not exceeded, the assessment suggests that adverse effects could occur in shallow bodies of water that are not represented by standard scenarios. No data are available to assess risk to estuarine and marine organisms. Also, as noted for the terrestrial risk assessment, an element of uncertainty is added to the aquatic risk assessment by the lack of established application intervals on propargite labels. The time between applications could have an impact on exposure levels used to assess aquatic risk.

Chronic toxicity effect levels were low for freshwater aquatic invertebrates and fish. Given the persistence characteristics of propargite, the potential for chronic effects is most likely if residues reach aquatic habitats in concentrations exceeding 9-16 ug/L (the *Daphnia magna* No Observable Effect Concentration [NOEC] = 9 ug/L; fathead minnow NOEC =16 ug/L). Chronic LOCs for invertebrates were exceeded in three of the five scenarios in Tier II modeling simulations. There were no data available to assess potential chronic effects to estuarine and marine organisms.

In aerobic and anaerobic aquatic metabolism studies, propargite half-lives were 38 and 46 days, respectively. These data, along with hydrolysis half-lives of 75 and 120 days at pH 7 and 5, respectively, suggest that propargite will be relatively persistent in aquatic environments. Any impact on aquatic life, then, is likely to be greatest where neutral to acidic conditions predominate (pH 5.0 to 7.0). This could include tributaries fed by acid drainage or that receive runoff from watersheds where highly organic soils predominate. Because aqueous photolysis of residues is not an important process, water clarity is not likely to play an important role in degradation. Because of its high affinity for soil, propargite has the potential to move into aquatic habitats through runoff or wind erosion of soil particles. Other offsite transport is possible by spray drift from aerial, airblast, or ground boom applications. Given the moderate to slow degradation rates for metabolism and photolysis, and the high K_{oc} values, propargite is likely to partition to sediment and organic material found in surface waters. Thus, impacts to benthic- dwelling organisms from prolonged exposure to contaminated sediments must be a consideration when characterizing long-term risk potential for exposed aquatic areas. Toxicity to these organisms from residues on sediment is uncertain because relevant data are not available.

Though propargite is highly toxic to all fish and invertebrate species tested (96 hour LC_{50} values for 7 aquatic species were below 168 ug/L), the RQs calculated from EECs derived from Tier II simulations suggest little potential for acute risk to fish or invertebrates. However, several RQs ranged between 0.2 and 0.5 suggesting that exposure in small, shallow water bodies (i.e., those not represented by EPA's standard aquatic risk scenario) could result in adverse effects to organisms present. Acute restricted use exceedences (RQ=0.2) for fish and invertebrates are noted for a number of application scenarios. For endangered aquatic species, all modeled scenarios exceeded Agency acute levels of concern (RQ>0.05).

c. Endangered Species

At currently proposed rates, endangered species risk presumption levels are exceeded for both freshwater and estuarine/marine fish and invertebrates at the label permitted application scenarios for propargite. Although concern levels for estuarine invertebrates are exceeded, there are no federally listed estuarine invertebrates. Mammalian and avian acute risk for endangered species is exceeded for certain species which may feed heavily on vegetation or insects. Chronic risk concern levels for listed birds and mammals are indicated for many uses.

The Agency consulted with the US Fish and Wildlife Service (FWS or the Service) on the corn use of propargite as part of the corn cluster analysis in 1983 and on several agricultural uses of propargite in the "reinitiation" of the cluster assessments in 1988. The resulting Opinions found

jeopardy to one amphibian species, eight fish species and one invertebrate species. The Service proposed Reasonable and Prudent Alternatives (RPAs) to avoid the likelihood of jeopardizing the continued existence of these species. In addition, the Service had Reasonable and Prudent Measures (RPMs) to reduce incidental take of 22 fish and one aquatic invertebrate species. 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.

EPA'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. Therefore, the Reasonable and Prudent Measures (RPMs) in the Biological Opinion(s) may need to be reassessed and modified based on these new approaches.

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 propargite use to federally listed threatened and endangered species. At that time, the Agency will also consider any regulatory changes recommended in the RED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets described below which address propargite, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to propargite at levels of concern.

3. Ecological Incidents

The Agency incident database contains a single incident with propargite. The incident involved crop injury to 82 acres of newly planted cotton crops in Arvin, CA. Propargite, chlorpyrifos, and amitraz were all applied. Propargite (Comite) labels warn against possible phytotoxicity to young cotton plants.

No mortality incidents with wildlife, non-target insects, or aquatic organisms have been reported for propargite. However, the types of chronic concerns for birds and mammals expressed for propargite are unlikely to be observed in normal usage. Also, acute mortality to non target invertebrates (terrestrial or aquatic) is generally not observed or reported in incident reports, even when high mortality is reported for birds, mammals, amphibians or fish.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing the active ingredient propargite.

The Agency has completed its assessment of the occupational, non-occupational, and ecological risks associated with the use of pesticides containing the active ingredient propargite, as well as a propargite-specific dietary risk assessment. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient propargite, EPA has sufficient information on the human health and ecological effects of propargite to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that propargite products are eligible for reregistration provided that: (i) current data gaps and additional confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of propargite that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propargite, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of propargite, the Agency has determined that propargite products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, 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 propargite. If all changes outlined in this document are incorporated into the product labels, then all current risks for propargite will be adequately mitigated for the purposes of this determination.

B. Summary of Public Comments and Responses

When making its initial reregistration decision in 2001, the Agency took into account all comments received after opening of the public docket. These comments in their entirety are available in the docket. A summary of the comments and the Agency response is noted below.

Comment: During the public comment period provided for the preliminary risk assessment, EPA received comments from the Almond Hullers and Processors Association and the National Agricultural Aviation Association (NAAA). The Almond Hullers and Processors Association questioned the appropriateness of the transfer coefficients that EPA used to determine post-application risks. The Almond Hullers also expressed concern that the 31-day REI that was proposed

in the preliminary risk assessment was too long. The Almond Hullers also asked for guidance on what activities would be restricted by the REI.

Response: EPA has revised the post-application risk assessment using new transfer coefficients derived from the Agricultural Reentry Task Force (ARTF). These new transfer coefficients can be found in the Science Advisory Council for Exposure, Policy number 3.1 dated August 7, 2000. The propargite RED uses the standard values found in this new policy unless a chemical/crop specific study is available, as was the case for tree shakers for nut crops (MRID 418486-04). As a result of using the new transfer coefficients, the REI for almonds (at maximum use rate of 3lbs ai/A) is now 22 days. Many of the other activities of concern to almond growers can be accommodated with existing exemptions under the Worker Protection Standard. Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the handler personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS (40CFR170.112(e)), the individual can determine the appropriate PPE to be used. For many of these crops, irrigation equipment is not routinely moved by hand. For these methods, the primary activity involves entering the field to turn the watering equipment on and off. This activity is allowed during the REI under the no contact exception to WPS (40CFR170.112(b)). Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field provided early entry PPE is used (40CFR170.112(c)). This exception also applies to mechanical harvesting, tree shaking or winrowing for nut crops in enclosed cabs, and often applies to mowing.

Comment: The NAAA was concerned that EPA's occupational risk assessment for propargite is based on out-of-date data that are not reflective of current practices. Their comments specifically mentioned that technological advances such as use of Global Positioning Satellite (GPS) and automatic flagging systems have replaced human flagging; and mixers/loaders for aerial applicators routinely use personal protective equipment and engineering controls, such as closed mixing loading systems, body suits, respirators and other equipment.

Response: The risk mitigation measures outlined in this RED are consistent with the standard practices that are currently followed in the industry, as described by the NAAA comments on propargite. Based on the risk assessment, there will be no new requirements for human flaggers; closed mixing/loading systems will be required for aerial applications of propargite for corn and cotton; and enclosed cockpits will be required. With these risk mitigation measures in place, EPA believes that risks will not be unreasonable.

Other Comments: Subsequent to the comment period for the propargite preliminary risk assessment, EPA also received a series of letters and e-mails attesting to the benefits of propargite. Comments were received from: the Allied Grape Growers; California Association of Wine Grape Growers; California Grape and Tree Fruit League; Allied Grape Growers; Washington Association of Wine Grape Growers; Sun-Maid Growers of California on the benefits of propargite use for raisin production; University of California Cooperative Extension regarding alfalfa seed production; the Northwest Alfalfa Seed Growers Association; the Oregon Alfalfa Seed Commission; University of

California, Davis in support of propargite use on almonds, cotton, corn and dry beans; Washington Mint Commission; the California Cotton Growers Association; the Texas Corn Producers Board and the Texas Agricultural Extension Service on the benefits of propargite on corn grown in Texas; U.S. Hop Industry Plant Protection Committee; Oregon Hop Commission; Western Growers Association regarding the benefits of the use of propargite on fresh fruits, nuts and vegetables; Washington State Potato Commission regarding the benefits of propargite for use on potatoes and the need to lower the PHI from the current 7-days to 5-days.

C. Regulatory Position

1. FQPA Assessment

a. “Risk Cup” Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to propargite is within its own “risk cup.” In other words, EPA has concluded that the tolerances for propargite meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the acute and chronic food exposure. An aggregate assessment was conducted for exposures through food and drinking water exposure only since there are no residential uses of propargite. Results of this aggregate assessment indicate that the human health risks from these combined exposures are within acceptable levels; that is, that is, when aggregated, propargite exposures fit within the risk cup.

Therefore, there are no changes in propargite tolerances due to risk concerns and most tolerances will remain in effect (except the dried citrus pulp, poultry meat and meat by-products tolerances are no longer needed for other reasons discussed below). The Agency will establish tolerances for aspirated grain fractions; cotton gin byproducts, and citrus oil.

b. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for propargite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices, and scenarios, and the environmental behavior of propargite. As discussed in chapter 3, the acute and chronic dietary (food alone) risk is below the level of concern, as is the cancer dietary risk from food alone. Regarding risks from drinking water exposures, acute and chronic risks from drinking water are not of concern for surface or groundwater supplies, and although the projected surface water concentrations exceed the Agency’s cancer concern level, the Agency believes that those projections are conservative and over-estimate the human exposure to propargite that will result from drinking water sources from surface water (See Regulatory Rationale

under Drinking Water in section IV.D.1.a.iv.).

c. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for propargite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of propargite residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from propargite residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. An FQPA safety factor is not required for propargite because (1) the toxicology database is complete for the FQPA assessment, and provides no indication of increases susceptibility of young rats or rabbits to propargite; (2) the Agency determined that a developmental neurotoxicity study is not required; (3) the exposure estimates do not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of propargite; and (4) there are no residential uses of propargite.

d. Endocrine Disruptor Effects

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

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

e. Cumulative Risks

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Propargite is the only organosulfur pesticide with registered food uses and therefore the only organosulfur chemical that is subject to tolerance assessment under the FQPA. Although chemical class is not necessarily synonymous with a common mechanism of toxicity, structurally similar chemical substances do frequently exhibit common modes of toxicity and are being considered together by EPA for purposes of cumulative risk assessment. The Agency does not believe that propargite shares a common mechanism of toxicity with other chemicals, however. Therefore, propargite is not subject to any cumulative risk assessment as required by the Food Quality Protection Act (FQPA).

f. Tolerances Summary

A summary of the propargite tolerance reassessments is presented in Table 10. In the assessment, tolerances for residues of propargite in/on plant commodities [40 CFR §180.259] are presently expressed in terms of the parent only. Adequate field trials are available pending submission of required storage stability data, sample storage information, or required label amendments.

i. Tolerances Listed Under 40 CFR §180.259(a)

- **Citrus pulp, dried:** The citrus processing study did not detect residue concentration in dried pulp, indicating that the current 40 ppm tolerance is not necessary and should be revoked.
- **Cottonseed:** Although one sample of cottonseed showed a residue of 0.11 ppm, based on the residue data for other samples after treatment at higher rates, the Agency considers the existing 0.1 ppm tolerance adequate to cover the current label use. This 0.1 ppm tolerance is also in harmony with the Codex level.
- **Oranges:** Data on oranges indicate that residues up to 8.3 ppm may occur from registered use and that the 5 ppm tolerance is inadequate. This tolerance should be increased to 10 ppm.
- **Poultry meat and meat byproducts:** These tolerances are not necessary and can be revoked; propargite was absent from muscle and liver in the metabolism study and <LOQ in a 10x feeding study.
- **Sorghum grain:** The residue data show maximum propargite residues were as high as 3.8 ppm, supporting a reduction in the current 10 ppm tolerance to a new tolerance of 5 ppm.
- **All other tolerances for propargite in 40 CFR §180.259(a):** For all other crops the residue data support the established tolerances.

Previous rulemaking revoked the following tolerances effective October 19, 1999; propargite residues in/on apples, apricots, succulent beans, cranberries, figs, peaches, pears, plums, and strawberries [established under §180.259(a)] and dried figs (§186.5000) [64 FR 39068; July 21,

1999]. Uses of propargite on these crops have been canceled for over 3 years. Previous rulemaking also revoked the tolerances for dried apple pomace, dried grape pomace, and peanut hulls because these are no longer considered significant feed items [62 FR 66020; November 14, 1997].

Adequate processing studies have been submitted for potatoes, citrus, field corn, grapes and peanuts. Storage stability data are required to support the corn and peanut processing studies.

ii. Tolerances to be Proposed Under 40 CFR §180.259(a)

- **Aspirated Grain Fractions of Field Corn:** The available data indicate that residues of propargite concentrated in the aspirated grain fractions of field corn but do not concentrate in the aspirated grain fractions of sorghum. A tolerance for aspirated grain fractions must be proposed at 0.4 ppm.
- **Cotton Gin Byproducts:** A tolerance for residues in/on cotton gin byproducts is required. Additional field trials are needed on cotton to determine a tolerance for propargite residues in/on cotton gin byproducts.
- **Orange oil:** Propargite residues concentrated 7x in orange oil. Based upon this observed concentration and Highest Average Field Trial (HAFT) residues of 4 ppm in oranges, a tolerance of 30 ppm would be appropriate for residues in citrus oil.

Although residues concentrated in raisins by 1.7x, this factor applied to the HAFT of 4.7 ppm yields a concentration in raisins of 8 ppm, which is lower than the 10 ppm tolerance for residues in/on grapes. Therefore, a tolerance for raisins is not required.

iii. Tolerances Listed Under 40 CFR §180.259(b)

The established tolerance, with regional registration, for propargite residues in/on corn, fresh (including sweet K+CWHR) is adequate.

Table 10. Tolerance Reassessment Summary for Propargite.

| Commodity | Established Tolerance, ppm | Reassessed Tolerance, ppm | Comments [Correct Commodity Definition] |
|---|----------------------------|---------------------------|---|
| Tolerances Listed Under 40 CFR §180.259(a) | | | |
| Almond | 0.1 | 0.10 | Field trial data support current tolerance. |
| Almond, hulls | 55 | 55 | Field trial data support current tolerance. |
| Apple | 3 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Apricot | 7 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Bean, dry | 0.2 | 0.20 | Field trial data support current tolerance. |
| Bean, succulent | 20 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |

| Commodity | Established Tolerance, ppm | Reassessed Tolerance, ppm | Comments [Correct Commodity Definition] |
|--------------------|----------------------------|---------------------------|---|
| Cattle, fat | 0.1 | 0.10 | Supported by data. |
| Cattle, meat | 0.1 | 0.10 | Supported by data. |
| Citrus pulp, dried | 40 | Revoke | Residues do not concentrate. Will be covered by RAC. |
| Corn, fodder | 10 | 10 | corn, field, stover. Field trial data support current tolerance. |
| Corn, forage | 10 | 10 | corn, field, forage. Field trial data support current tolerance. |
| Corn, grain | 0.1 | 0.10 | corn, field, grain. Field trial data support current tolerance. |
| Cottonseed | 0.1 | 0.10 | [cotton seed, undelinted]. Field trial data support current tolerance. |
| Cranberry | 10 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Eggs | 0.1 | 0.10 | Field trial data support current tolerance. |
| Figs | 3 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Figs, dried | 9 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Goats, fat | 0.1 | 0.10 | Supported by data. |
| Goat, meat | 0.1 | 0.10 | Supported by data. |
| Grapefruit | 5 | 5.0 | Field trial data support current tolerance. |
| Grape | 10 | 10 | Field trial data support current tolerance. |
| Hog, fat | 0.1 | 0.10 | Supported by data. |
| Hog, meat | 0.1 | 0.10 | Supported by data. |
| Hops | 15 | Revoke | The RAC for hops is dried hops. |
| Hops, dried | 30 | 30 | Field trial data support current tolerance. |
| Horse, fat | 0.1 | 0.10 | Supported by data. |
| Horse, meat | 0.1 | 0.10 | Supported by data. |
| Lemon | 5 | 5.0 | Field trial data support current tolerance. |
| Milk, fat | 2 | 2.0 | Supported by data. |
| Milk | 0.08 | 0.08 | Supported by data. |
| Mint | 50 | 50 | Field trial data support current tolerance. |
| Nectarine | 4 | 4.0 | Field trial data support current tolerance. |
| Orange | 5 | 10 | The available data indicate that a tolerance increase is required, given the current use pattern. |
| Peach | 7 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Peanut | 0.1 | 0.10 | Field trial data support current tolerance. |

| Commodity | Established Tolerance, ppm | Reassessed Tolerance, ppm | Comments [Correct Commodity Definition] |
|---|----------------------------|---------------------------|---|
| Peanut, forage | 10 | Revoke | Peanut forage is not recognized as a significant livestock feed item. |
| Peanut, hay | 10 | Revoke | Labels prohibit the feeding of hay. |
| Peanuts, hulls | 10 | Already Revoked | revoked 62 FR 66020; November 14, 1997. No longer considered a significant feed item. NOTE: This tolerance still appears in CFR even though it was revoked. |
| Pear | 3 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Plum (fresh prune) | 7 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Poultry, fat | 0.1 | 0.10 | Supported by data. |
| Poultry, meat | 0.1 | Revoke | propargite was absent from muscle and liver in the metabolism study and <LOQ in a 10x feeding study. Therefore, no reasonable expectation of finite residues and tolerance is not needed. |
| Potato | 0.1 | 0.10 | Field trial data support current tolerance. |
| Sheep, fat | 0.1 | 0.10 | Supported by data. |
| Sheep, meat | 0.1 | 0.10 | Supported by data. |
| Sorghum, fodder | 10 | 10 | sorghum, grain, stover. Field trial data support current tolerance. |
| Sorghum, forage | 10 | 10 | sorghum, grain, forage. Field trial data support current tolerance. |
| Sorghum, grain | 10 | 5.0 | The available data support lowering the tolerance. Sorghum, grain. |
| Strawberry | 7 | Already Revoked | revoked 64 FR 39068; July 21, 1999. No longer registered. |
| Tea, dried | 10 | 10 | Field trial data support current tolerance. |
| Walnut | 0.1 | 0.10 | Field trial data support current tolerance. |
| Tolerances Listed Under 40 CFR §180.259(b) | | | |
| Corn, fresh (including sweet K+CWHR) | 0.1 | 0.10 | Field trial data support current tolerance. |
| Tolerances Listed Under 40 CFR §186.5000 | | | |
| Apple pomace, dried | 80 | Already Revoked | revoked 62 FR 66020; November 14, 1997. No longer considered a significant feed item. |
| Grape pomace, dried | 40 | Already Revoked | revoked 62 FR 66020; November 14, 1997. No longer considered a significant feed item. |

| Commodity | Established Tolerance, ppm | Reassessed Tolerance, ppm | Comments [Correct Commodity Definition] |
|---|----------------------------|---------------------------|--|
| Tolerances Needed Under 40 CFR §180.259(a) | | | |
| Citrus oil | -- | 30 | |
| Cotton gin byproducts | -- | TBD * | |
| Aspirated grain fractions | -- | 0.4 | |

* TBD = To be determined. This term means the tolerance to be set will be safe. However, additional confirmatory data are needed to be able to set the tolerance level.

iv. Codex Harmonization

The U.S. tolerances for propargite residues and Codex MRLs are identical with respect to the residue regulated; both are defined as the parent compound. Codex MRLs and U.S. Tolerances are inharmony for the following commodities: almonds, bean (dry), cotton seed, eggs, grape, hops (dry), corn, corn fodder, corn forage, meat, peanut forage (green), potato, poultry meat, sorghum, sorghum forage (green), sorghum straw and fodder (dry), tea green and black, and walnut. Harmonization with the Codex tolerance limit in/on citrus fruits, nectarines, and milk is not possible at this time because data indicate the need for different tolerances. The U.S. tolerance for citrus fruits is being proposed as 10 ppm (raise from 5 ppm), while the Codex MRL is 5 ppm. The U.S. tolerance for nectarines is 4 ppm, while the Codex MRL is 7 ppm. And finally, the U.S. tolerance for milk is 0.08 ppm, while the Codex MRL is 0.1 ppm..

Residue Analytical Methods

Analytical methods available for enforcing propargite tolerances include Methods II, V, and VI for plant commodities and Methods III and IV for animal commodities in PAM, Volume II (Sec. 180.259). The preferred enforcement analytical method for plant commodities is Method V. All are gas liquid chromatography (GLC) methods with either sulfur-specific microcoulometric detection (Method II), microcoulometric detection (Method III), or flame photometric detection (Methods IV, V, and VI). Limits of quantitation are 0.08 (milk) and 0.1 ppm (plant and animal commodities).

GC/FPD methods used for collecting data on propargite *per se* in plant and animal matrices are adequate and have been successfully radiovalidated using samples from metabolism studies. However, the extraction solvents used in these methods are not the same as those employed in the PAM II methods. Radiovalidations should be conducted using the extraction solvents in the preferred PAM II plant and animal enforcement methods, or other methods should be proposed as enforcement methods. For other methods to be enforcement methods, independent laboratory method validations and EPA method validations would be needed.

The GC/FPD data collection methods that are based on the PAM II methods are sensitive to 0.05 ppm. If these methods were tested and approved for enforcement purposes, numerous tolerances currently set at the 0.1 ppm LOQ for the PAM methods could be lowered to 0.05 ppm.

This should be considered only after detailed scientific review by the Agency of the residue data..

Methods have been submitted for enforcement of tolerances for residues in dried tea leaves. The Agency has determined that the method must be modified to include Soxhlet extraction.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the current use of propargite. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

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

i. Acute Dietary (Food)

Based on estimates for acute exposure to propargite, the percentage of the acute Population Adjusted Doses utilized is 2 percent for females 13 - 50, the only sub-population for which an acute endpoint was identified. Therefore, the acute dietary (food) risk estimate for propargite is not of concern, and no mitigation measures are needed.

ii. Chronic Dietary (Food)

The chronic dietary analysis utilized USDA Pesticide Data Program (PDP) monitoring data, field trial data, calculated livestock anticipated residues, and percent crop treated information. Based on that analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic dietary (food) risk estimate is also not of concern, and no mitigation measures are needed.

iii. Chronic Cancer Dietary (Food)

A cancer dietary exposure and risk analysis was performed based upon revised cancer Q_1^* of $0.033 \text{ (mg/kg/day)}^{-1}$ derived from a 2-year cancer bioassay on rats and upon Agency analyses anticipated residues of propargite in food. Based on that analysis, which yielded a cancer risk of 1.8×10^{-7} , the Agency has concluded that the cancer dietary risk from food alone is not of concern, and that no mitigation measures are needed to address the cancer food risk.

iv. Drinking Water

The Agency has determined that there are no acute or chronic (non-cancer) drinking water concerns (see Section III.A.3). However, the Agency risk assessment shows potential dietary cancer risks of concern for drinking water derived from surface waters. This assessment was based on modeling simulations and United States Geological Survey (“USGS”) monitoring data. The modeling simulations predict that propargite residues in surface waters have a 20-year mean concentration of 4.8 ppb, and can be as high as 34 ppb. The annual mean concentrations detected at the USGS monitoring sites ranged from 0.3ppb to 1.24 ppb. The cancer DWLOC is 0.71.

As described previously, EPA believes that, in the case of propargite, the modeling simulations and monitoring data over-estimate the actual exposures through drinking water. In the modeling simulations, for example, the model input variables assumed maximum use rates and frequencies for the highest use crop. Data obtained from the State of California, where about 75 percent of all domestic propargite is used, indicate, however, that typical use rates are significantly below maximum use rates. In fact, the California data indicate that the maximum use rate is utilized in fewer than 5 percent of all applications. This figure is consistent with information provided to EPA from several grower groups indicating that propargite, because of its efficacy against adult mites, is frequently used as a spot-treatment on an as-needed basis. Similarly, in the case of propargite, the Agency believes that the model simulations are conservative because they do not account for the effect of water treatment processes. Conventional water treatment (coagulation-flocculation-sedimentation) will be effective in removing propargite because test data verifies that propargite has a high affinity to bind with soil particles.

Regarding the USGS monitoring data, which measured annual mean concentrations of propargite in the San Joaquin, California watershed at 0.3 ppb and 1.24 ppb in 1992 and 1993, respectively, it is critical to note that these data were developed to assess ambient surface water levels of pesticides rather than drinking water exposures. As such, the data does not account for such factors as distance between sampling locations and public drinking water uptakes, or pesticide

removal by water treatment processes. In the case of Oristimba Creek, the propargite concentrations in that location measured 20 ppb on one occasion during the 2-year study. However, the monitoring station on that creek is located 23 to 30 miles upstream of the two nearest drinking water intakes, and the water from that creek empties into the much larger San Joaquin river shortly after the monitoring site. If the values from that one creek are omitted from the data set, the time weighted average would be .02 ppb, a value below the cancer DWLOC.

Because propargite has a strong affinity to bind to soil, it is likely that a significant portion of the residues in surface water are the result of direct spray drift rather than run-off from soil. Therefore, reducing spray drift is likely to produce a significant risk reduction in propargite residues in surface water. The registrant has agreed to add buffer zones (no application of propargite by ground within 50 feet or by air within 75 feet of aquatic areas) and spray drift requirements to the label to minimize propargite runoff into surface waters.

The registrant has also agreed to decrease the maximum seasonal application and frequencies for several crops (beans (dry), citrus, corn, cotton, mint, walnuts), and increase spray intervals for several crops from 7 to 21 days (28 days for citrus). See Table 11 for new seasonal maximum rates, and see Table 12 for new spray intervals. These measures will reduce environmental loading of propargite. The registrant has further agreed to conduct a confirmatory monitoring study to ensure that actual drinking water exposures are below the Agency's level of concern. That study will institute a 3-year sampling regimen designed to measure concentrations of propargite residues in surface drinking water supplies under highly vulnerable conditions.

Table 11. Reductions in Annual Application Rates

| Crop | Existing annual maximum application rate (lbs. a.i./Acre) | Proposed annual maximum application rate (lbs. a.i./Acre) |
|---------------------------|---|---|
| Beans (6 lbs/gal EC) | 5.1 | 4.5 |
| Beans (6.55 lb/gal EC) | 4.9 | 3.7 |
| Citrus | 4.9 | 4.1 |
| Cotton | 4.9 | 3.3 |
| Field Corn/Popcorn | 30 | 15 |
| Jojoba | 3.3 | 1.6 |
| Mint | 5.0 | 4.5 |
| Oranges/Grapefruit/Lemons | 6.7 | 5.8 |
| Walnuts (6 lb/ga EC) | 9 | 6.8 |
| Walnuts (32% WP (WSP)) | 8 | 6.4 |

Table 12. New Spray Intervals Required for Propargite

| Crop | Minimum Spray Interval (Days) | Total # of Applications per year |
|--|--|----------------------------------|
| almonds; beans (dry); cherries; cotton; grapes; hops; nectarines; potatoes ¹ ; walnuts; non-bearing crops | 21 | 2 |
| jojoba | 21 | 1 |
| citrus (orange, grapefruit, lemons) | 28 | 2 |
| mint | 14 | 2 |
| Ornamentals, Christmas Trees and Conifers | 28 (west of Rocky Mts) 7 (east of Rocky Mts). | 3 |
| Roses, other onamentals | 14 | 3 |
| peanuts | 14 | 2 |

¹- New spray interval for potatoes in Washington state is 14 days

v. Aggregate Risk Mitigation (acute and chronic)

Because there are no residential uses of propargite, the aggregate risks are limited to dietary (food and water) exposure. The risks from those combined exposures are discussed above in the preceding section.

b. Occupational Risk Mitigation

As discussed in Chapter III, EPA combines chemical-specific studies with similar surrogate data from the Pesticide Handlers Exposure Database (“PHED”) to assess handler exposures for regulatory actions. In addition, the exposure estimates from PHED are used to assess exposure where no chemical specific data are available. The handler exposure assessments encompass all of the major uses of propargite throughout the country. Because it is difficult to assess “typical” agricultural uses, an assessment has been developed that is believed to be realistic and yet provides a reasonable certainty that the exposures are not underestimated. For example, for handlers, the assessment assumes that handlers are exposed to the maximum concentrations of propargite, for the highest estimated acreage, for 8 hours per day for 14 days per year. Similarly, for post-application workers, exposure values are calculated assuming that fields are 100% treated at maximum allowable rates, and that workers work exclusively in those treated field for 8 hours/day, for 30 days/year. The cancer post-application assessment assumes that same exposure over a 35-year period. Also, no allowance is made for environmental degradation of propargite, further ensuring that risks are not likely to be under-estimated.

i. Handler Exposure

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of mitigation (PPE and engineering controls) to achieve a margin of exposure (MOE) of 100 or greater for dermal exposure and 1,000 or greater for inhalation exposure. For non-dietary cancer risks, the Agency seeks to reduce individual risks to the greatest extent feasible; risks greater than 1×10^{-6} are of concern. The Agency typically will not accept risks greater than 1×10^{-4} . For risks between 10^{-6} and 10^{-4} , EPA carefully evaluates exposure scenarios to seek ways to reduce the cancer risks to the greatest extent feasible, preferably a risk less than 1×10^{-6} .

To mitigate risks to mixers, loaders, and applicators from propargite, the following measures have been agreed to by the Registrant:

- To address the risk from mixing and loading liquids for aerial application of propargite to corn and cotton (scenario 1a in table 8), a closed mixing loading system will be necessary.
- To protect applicators in fixed-wing aircraft (scenario 3), enclosed cockpits will be required.
- To address the risk from mixing and loading wettable powders (scenario 2) water soluble packaging is necessary.
- To address the risk from airblast spray applications (scenario 5) enclosed cabs (that provide dermal protection) will be required.

- To protect against risks for all other scenarios, personal protective equipment (socks, shoes, long-sleeved shirts, long pants, and gloves are necessary for all scenarios [except gloves are not necessary for flagging during aerial application (scenario 7).

In addition, as a Toxicity Category 1 pesticide that is corrosive to both the eye and skin (MRID ## 42857004 and 42857005), propargite end-use products meet the restricted use criteria under 40 CFR 152.170(2)(v) and (vi). As such, EPA will reclassify propargite as a restricted use pesticide (RUP).

For most worker exposure scenarios, these protections provide estimated dermal/inhalation MOEs equal to or greater than the 100/1000 MOE target values described above. The exception is mixing and loading at the maximum application rate for aerial application on corn. While the registrant has agreed to the maximum protection feasible for this scenario, which is requiring closed mixing and loading systems, the MOE achieved is only 80. However, because the MOE is based on the conservative assumptions that workers would be mixing and loading for the maximum rate for the maximum acres treated, the Agency believes workers are adequately protected for this scenario. Although the estimated cancer risks for some of the scenarios are slightly above the 1×10^{-6} target value, the Agency is confident that, with the above-described conservative assumptions built into its exposure models, the identified mitigation measures provide an acceptable level of protection.

ii. Post-application Exposure

EPA completes exposure assessments on post-application workers for various crops and activities at intervals following the application until risk falls below a target level. For propargite, the target level for dermal risk concerns is an MOE of 100; for inhalation risk concerns, it is an MOE of 1000; and for cancer, the target risk is 1×10^{-6} . For cancer risks between 1×10^{-4} and 1×10^{-6} , the Agency strives for risk reduction with mitigation measures where feasible.

In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target risk estimate (usually expressed as an MOE). The Agency also estimates cancer risk at that target interval. In addition, occupational risks are regulated under the FIFRA section 3(c)(5) standard - "without unreasonable adverse effects on the environment" - which means that both risks and benefits must be considered in making a risk management decision. This standard may be met at a level below the target MOE when there are significant benefits associated with a specific activity. As the worker exposure database has improved, risk assessments are now conducted for a variety of postapplication activities based on the level of exposure for each worker activity (see table 9, "Occupational Postapplication Risk from Propargite: Days After Treatment at Which the MOE is ≥ 100 "). For a specific crop/pesticide combination, the duration required to achieve the target MOE can vary depending on the activity assessed.

In general, EPA prefers to set a single REI for all activities related to a crop or crop group

without additional activity-based labeling. This approach is favored because handlers and workers are more likely to understand and comply with simpler labels. Also, permitting activity-based entry for one crop could cause confusion and compromise the effectiveness of the WPS. However, when the consideration of risks and benefits indicate that a simple REI is unworkable, EPA may consider either setting an REI with early entry exceptions for one or more critical tasks or establishing a entry prohibition for a specific task after the REI has expired. For most propargite uses, a single REI is being proposed because no critical use was identified that warrants the use of an exception or prohibition. During the 60-day comment period for this RED, however, EPA will accept further comments from growers regarding needs for additional REI exceptions for specific activities, and will add such exceptions where needed if there are adequate MOEs and/or benefits associated with such activities.

In considering worker risks and benefits, the Agency considered the timing of field activities that are critical to crop production. For many of the propargite uses discussed below, scouting and irrigation are critical activities in crop production, and these activities routinely need to be performed soon after application. In evaluating the restricted entry intervals, the Agency considered the exceptions to the Worker Protection Standard that could inform the decision. EPA's proposed REIs take into account the flexibility already provided by these exceptions. Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the handler personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS (40 CFR 170.204(b)), the individual can determine the appropriate PPE to be used. For many of these crops, irrigation equipment is not routinely moved by hand. For these methods, the primary activity involves entering the field to turn the watering equipment on and off. This activity is allowed during the REI under the no contact exception to WPS (40 CFR 170.112(b)). Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field provided early entry PPE is used (40 CFR 170.112(c)). This exception also usually applies to mechanical harvesting, tree shaking for nut crops in enclosed cabs, and often applies to mowing.

For all post-application worker exposure scenarios described above, the proposed REIs provide estimated dermal/inhalation MOEs equal to or greater than the 100/1000 MOE target values described above. Although the estimated cancer risks for some of the scenarios are slightly above the 1×10^{-6} target value (see table 9), the Agency believes REIs provide an acceptable level of protection. Many, if not most, workers are actually not at risk at this level because the assessment assumes workers perform their activities for 8 hours a day, 30 days a year, for 35 years in propargite treated crops that were treated at the maximum rate. The probability of a worker meeting all these conditions is small. Further, it was determined to be infeasible to decrease the estimated cancer risk by increasing the REIs. Even large increases in the REI produced only marginal decreases in cancer risk when calculated over a 35 year lifetime exposure. This is because of the persistence of propargite residues on foliage.

To address potential risks to post-application workers, the Agency is modifying the REIs for propargite as described in table 13 below.

Table 13. Restricted Entry Intervals (REIs) for Propargite

| Crop | PHI (days) | REI (days) | Exceptions | Comments |
|---|-----------------------|-----------------------|--|---|
| Alfalfa (grown for seed) | NS | 9 | None | REI set on 2.5 lb ai/A rate where irrigation/scouting MOE ≥ 100 . There are no data on harvesting exposures. However, harvesters are expected to be protected with REI set on irrigation/ scouting exposure data. |
| Almond | 28 | 22 | None | REI set on 3 lb ai/A rate where pruning MOE ≥ 100 . This REI is also expected to protect sweeping and blowing of the nuts. Tree shaking (and other activities done in enclosed cabs) and irrigation would allowed before REI expires under the WPS “no contact” exemption. |
| Avocado (non-bearing) | NA ¹ | 11 | None | REI set on 4.5 lb ai/A rate where pruning MOE ≥ 100 . |
| Beans, dry | 14 | 9 | None | REI set on 2.5 lb ai/A rate where irrigation/scouting MOE ≥ 100 . Harvesters are protected by PHI. |
| Boysenberry (non-bearing) | NA ¹ | 10 | None | REI set on 2 lb ai/A rate where pruning and tying MOE ≥ 100 . |
| Carrot (grown for seed) | NS | 2 ² | Hand harvesting prohibited for 13 days | REI set on 2.5 lb ai/A rate where all activities except hand harvesting have MOE ≥ 100 . Hand harvesting prohibited for 13 days |
| Cherry (foliar application after harvest) | NA ¹ | 2 ² | None | REI set on 1.5 lb ai/A rate where pruning MOE ≥ 100 . Since this is a foliar application after harvest, there are no harvesters to protect. |
| Christmas Tree, Ornamental and/or shade trees, Ornamental Herbaceous Plants | NS | 14 | None | REI set on 2.5 lb ai/A rate where harvesting MOE ≥ 100 . |
| Clover (grown for seed) | NS | 9 | None | REI set on 2.5 lb ai/A rate where irrigation/scouting MOE ≥ 100 . There are no data on harvesting exposures. However, harvesters are expected to be protected with REI set on irrigation/ scouting exposure data. |
| Corn (field, pop, sweet) | 30 | 13 | None | REI set on 2.5 lb ai/A rate where hand harvesting and detasseling MOE ≥ 100 . |
| Cotton | 50 | 6 | None | REI set on 1.5 lb ai/A rate where harvesting MOE ≥ 100 . |
| Currant (non-bearing) | NA ¹ | 10 | None | REI set on 2 lb ai/A rate where harvesting, pruning and tying MOE ≥ 100 . |
| Date (non-bearing) | NA ¹ | 2 ² | None | REI set on 1.5 lb ai/A rate where pruning MOE ≥ 100 . |

| Crop | PHI (days) | REI (days) | Exceptions | Comments |
|-----------------------------|-----------------|---|---|--|
| Grapefruit | 7-21 | 20 | None | REI set on 3.15 lb ai/A rate where harvesting MOE \geq 100. |
| Grapes | 21 | 27 days for grapes (table) turning cane. 16 days for all other grapes. | None | REI set on 3 lb ai/A rate where cane turning for table grapes MOE \geq 100. REI set on 3 lb ai/A rate where harvesting, pruning, tying MOE \geq 100. |
| Hazel nut (non-bearing) | NA ¹ | 22 | None | REI set on 3 lb ai/A rate where pruning MOE \geq 100. |
| Hops | 14 | 21 | Special Local Needs (SLN) registrations over 1.9 lbs ai/A are 30 days | REI set on 1.5 lb ai/A rate on FIFRA§3 labels where harvesting and training MOE \geq 100. REI for SLN set on 2.5 lb ai/A rate where harvesting and training MOE \geq 100. |
| Jojoba | NS | 2 ² | None | REI set on 1.5 lb ai/A rate. |
| Lemon | 7 | 20 | None | REI set on 3.15 lb ai/A rate where harvesting MOE \geq 100. Exception for pruning is set where MOE \geq 100. |
| Lime (non-bearing) | NA ¹ | 16 | 20 days for pruning. | REI set on 2.5 lb ai/A rate where pruning MOE \geq 100. Exception for pruning is set where MOE \geq 100. |
| Macadamia Nut (non-bearing) | NA ¹ | 22 | None | REI set on 3 lb ai/A rate where pruning MOE \geq 100. |
| Mint | 14 | 7 | None | REI set on 2.25 lb ai/A rate. |
| Nectarine | 14 | 5 | None | REI set on 2.5 lb ai/A rate where pruning MOE \geq 100. Harvesters are protected by the PHI. |
| Orange | 7-21 | 20 | None | REI set on 3.15 lb ai/A rate where harvesting MOE \geq 100. |
| Peanuts | 14 | 2 ² | None | REI set on 1.5 lb ai/A rate. |
| Pecan (non-bearing) | NA ¹ | 22 | None | REI set on 3 lb ai/A rate at days where pruning MOE \geq 100. |
| Persimmon (non-bearing) | NA ¹ | 2 ² | None | REI set on 1.5 lb ai/A rate where pruning MOE \geq 100. |
| Pistachio (non-bearing) | NA ¹ | 22 | None | REI set on 3 lb ai/A rate where pruning MOE \geq 100. |
| Potato | 14 | 2 ² | None | REI set on 2.5 lb ai/A rate where all activities except hand harvesting have MOE \geq 100. Harvesters are protected by the PHI. |

| Crop | PHI (days) | REI (days) | Exceptions | Comments |
|---------------------------------|-----------------|----------------|--------------------------|---|
| Quince (non-bearing) | NA ¹ | 2 ² | None | REI set on 1.5 lb ai/A rate where pruning MOE \geq 100. |
| Raspberry (non-bearing) | NA ¹ | 10 | None | REI set on 2 lb ai/A rate where pruning and tying MOE \geq 100. |
| Sorghum | 30-45 | 2 ² | None | REI set on 2.5 lb ai/A rate. |
| Sugar beets (grown for seed) | 21 | 2 ² | None | REI set on 2.5 lb ai/A rate where all activities have MOE \geq 100. Assumes no hand harvesting. |
| Tangerines (non-bearing) | NA ¹ | 16 | None | REI set on 2.5 lb ai/A rate where pruning MOE \geq 100. |
| Walnuts | 21 | 30 | 21 days for tree shaking | REI set on 4.5 lb ai/A rate where pruning MOE \geq 100. |

NS = None specified

¹ NA = Not applicable. In case of a non-bearing crops, there are no harvesting activities and an REI is not necessary to protect harvesters.

² REI is set on the WPS default of 48 hours (72 hours for arid areas) for a pesticide that is an acute Toxicity Category 1 for eye and skin irritation.

2. Environmental Risk Mitigation

a. Avian and Mammalian Risk Mitigation

As described in Chapter III., chronic toxicity testing on bobwhite quail and mallard duck indicates that propargite has adverse reproductive effects on avian species. Based on a NOAEL of 43.2 ppm from these studies, exposures projected in the Agency's risk assessment are expected to result in chronic risk concerns for birds ($RQs \geq 1.0$). These chronic risk concerns for birds are predicted by the risk assessment for all propargite crop applications scenarios with rates over 0.5 lb ai/acre. For mammals, chronic risk concerns for herbivorous/insectivorous mammals were exceeded for all five modeled single and multiple application crop use scenarios, and is predicted for any application scenario over 1.5 lb ai/A. Acute risk concerns were approached or exceeded by predicted exposures to multiple applications of propargite at rates of 3.0 to 4.5 lb ai/A.

Before discussing the avian and mammalian risk management aspects of this reregistration eligibility decision, it should be noted that there are some uncertainties in the Agency's terrestrial risk assessment which suggest that identified risks to birds and mammals may be lower than projected in this specific case. First, because there are no spray intervals on the current product labels, the risk assessment assumed a 7-day spray interval in its exposure model. Given propargite's expected high persistence on foliage, however, it is unlikely that many growers actually apply it with such frequency. Moreover, although neither EPA nor USDA were provided with specific documentary data, both

Agencies have been advised by numerous grower groups that a significant portion of propargite applications are spot applications used to address localized mite outbreaks, whereas, the Agency's model assessed exposures from full field applications. Second, as described in the drinking water section of this chapter, use data compiled by the State of California, where 75 percent of total propargite is used, indicate that propargite is frequently applied at rates well below the maximum permitted use concentrations used in EPA's modeling scenarios.

In light of these uncertainties surrounding exposures and risks to avian and mammalian species, the registrant has agreed to develop further data to better characterize the risk to avian species likely to be exposed to propargite. The registrant has also agreed to a number of measures which will reduce exposures to birds and mammals. These measures are as follows:

- Lowering annual application amounts for mint, walnuts, citrus, dry beans, cotton, jojoba, field corn, and pop corn (see Table 11);
- lowering the number of annual applications for cotton and jojoba;
- adding spray intervals of 21 days for most food crops (28 days for citrus) (see Table 12)
- Adding requirements to minimize spray drift;
- Adding label language advising against use of maximum application rates unless high mite infestations exist.

Given the conservative assumptions used in the propargite model, the mitigation outlined above and the considerable benefits (discussed below in Section IV.D.2.c.), the Agency believes that no further action is required at this time to address avian and mammalian risks from the use of propargite.

b. Aquatic Risk Mitigation

As stated in Chapter III., although propargite is highly toxic to all fish and invertebrate species tested (96 hour LC_{50} values for 7 aquatic species were below 168 ug/L), the RQs calculated from EECs derived from Tier II simulations suggest little potential for acute risk to fish or invertebrates. However, several RQs ranged between 0.2 and 0.5 suggesting that exposure in small, shallow water bodies (i.e., those not represented by EPA's standard aquatic risk scenario) could result in adverse effects to organisms present.

All of the risk mitigation measures described above in the avian and mammalian risk mitigation section above also serve to mitigate risks to aquatic species. In addition to those measures, the registrant has also agreed to institute no-spray zones around lakes reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, and commercial fish farm ponds. The buffer zones will be 50 feet for ground applications and 75 feet for aerial applications. This requirement will decrease the amount of propargite reaching surface waters directly via spray applications and indirectly via field runoff of precipitation and irrigation water. The Agency's current models are unable to quantify reductions in surface water concentrations attributable to buffers because of the large number of variables that affect the calculation (type of vegetation in the buffer area, grade and topography of

the buffer area, soil type, etc.) It is clear, however, that some reduction in runoff concentrations reaching surface waters will occur .

c. Benefits

In making a reregistration eligibility determination for a given pesticide, the Agency assesses not only the potential risks that the pesticide may present to human health or the environment, but also the benefits which accrue from its use. In the case of propargite, the Agency identified several significant benefits. First, as shown on Table 14 below, there are very few other registered miticides on the market which have the efficacy of propargite, and those alternatives that do exist are either not approved for use in some key states, or are significantly more expensive to apply. Second, several of the miticides which are potential alternatives to propargite have been reported as having increasing levels of resistance over the last few years. Mites, some species of which undergo 20 life-cycles per growing season, are particularly adept at developing pesticide resistance. Third, because it is non-toxic to 4 out of the 5 mite predator species tested, propargite is expected to be an important component of several Integrated Pest Management (IPM) programs currently under development by grower groups. Finally, because propargite is effective against adult mites, application can be delayed until actual infestations are detected. Most alternative chemicals need to be applied prophylactically at the beginning of the growing season; because propargite can be used as a spot treatment on an as-needed basis, lower overall amounts of pesticides are frequently used on mite-prone fields propargite is the miticide selected.

Table 14. Propargite Benefits, by crop

| Crop | Propargite | | Alternatives (Mkt Share) | Notes | Estimated yield loss ¹ |
|-----------------|-------------------|--------------|--|---|--------------------------------------|
| | % crop treated | mkt share | | | |
| alfalfa seed | 17% | 100% | formetanate Hcl (0%) sulfur (0%) | Used in NV, CA, WA, ID. | 32% |
| Almond | 35% | 75% | abamectin (10%) clofentezine (1%) fenbutatin-oxide (10%) pyridaben (2%) | CA Propargite is used to control spider mites and European red mite. Fenbutatin oxide, the primary alternative is equally effective but more expensive. | 0.2% |
| Beans, dry | 2% | 95% | dicofol (5%) sulfur | CA, ID, WA Dicofol is the primary alternative. | 20% |
| Corn | 0.4% | 53% | bifenthrin (47%) | CA. NE. CO, KS Bifenthrin is the best alternative but is not available in CA. | 8% |

| Crop | Propargite | | Alternatives (Mkt Share) | Notes | Estimated yield loss ¹ |
|-------------------|-------------------|--------------|--|--|--------------------------------------|
| | % crop treated | mkt share | | | |
| Cotton | 1.6% | 7% | abamectin (60%) amitraz bifenthrin (1%) dicofol (32%) hexathiazox sulfur | CA, AZ, TN Abamectin and dicofol are the primary alternatives. | 2% |
| Grapes, raisin | 54% | 86% | cinnamaldehyde (1%) dicofol (2%) fenbutatin oxide (5%) sulfur (6%) | CA Fenbutatin oxide and dicofol, the primary alternatives, are equally effective but more expensive. | 1% |
| Grapes, table | 20% | 27% | dicofol (32%) fenbutatin oxide (41%) | CA | 1% |
| grapes, wine | 11% | 71% | abamectin (<1%) cinnamaldehyde (1%) dicofol (8) fenbutatin oxide (3) sulfur (18%) | CA | 1% |
| Hops | 5% | 100% | dicofol oxythioquinox sulfur | Mites in WA are resistant to dicofol | 59% |
| Mint | 22% | | dicofol oxydemeton-methyl | ID. OR, WA propargite is the only effective acaricide in OR | 41% |
| Nectarines | 22% | 25% | clofentezine (15%) dicofol (20%) formetanate Hcl (20%) fenbutatin oxide (10%) sulfur (10%) | CA Fenbutatin oxide is the most likely alternative | 10% |
| peanut | 0.7% | 100% | none | AL, GA, NC, FL, VA | 6% |
| Potato | 2% | 100% | insecticidal soap sulfur | WA Alternatives are ineffective | 20% |
| Walnut | 25% | 78% | abamectin (2%) clofentezine (5%) dicofol (5%) fenbutatin oxide (10%) narrow range oil oxythioquinox | CA | 8% |

1/ Based on USDA NAPIAP Propargite report (Osteen, 1994), Table 1 and pages 177-185. In some cases, per acre dollar losses compared to 1993 gross revenues from Agricultural Statistics 1995-96, table 543 to derive

percent losses of gross revenues.

3. Other Label Statements

In order to be eligible for reregistration, various use and safety information must also be placed on the labeling of all end-use products containing propargite. For the specific labeling statements, refer to Section V of this document

a. 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, EPA 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 pesticides 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 RED that are being implemented at that 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. These Pamphlets are available for voluntary use by pesticide applicators, on EPA's web site 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.

b. Spray Drift Management

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, EPA published draft guidance for label statements in a pesticide registration (PR) notice ("Draft PR Notice 2001-X" http://www.epa.gov/PR_Notices/#2001). A *Federal Register* notice was published on August 22, 2001, 66 FR 44141 (<http://www.epa.gov/fedrgstr>) announcing the availability of this draft guidance for a 90-day public comment period. After receipt, and review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

Until EPA decides upon, and publishes the final label guidance for spray, and dust drift, the registrant for propargite has agreed to add the following spray drift related language, in part to address concerns of surface water runoff of propargite.

Do not allow this product to drift off target site.

Do not apply by ground within 50 ft. or by air within 75 ft. of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds; estuaries and commercial fish farm ponds.

For ground applications apply the coarsest droplet size spectrum that provides sufficient coverage and mite control. Use the lowest nozzle height that provides uniform coverage. Apply only when wind speeds are 10 mph or less when measured by an anemometer outside the spray area on the upwind side.

For aerial applications apply the coarsest droplet size spectrum that provides sufficient coverage and mite control. Apply from the lowest possible height that provides good pest control and flight safety. Use the shortest boom length that is practical. Apply only when wind speeds are 10 mph or less when measured by an anemometer outside the spray area on the upwind side.

Risk of exposure to sensitive aquatic areas can be reduced by making applications when the wind direction is away from the aquatic area.

Do not make aerial or ground applications during temperature inversions.

V. What Registrants Need To Do

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

For Propargite technical grade active ingredient products, 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 registrant's response form); and
- (2) submit any time extension and/or waiver requests with a full written justification.

Within the 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.

Please contact Dayton Eckerson at 703/308-8038 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Chemical Review Manager's Name
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Chemical Review Manager's Name
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

For products containing the active ingredient Propargite, 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) Complete response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- (2) Submit 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 reregistration (EPA Form 8570-1).
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 [insert table number] 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.

Please contact Bonnie Adler at (703)308-8523 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:

Document Processing Desk (PDCI/PRB)
Chemical Review Manager’s Name
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)
Chemical Review Manager’s Name
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 propargite for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

- OPPTS GLN 830.7050 - (UV/Visible absorption)
- OPPTS GLN 860.1200 (directions for Use) - Label revisions are required.
- OPPTS GLN 860.1380 - Additional storage stability data are required for peanut, walnut, corn and tea.
- OPPTS GLN 860.1520 - Additional residue data are required for cotton gin byproducts.
- OPPTS GLN 860.1360 - Multi-residue testing
- OPPTS GLN 840.1100 Droplet size spectrum
- OPPTS GLN 835.7200 - Special Study - Surface Source Drinking Water Monitoring Study.
- OPPTS GLN 840.1200 - Drift field evaluation
- OPPTS GLN 850.1450 - Estuarine/marine life cycle (mysid)
- OPPTS GLN 850.1500 Freshwater fish full life cycle
- OPPTS GLN 850.3030 - Honey Bee Toxicity of Residues on Foliage
- Special Study - Avian Dietary Exposure Study.
- OPPTS GLN 835.2370 - Photodegradation in air
- OPPTS GLN 835.1410 - Laboratory Volatilization
- OPPTS GLN 835.8100 - Field Volatility
- OPPTS GLN 835.6200 - Aquatic Sediment Field Dissipation
- OPPTS GLN 835.6400 - Combination Products and Tank Mixes Dissipation

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 15 at the end of this section.

B. End-Use Products

1. Additional Generic Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current

testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section V above. Specific language to implement these changes is specified in the Table 15 at the end of this section..

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell propargite products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in section IV. Table 15 describes how language on the labels must be amended.

Required Labeling Changes Summary Table

| Table 15 Summary of Required Labeling Changes for Propargite | | |
|---|--|--------------------|
| Description | Required Labeling | Placement on Label |
| Manufacturing Use Products | | |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group | “Only for formulation into an miticide for the following use(s): alfalfa grown for seed; almond; apples (non-bearing); apricots (non-bearing); avocado (non-bearing); bean, dry (including dry lima beans); berries (non-bearing); boysenberry (non-bearing); carrot (grown for seed); cherry (foliar after harvest); Christmas tree, ornamental and/or shade, ornamental herbaceous plants; clover grown for seed; corn (field, pop, sweet); cotton; currant (non-bearing); dates (non-bearing); figs (non-bearing); grapefruit; grapes; hazel nut (non-bearing); hops; jojoba; lemon; lime (non-bearing); macadamia nut (non-bearing); mint (field grown); nectarine; orange; peaches (non-bearing); pears (non-bearing); peanuts; pecan (non-bearing); persimmon (non-bearing); pistachio (non-bearing); plums (non-bearing); potato; pruns (non-bearing); quince (non-bearing); raspberry (non-bearing); roses(field grown); strawberries (non-bearing); sorghum; sugar beets (grown for seed); tangerines (non-bearing); and walnuts. | Directions for Use |
| | <p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> | Directions for Use |
| Environmental Hazards Statements Required by the RED and Agency Label Policies | This pesticide is toxic to fish. Do not discharge effluent into lakes, streams, ponds, estuaries, oceans, or public 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 sewage without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. | Directions for Use |

| Description | Required Labeling | Placement on Label |
|--|---|--|
| End Use Products Intended for Occupational Use (WPS) | | |
| Restricted Use Pesticide Requirement (all formulations) | Restricted Use Pesticide “Due to acute skin and eye effect. For retail sale to and use only by Certified Applicators, or persons under their supervision, and only for those uses covered by the Certified Applicator’s certification.” | |
| PPE Requirements Established by the RED ¹ for liquid products | <p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers must wear:</p> <p>Long-sleeved shirt and long pants Shoes plus socks Chemical-resistant gloves (except for flaggers and applicators using closed cabs) Chemical-resistant apron for mixers and loaders and persons exposed to the concentrate</p> <p>See engineering controls for additional requirements”</p> | Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals |

| Description | Required Labeling | Placement on Label |
|--|---|--|
| <p>PPE Requirements Established by the RED¹ for Wettable Powder product formulations must be packaged in Water Soluble Packaging (WSP) to be eligible for reregistration.</p> | <p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>Mixers, loaders, applicators and other handlers must wear:</p> <p>Long-sleeved shirt and long pants Shoes plus socks Chemical-resistant gloves (except for flaggers and applicators using closed cabs) Chemical-resistant apron for mixers and loaders.</p> <p>See engineering controls for additional requirements”</p> | <p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p> |
| <p>User Safety Requirements</p> | <p>“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.”</p> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p> |

| Description | Required Labeling | Placement on Label |
|--|--|---|
| Engineering Controls Established by the RED ¹ for liquid products | <p>“Engineering Controls</p> <p>“Mixers and loaders supporting aerial applications to corn and cotton must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], and must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required above for mixers/loaders, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, and chemical-resistant footwear .” <p>"Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];</p> <p>“Applicators using airblast spray equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required above for applicators, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” <p>“When other applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p> | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |

| Description | Required Labeling | Placement on Label |
|---|---|---|
| <p>Engineering Controls Established by the RED¹ for Wettable Powders in Water Soluble Packaging. All WP product must be packaged in Water Soluble Packaging (WSP) to be eligible for reregistration.</p> | <p>“Engineering Controls</p> <p>Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required above for mixers/ loaders, and -- be provided and must have it immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant footwear, and a NIOSH approved respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or an organic vapor cartridge or canister with any N, R, P or HE prefilter, and <p>-Chemical-resistant headgear, if overhead exposure.”</p> <p>"Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];</p> <p>“Applicators using airblast spray equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required above for applicators, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” <p>“When other applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p> |

| Description | Required Labeling | Placement on Label |
|-----------------------------|---|--|
| User Safety Recommendations | <p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>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.”</p> | <p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p> |
| Environmental Hazards | <p>“This product is toxic to aquatic invertebrates and wildlife. 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. Do not apply by ground application equipment within 50 feet of surface waters or by aerial application equipment within 75 feet of surface water. See Directions for Use for additional restrictions. Do not contaminate water when disposing of equipment wash water.”</p> | <p>Precautionary Statements immediately following the User Safety Recommendations</p> |
| Restricted-Entry Interval | <p>In the Agricultural Use Requirements box, place the following statements:</p> <p>“Do not enter or allow workers to enter during the restricted-entry interval (REI), except as provided for by the WPS. The REI and Exceptions are listed in the Directions for Use associated with the crop.”</p> <p>“Notify workers of the exception (including when entry is permitted for each of the tasks named in the exception).”</p> | <p>Directions for Use, Agricultural Use Requirements Box and Application Instructions for Appropriate Crop</p> |

| Description | Required Labeling | Placement on Label |
|-------------|--|--------------------|
| | <p>In the Directions for Use under Application Instructions for each crop, specify the following REIs:</p> <p>Carrots, cherries, dates, jojoba, peanuts, persimmon, potatoes, quince, sorghum, and sugar beets. enter crop or crop group): The REI is 48 hours.</p> <p>Nectarine: The REI is five days.</p> <p>Cotton: The REI is six days.</p> <p>Alfalfa, beans (dry), clover, mint: The REI is nine days.</p> <p>Mint: The REI is seven days.</p> <p>Berry Crops: The REI is ten days,</p> <p>Avocado, The REI is eleven days,</p> <p>Corn (field, pop and sweet): The REI is thirteen days,</p> <p>Christmas Tree, ornmental and shade trees, ornamental herbaceous plants: The REI is fourteen days.</p> | |

| Description | Required Labeling | Placement on Label |
|--|--|---|
| | <p>Lime: The REI is sixteen days,</p> <p>Hops: The REI is twenty-one days,</p> <p>Almonds, hazel nut, macadamia, pecan, pistachio: The REI is twenty-two days,</p> <p>Grapes (except table): The REI is sixteen days,</p> <p>Table Grapes: The REI is twenty-seven days,</p> <p>Walnuts: The REI is thirty days. <u>Exception:</u> In addition to the early entry exceptions allowed by the Worker Protection Standard, you may enter or allow workers to enter treated areas to perform tree shaking tasks twenty one days following application as long as the worker wears long pants, long sleeved shirt and shoes plus socks.”</p> <p>Citrus: The REI is twenty days.</p> | |
| Early Re-entry Personal Protective Equipment established by the RED. | <p>“ PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> -- coveralls over long-sleeved shirt and long pants, -- chemical-resistant gloves made of any waterproof material, -- chemical-resistant footwear plus socks, and -- protective eyewear.” <p>“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.”</p> | Directions for Use, Agricultural Use Requirements Box |
| Notification Statement | “Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.” | Directions for Use, Agricultural Use Requirements Box |

| Description | Required Labeling | Placement on Label | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|--|----------------------|-----|-------------------------|-----|--------------------|-----|--------|-----|--------------------|-----|--------|-----|------|-----|--------------------------------|-----|------------------------|-----|-----------------------|-----|
| 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." | Place in the Direction for Use directly above the Agricultural Use Box. | | | | | | | | | | | | | | | | | | | | | |
| Other Application Restrictions | <div><div>The following risk mitigation measures must be reflected in the directions for use:</div><div>New Annual Application Rates Restrictions:</div><table><thead><tr><th>Crop</th><th>Annual Application Rate (lbs.a.i./Acre)</th></tr></thead><tbody><tr><td>Beans (6 /bs/gal EC)</td><td>4.5</td></tr><tr><td>Beans (6.55 /bs/gal EC)</td><td>3.7</td></tr><tr><td>Citrus (Liquid EC)</td><td>4.1</td></tr><tr><td>Cotton</td><td>3.3</td></tr><tr><td>Field corn/Popcorn</td><td>1.5</td></tr><tr><td>Jojoba</td><td>1.6</td></tr><tr><td>Mint</td><td>4.5</td></tr><tr><td>Oranges/Grapefruit/Lemons (WP)</td><td>5.8</td></tr><tr><td>Walnuts (6 /bs/gal EC)</td><td>6.8</td></tr><tr><td>Walnuts (32% WP(WSP))</td><td>6.4</td></tr></tbody></table></div> <div>Directions for Use</div> | Crop | Annual Application Rate (lbs.a.i./Acre) | Beans (6 /bs/gal EC) | 4.5 | Beans (6.55 /bs/gal EC) | 3.7 | Citrus (Liquid EC) | 4.1 | Cotton | 3.3 | Field corn/Popcorn | 1.5 | Jojoba | 1.6 | Mint | 4.5 | Oranges/Grapefruit/Lemons (WP) | 5.8 | Walnuts (6 /bs/gal EC) | 6.8 | Walnuts (32% WP(WSP)) | 6.4 |
| Crop | Annual Application Rate (lbs.a.i./Acre) | | | | | | | | | | | | | | | | | | | | | | |
| Beans (6 /bs/gal EC) | 4.5 | | | | | | | | | | | | | | | | | | | | | | |
| Beans (6.55 /bs/gal EC) | 3.7 | | | | | | | | | | | | | | | | | | | | | | |
| Citrus (Liquid EC) | 4.1 | | | | | | | | | | | | | | | | | | | | | | |
| Cotton | 3.3 | | | | | | | | | | | | | | | | | | | | | | |
| Field corn/Popcorn | 1.5 | | | | | | | | | | | | | | | | | | | | | | |
| Jojoba | 1.6 | | | | | | | | | | | | | | | | | | | | | | |
| Mint | 4.5 | | | | | | | | | | | | | | | | | | | | | | |
| Oranges/Grapefruit/Lemons (WP) | 5.8 | | | | | | | | | | | | | | | | | | | | | | |
| Walnuts (6 /bs/gal EC) | 6.8 | | | | | | | | | | | | | | | | | | | | | | |
| Walnuts (32% WP(WSP)) | 6.4 | | | | | | | | | | | | | | | | | | | | | | |

| Description | Required Labeling | Placement on Label | | | | | | | | | | | | | | | | | | | | | |
|---|---|---------------------------------|-------------------------------|---------------------------------|---|----|---|--------|----|---|-------------------------------------|----|---|---|---|---|--------------------------|----|---|------------------------------------|----|---|--|
| Other Application Restrictions (continued) | <p>The following risk mitigation measures must be reflected in the directions for use:</p> <p>New Spray Intervals Required for Propargite:</p> <table border="1" data-bbox="596 418 1604 1268"> <thead> <tr> <th data-bbox="615 435 1102 574">Crop</th><th data-bbox="1102 435 1331 574">Minimum Spray Interval (Days)</th><th data-bbox="1331 435 1585 574">Total Number of Sprays per year</th></tr> </thead> <tbody> <tr> <td data-bbox="615 574 1102 751">Almonds; beans (dry); cotton; grapes; hops; nectarines; potatoes (excluding Washington); walnuts; non-bearing crops</td><td data-bbox="1102 574 1331 751">21</td><td data-bbox="1331 574 1585 751">2</td></tr> <tr> <td data-bbox="615 751 1102 813">Jojoba</td><td data-bbox="1102 751 1331 813">21</td><td data-bbox="1331 751 1585 813">1</td></tr> <tr> <td data-bbox="615 813 1102 875">Citrus (orange, grapefruit, lemons)</td><td data-bbox="1102 813 1331 875">28</td><td data-bbox="1331 813 1585 875">2</td></tr> <tr> <td data-bbox="615 875 1102 1089">Ornamentals, Christmas Trees and Conifers</td><td data-bbox="1102 875 1331 1089">28 (west of Rocky Mts.) 7 (east of Rocky Mts.)</td><td data-bbox="1331 875 1585 1089">3</td></tr> <tr> <td data-bbox="615 1089 1102 1151">Roses, other ornamentals</td><td data-bbox="1102 1089 1331 1151">14</td><td data-bbox="1331 1089 1585 1151">3</td></tr> <tr> <td data-bbox="615 1151 1102 1213">Potato (Washington); peanuts; mint</td><td data-bbox="1102 1151 1331 1213">14</td><td data-bbox="1331 1151 1585 1213">2</td></tr> </tbody> </table> | Crop | Minimum Spray Interval (Days) | Total Number of Sprays per year | Almonds; beans (dry); cotton; grapes; hops; nectarines; potatoes (excluding Washington); walnuts; non-bearing crops | 21 | 2 | Jojoba | 21 | 1 | Citrus (orange, grapefruit, lemons) | 28 | 2 | Ornamentals, Christmas Trees and Conifers | 28 (west of Rocky Mts.) 7 (east of Rocky Mts.) | 3 | Roses, other ornamentals | 14 | 3 | Potato (Washington); peanuts; mint | 14 | 2 | |
| Crop | Minimum Spray Interval (Days) | Total Number of Sprays per year | | | | | | | | | | | | | | | | | | | | | |
| Almonds; beans (dry); cotton; grapes; hops; nectarines; potatoes (excluding Washington); walnuts; non-bearing crops | 21 | 2 | | | | | | | | | | | | | | | | | | | | | |
| Jojoba | 21 | 1 | | | | | | | | | | | | | | | | | | | | | |
| Citrus (orange, grapefruit, lemons) | 28 | 2 | | | | | | | | | | | | | | | | | | | | | |
| Ornamentals, Christmas Trees and Conifers | 28 (west of Rocky Mts.) 7 (east of Rocky Mts.) | 3 | | | | | | | | | | | | | | | | | | | | | |
| Roses, other ornamentals | 14 | 3 | | | | | | | | | | | | | | | | | | | | | |
| Potato (Washington); peanuts; mint | 14 | 2 | | | | | | | | | | | | | | | | | | | | | |

| Description | Required Labeling | Placement on Label |
|--------------------------|--|--------------------|
| Spray Drift Restrictions | <p>The following spray drift statement is required.</p> <p>Do not apply by ground within 50 ft. or by air within 75 ft. of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds; estuaries and commercial fish farm ponds.</p> <p>The following statements or equivalent statements required by the proposed spray drift PR Notice are required:</p> <p>Do not allow this product to drift off target site.</p> <p>Do not apply by ground within 50 ft. or by air within 75 ft. of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds; estuaries and commercial fish farm ponds.</p> <p>For ground applications apply the coarsest droplet size spectrum that provides sufficient coverage and mite control. Use the lowest nozzle height that provides uniform coverage. Apply only when wind speeds are 10 mph or less when measured by an anemometer outside the spray area on the upwind side.</p> <p>For aerial applications apply the coarsest droplet size spectrum that provides sufficient coverage and mite control. Apply from the lowest possible height that provides good pest control and flight safety. Use the shortest boom length that is practical. Apply only when wind speeds are 10 mph or less when measured by an anemometer outside the orchard/vineyard on the upwind side.</p> <p>Risk of exposure to sensitive aquatic areas can be reduced by making applications when the wind direction is away from the aquatic area.</p> <p>Do not make aerial or ground applications during temperature inversions.</p> | |

| Description | Required Labeling | Placement on Label |
|---------------------|---|--------------------|
| Runoff Restrictions | <p>Under some conditions, propargite may have a high potential for runoff into surface water for several days after application. Do not apply in the following areas:</p> <ul style="list-style-type: none"> -- frequently flooded areas (excluding artificially flooded areas). -- areas where intense or sustained rainfall is forecasted to occur within 48 hours. <p>Use best management practices for minimizing surface runoff in the following areas:</p> <ul style="list-style-type: none"> -- poorly draining or wet soils with readily visible slopes toward adjacent surface water. -- areas with in-field canals or ditches that drain to surface water. -- areas not separated from adjacent surface waters with vegetated filter | |

¹PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.

Instructions in the Labeling Required section not in quotes represent actions that the registrant must take to amend their labels or product registrations.

VI. Related Documents and How To Access Them

This Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP 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.

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/reregistration/propargite

Appendix A: Propargite Use Patterns Eligible for Reregistration

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|-------------------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|---|
| Food/Feed Crop Uses | | | | | | | | |
| Almond | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 3.2 lb/A | 2 | Not specified (NS) | 21 | 28 | 22 days | Use limited to AZ and CA. Applications may be made in a minimum of 50 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among trees is prohibited. |
| Broadcast foliar Ground and aerial | 6 lb/gal EC | 3 lb/A | 2 | NS | 21 | 28 | 22 days | Use limited to AZ and CA. Applications may be made in a minimum of 50 gal of finished spray/A by ground and 15 gal of finished spray/A by air. The grazing or feeding livestock on cover crops grown among the trees is prohibited. |
| Bean, dry (including dry lima beans) | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC | 2.46 lb/A | 2 | 3.7 lbs. ai/A | 21 | 14 | 9 days | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 20 gal of finished spray/A by ground and 5 gal of finished spray/A by air. |
| | 6 lb/gal EC | 2.53 lb/A | 2 | 4.5 lbs. ai/A | 21 | 14 | 9 days | |
| Bean (interplanted with nonbearing almonds and walnuts) | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | 2 | 3.37 lbs. ai/A | 21 | 14 | 9 days | Use limited to CA. Applications may be made in a minimum of 20 gal of water/A by ground and 5 gal of water/A by air. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|----------------------|---|--|---------------------------------|--|-----------------------------------|-------------------------------|---|
| Cherry | | | | | | | | |
| Foliar application after fruit harvest Ground | 32% WP (WSP) | 1.92 lb/A | NS | NS | 21 | Not applicable (NA) | 2 days | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the tree and vines is prohibited. |
| Corn (unspecified) | | | | | | | | |
| Broadcast foliar Ground and aerial | 6 lb/gal EC [SLN] | 1.69 lb/A | 2 | NS | NS | 30 | 13 days | Use limited to KS. Split applications may be made in a minimum of 20 gal of water/A by ground and 5 gal of water/A by air with a 3-4 week retreatment interval. The grazing or feeding of livestock on treated areas is prohibited. |
| Directed band spray Ground Early plant | 6 lb/gal EC [SLN] | 1.13 lb/A (directed spray) followed by: 1.69 lb/A (broadcast spray) | 2 | 2.53 lb/A | NS | 30 | 13 days | Use limited to NM. Split applications may be made in 10 gal of finished spray/A by ground during early season followed by an aerial application in a minimum of 5 gal of water/A during mid or late season. The grazing or feeding of livestock on treated areas is prohibited. |
| followed by: Broadcast foliar Aerial | 6 lb/gal EC [SLN] | 0.84 lb/A (directed spray) followed by: 1.69 lb/A (broadcast spray) | 2 | 2.53 lb/A | NS | 30 | 13 days | Use limited to TX. Split applications may be made in 10 gal of finished spray/A by ground during early season followed by an aerial application in a minimum of 5 gal of water/A during mid or late season. The grazing or cutting for silage within 30 days after treatment is prohibited. |
| Chemigation Overhead irrigation | 6 lb/gal EC [SLN] | 2.53 lb/A | 1 | NS | NS | 30 | 13 days | Use limited to TX. The grazing or cutting for silage of treated corn within 30 days is prohibited. |

| Site | Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--------------------|---|----------------------|-------------------------------------|---|---------------------------|-------------------------------|-----------------------------|-------------------------|---|
| Corn, field | | | | | | | | | |
| | Broadcast foliar Ground and aerial | 6 lb/gal EC | 1.5 lb/A | 1 | NS | NS | 56 | 13 days | Use limited to CA. Applications may be made in 20-50 gal of finished spray/A by ground and in a minimum of 10 gal of finished spray/A by air. |
| | Broadcast foliar Ground and aerial | 6.55 lb/gal EC | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | Applications may be made in a minimum of 20 gal of finished spray/A by ground and in KS and CO applications may be made in a minimum of 2 gal of finished 6 lb/gal EC 2.53 lb/A1NSNS3013 daysApplications may be made in a minimum of 20 gal of finished spray/A by ground and in KS and CO applications may be made in a minimum of 2 gal of finished spray/A by air and in TX and NM and other states, applications may be made in a minimum of 5 gal of finished spray/A by air. |
| | | 6.55 lb/gal EC [SLN] | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | Use limited to CA. Applications may be made in a minimum of 20 gal of finished spray/A by ground or 10 gal of finished spray/A by air. The grazing or feeding of livestock on treated areas is prohibited. |
| Corn, pop | | | | | | | | | |
| | Broadcast foliar | 6.55 lb/gal EC | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | See "Corn, field". |
| | Ground and aerial | 6 lb/gal EC | 2.53 lb/A | 1 | NS | NS | 30 | 13 days | See "Corn, field". |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|---|-------------------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|---|
| Corn, sweet | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | Use limited to CA. Applications may be made in a minimum of 20 gal of finished spray/A by ground and in 2 gal of finished spray/A by air. |
| Broadcast foliar or chemigation Ground, aerial, and overhead irrigation | 6.55 lb/gal EC [SLN] | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | Use limited to AZ, ID, OR, and WA. Applications may be made in a minimum of 20 gal of water/A by ground and in 10 gal of water/A by air. |
| Broadcast foliar Ground and aerial | 6 lb/gal EC [SLN] | 1.69 lb/A | 2 | NS | NS | 30 | 13 days | Use limited to CO. Split applications may be made in a minimum of 20 gal of water/A by ground and 5 gal of water/A by air with a 3-4 week retreatment interval. The grazing or cutting for silage of treated corn within 30 days is prohibited. |
| Broadcast foliar Aerial | 6 lb/gal EC [SLN] | 1.69 lb/A | NS | NS | NS | 30 | 13 days | Use limited to CO. Applications may be made in a minimum of 5 gal of water/A by air. The grazing or feeding livestock on treated areas is prohibited. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|----------------------|--|--|---------------------------------|--|---|---|---|
| Cotton | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC | 0.8-1.64 lb/A | 2 | 3.3 lbs ai/A | 21 | 50 | 6 days | Use limited to regions east of the Rocky Mountains. Use of the 6.55 lb/gal EC formulation also limited to AZ and CA. Applications may be made early season, midseason, and at layby to boll opening. Applications may be made in a minimum of 15-25 gal of finished spray/A by ground and in a minimum of 5 gal of finished spray/A by air. The feeding of treated foliage or cotton trash to livestock and application after bolls have opened are prohibited. |
| | 6 lb/gal EC | 0.94-1.69 lb/A | 2 | 3.3 lbs. ai/A | 21 | 50 | 6 days | |
| | 6.55 lb/gal EC [SLN] | 1.64 lb/A | 2 | 3.3 lbs. ai/A | 21 | 50 | 6 days | |
| ULV application Aerial | 6.55 lb/gal EC [SLN] | 1.64 lb/A | 3 | NS | 21 | 50 for AR830015 NS for MS830024 and TX830028 | 6 days | Use limited to AR, MS, and TX. Applications may be made midseason to layby and at layby to boll opening. ULV applications may be made in 2-3 qt of vegetable oil/A by air. Application after bolls have opened is prohibited. |
| Grape | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 2.88 lb/A | 2 | NS | NS | 21 | 27 days for Grapes (table) turning cane 16 days for al other Grapes | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 40 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the vines is prohibited. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|-----------------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|--|
| Grapefruit | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 3.36 lb/A | 2 | 5.8 lbs ai/A | 28 | 7 | 20 days | Use limited to CA. Applications may be made in 1,000 gal/A using ground equipment with a 42-day retreatment interval. The grazing or feeding of livestock on cover crops grown among the trees is prohibited. |
| Broadcast foliar Ground or aerial | 6.55 lb/gal EC | 2.46 lb/A | 2 | 4.1 lbs. ai/A | 28 | 21 | 20 days | Use limited to FL and TX. Applications may be made in a minimum of 25 gal of finished spray/A by ground and 10 gal of finished spray/A by air. |
| Broadcast foliar Ground | 32% WP (WSP) [SLN] | 3.2 lb/A | 2 | 5.8 lbs. ai/A | 28 | NS | 20 days | Use limited to CA. Applications may be made from October 1 to petal fall in a minimum of 200 gal of water/A by ground with a 21-day retreatment interval. |
| Foliar application after fruit harvest Ground | 32% WP (WSP) | 3.36 lb/A | 1 | NS | 28 | NA | 20 days | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 100 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the trees is prohibited. |
| Hops | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 1.6 lb/A | 2 | NS | 21 | 14 | 21 days | Use prohibited in CA. Applications may be made in a minimum of 200 gal of finished spray/A by ground. The grazing or feeding of livestock on cover crops is prohibited. |
| | 6 lb/gal EC | 1.5 lb/A | 2 | NS | 21 | 14 | 21 days | Applications may be made in a minimum of 200 gal of finished spray/A by ground. |
| | 32% WP (WSP) [SLN] | 1.92 lb/A | 3 | NS | 21 | 14 | 30 days | Use limited to ID. Applications may be made in 100-200 gal of water/A by ground. |
| | 32% WP (WSP) [SLN] | 2.4 lb/A | 3 | NS | 21 | 14 | 30 days | Use limited to OR and WA. Applications may be made in 100-200 gal of water/A by ground. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|-------------------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|--|
| Jojoba | | | | | | | | |
| Broadcast foliar Ground or aerial | 6.55 lb/gal EC | 1.64 lb/A | 1 | NS | 21 | NS | 2 days | Applications may be made in a minimum of 20 gal of finished spray/A by ground or 5 gal of finished spray/A by air with a 10-day retreatment interval. |
| Lemon | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 3.36 lb/A | 2 | 5.8 lbs. ai/A | 28 | 7 | 20 days | See "Grapefruit". |
| | 32% WP (WSP) | 3.2 lb/A | 2 | 5.8 lbs. ai/A | 28 | 7 | 20 days | Use limited to AZ. Applications may be made in 600-1,500 gal/A using ground equipment. The grazing or feeding livestock on cover crops grown among the trees is prohibited. |
| Mint | | | | | | | | |
| Broadcast foliar Ground | 6 lb/gal EC | 2.25 lb/A | 2 | 4.5 lbs. ai/A | 21 | 7 | 7days | Applications may be made in 20-50 gal of finished spray/A by ground. |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 2.05 lb/A | 2 | NS | 21 | 7 | 7 days | Use limited to ID, MT, NV, OR, UT, and WA. |
| Nectarine | | | | | | | | |
| Broadcast foliar Ground or aerial | 32% WP (WSP) | 2.88 lb/A | 2 | NS | 21 | 14 | 5 days | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 50 gal of finished spray/A by ground or 20 gal of finished spray/A by air. The grazing or feeding livestock on cover crops is prohibited. |

| Site | Application Type | Application Timing | Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|---------------|--|--------------------|-----------------------|----------------------|-------------------------------------|---|---------------------------|-------------------------------|-----------------------------|-------------------------|---|
| Orange | | | | | | | | | | | |
| | Broadcast foliar | | | 32% WP (WSP) | 3.36 lb/A | 2 | 5.8 lbs. ai/A | 28 | 7 | 20 days | See "Grapefruit". |
| | Ground | | | | | | | | | | |
| | Broadcast foliar | | | 6.55 lb/gal EC | 2.46 lb/A | 2 | 4.1 lbs. ai/A | 28 | 21 | 20 days | Use limited to FL and TX. Applications may be made in a minimum of 25 gal of finished spray/A by ground and 10 gal of finished spray/A by air. |
| | Ground or aerial | | | | | | | | | | |
| | Broadcast foliar | | | 32% WP (WSP) [SLN] | 3.2 lb/A | 2 | 5.8 lbs. ai/A | 28 | NS | 20 days | Use limited to CA. Applications may be made from October 1 to petal fall in a minimum of 200 gal of water/A by ground with a 21-day retreatment interval. |
| | Ground | | | | | | | | | | |
| | Foliar application after fruit harvest | | | 32% WP (WSP) | 3.36 lb/A | 1 | NS | 28 | NA | 20 days | Use limited to regions west of the Rocky Mountains. Applications may be made in a minimum of 100 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops is prohibited. |
| | Ground | | | | | | | | | | |
| Peanut | | | | | | | | | | | |
| | Broadcast foliar | | | 32% WP (WSP) | 1.6 lb/A | 2 | NS | 14 | 14 | 2 days | Applications may be made in a minimum of 20 gal of finished spray/A by ground. |
| | Ground | | | | | | | | | | |
| | Broadcast foliar Ground or aerial | | | 6.55 lb/gal EC | 1.64 lb/A | 1 | NS | 14 | 14 | 2 days | Applications may be made in a minimum of 20 gal of finished spray/A by ground or 5 gal of finished spray/A by air. The grazing or feeding of livestock on treated areas or cutting treated forage for hay is prohibited. |
| | | | | 6 lb/gal EC | 1.69 lb/A | 1 | NS | 14 | 14 | 2 days | |
| | | | | 6.55 lb/gal EC [SLN] | 1.64 lb/A | 2 | NS | 14 | 14 | 2 days | Use limited to AL, GA, NC, SC, and VA. Applications may be made in a minimum of 20 gal of finished spray/A by ground or 5 gal of finished spray/A by air. The feeding of hay from treated peanuts to livestock is prohibited. |

| Site | Application Type | Application Timing | Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|----------------|----------------------------------|--------------------|-----------------------|----------------------|-------------------------------------|---|---------------------------|-------------------------------|-----------------------------|-------------------------|---|
| Potato | | | | | | | | | | | |
| | Broadcast foliar | | | 6 lb/gal EC | 2.25 lb/A | 2 | 4.1 lbs. ai/A | 21 (14 for WA) | 14 | 2 days | Use limited to Pacific Northwest only. Applications may be made in 20-50 gal of finished spray/A by ground and a minimum of 10 gal of finished spray/A by air. |
| | Broadcast foliar | | | 6.55 lb/gal EC | 2.05 lb/A | 2 | 3.7 lbs. ai/A | 21 (14 for WA) | 14 | 2 days | Use limited to Pacific Northwest only. Applications may be made in 20-50 gal of finished spray/A by ground and a minimum of 10 gal of finished spray/A by air. |
| | Ground or aerial | | | 6 lb/gal EC | 2.06 lb/A | 2 | 4.1 lbs. ai/A | 21 (14 for WA) | 14 | 2 days | |
| | Chemigation Sprinkler irrigation | | | 6.55 lb/gal EC [SLN] | 2.05 lb/A | 2 | 3.7 lbs. ai/A | 21 (14 for WA) | 14 | 2 days | Use limited to OR and WA. |
| Sorghum | | | | | | | | | | | |
| | Broadcast foliar | | | 6.55 lb/gal EC | 1.64 lb/A | 1 | NS | NS | 30 (silage) | 2 days | Use limited to regions east of the Rocky Mountains. Applications may be made in a minimum of 20 gal of finished spray/A by ground and 5 gal of finished spray/A by air. |
| | Ground or aerial | | | 6 lb/gal EC] | 1.69 lb/A | 1 | NS | NS | 60 (grain) | 2 days | |
| | Broadcast foliar | | | 6.55 lb/gal EC [SLN] | 1.64 lb/A | NS | NS | NS | 30 (silage) | 2 days | Use limited to AZ. Applications may be made in a minimum of 10 gal of finished spray/A by air. |
| | Aerial | | | 6.55 lb/gal EC [SLN] | 1.64 lb/A | NS | NS | NS | 60 (grain) | 2 days | Use limited to CA. Applications may be made in a minimum of 10 gal of finished spray/A by air. |

| Site | Application Type | Application Timing | Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|---------------------------------------|----------------------|--------------------|-----------------------|---------------|-------------------------------------|---|-----------------------------------|---|-----------------------------|-------------------------|---|
| Walnut | | | | | | | | | | | |
| Broadcast foliar Ground or aerial | 6 lb/gal EC | 4.5 lb/A | 2 | 6.8 lbs ai/A | 21 | 21 | 30 days (21days for tree shaking) | Applications may be made in a minimum of 100 gal of finished spray/A by ground or 20 gal of finished spray/A by air. The grazing or feeding livestock on cover crops is prohibited. | | | |
| | 32% WP (WSP) | 4 lb/A | 2 | 6.4 lbs. ai/A | 21 | 21 | 30 days (21days for tree shaking) | Use limited to CA. Applications may be made in a minimum of 100 gal of finished spray/A by ground or 10 gal of finished spray/A by air. The grazing or feeding livestock on cover crops is prohibited. | | | |
| Crops Grown for Seed | | | | | | | | | | | |
| Alfalfa | | | | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | NS | NS | NS | NS | 9 days | Use limited CA, ID, MT, NV, OR, UT, WA, and WY for alfalfa grown for seed. Applications may be made in 25-40 gal of water/A by ground and in a minimum of 10 gal of water/A by air. The feeding of treated foliage, alfalfa trash or seed screenings to livestock and the grazing of treated fields are prohibited (for SLN Nos. CA830024, MT890010, and UT790015). The cutting of the current years treated alfalfa seed crop for hay or forage, the grazing the current years treated alfalfa seed crop, and the sprouting of treated alfalfa seed are prohibited (for SLN Nos. ID960016, NV880007, WA890020, and WY960001). The feeding or grazing of treated alfalfa, the cutting of treated alfalfa for hay or for forage, and the use of harvested seed for sprouting are prohibited (for SLN No. OR9400012). | | | |
| | 6.55 lb/gal EC [SLN] | 2.05 lb/A | NS | NS | NS | NS | 9 days | | | | |
| | 6.55 lb/gal EC [SLN] | 1.64 lb/A | NS | NS | NS | NS | 9 days | | | | |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|-------------------------|--|--|---------------------------------|--|-----------------------------------|---|---|
| Beet, sugar | | | | | | | | |
| Broadcast foliar Aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | 2 | NS | NS | 21 | 2 days | Use limited to OR for sugar beets grown for seed. Applications may be made in a minimum of 10 gal of finished spray/A by air. The feeding of treated sugar beet tops to livestock is prohibited. |
| Carrot | | | | | | | | |
| Broadcast foliar Aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | NS | NS | NS | NS | 2 days Hand Harvesting prohibited for 13 days | Use limited to ID, OR, and WA for carrots grown for seed. Applications may be made in minimum of 10 gal of water/A by air. |
| Clover | | | | | | | | |
| Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | NS | NS | NS | NS | 9 days | Use limited to ID, OR, and WA for clover grown for seed. Applications may be made in 25-40 gal of water/A by ground and in a minimum of 10 gal of water/A by air. The feeding of treated foliage, clover trash, or seed screenings to livestock and the grazing of treated fields are prohibited. |

| Site | Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|---------------------------|---|----------------------|---|---|---------------------------|-------------------------------|-----------------------------|-------------------------|---|
| Corn (unspecified) | | | | | | | | | |
| | Directed band spray Ground Early plant | 6 lb/gal EC [SLN] | 1.13 lb/A (directed spray) followed by: 1.69 lb/A (broadcast spray) | 2 | 2.53 lb/A | NS | 30 | 13 days | Use limited to NM for corn grown for seed. Split applications may be made in 10 gal of finished spray/A by ground during early season followed by an aerial application in a minimum of 5 gal of water/A during mid or late season. The grazing or feeding of livestock on treated areas is prohibited. |
| | followed by: Broadcast foliar Aerial | 6 lb/gal EC [SLN] | 0.84 lb/A (directed spray) followed by: 1.69 lb/A (broadcast spray) | 2 | 2.53 lb/A | NS | 30 | 13 days | Use limited to TX for corn grown for seed. Split applications may be made in 10 gal of finished spray/A by ground during early season followed by an aerial application in a minimum of 5 gal of water/A during mid or late season. The grazing or cutting for silage within 30 days after treatment is prohibited. |
| Corn, sweet | | | | | | | | | |
| | Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 2.46 lb/A | 1 | NS | NS | 30 | 13 days | Use limited to OR and WA for sweet corn grown for seed. |
| | Broadcast foliar Aerial | 6 lb/gal EC [SLN] | 1.69 lb/A | NS | NS | NS | 30 | 13 days | Use limited to CO for sweet corn grown for seed. Applications may be made in a minimum of 5 gal of water/A by air. The grazing or feeding livestock on treated areas is prohibited. |
| | Broadcast foliar Ground and aerial | 6.55 lb/gal EC [SLN] | 1.64 lb/A | NS | NS | NS | NS | 13 days | Use limited to ID for sweet corn grown for seed. Applications may be made in a minimum of 20 gal of water/A by ground and 10 gal of water/A by air. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|-----------------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|--|
| Nonbearing Crops | | | | | | | | |
| Almond (interplanted with beans) | | | | | | | | |
| Broadcast foliar Ground and aerial | 32% WP (WSP) [SLN] | 2.46 lb/A | 2 | NS | 21 | NA | 9 days | For use on nonbearing almonds interplanted with beans. Use limited to CA. Applications may be made in a minimum of 20 gal of water/A by ground and 5 gal of water by air. |
| Avocado | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) [SLN] | 4.8 lb/A | 2 | NS | 21 | NA | 11 days | Use limited to CA. Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in a minimum of 100 gal of water/A by ground. |
| Berries (boysenberry, raspberry, strawberries, etc.) | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 1.92 lb/A | 2 | NS | 21 | NA | 10 days | Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the tree and vines is prohibited. |
| | 6 lb/gal EC | 1.5 lb/A | 2 | NS | 21 | NA | 10 days | |
| | 32% WP (WSP) | 1.92 lb/A | NS | NS | 21 | NA | 10 days | Use prohibited in CA. Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops prohibited. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|--|--------------|--|--|---------------------------------|--|-----------------------------------|-------------------------------|--|
| Citrus (including grapefruit, lemon, lime orange, tangerine, etc.) | | | | | | | | |
| Broadcast foliar Ground and aerial | 32% WP (WSP) | 1.92 lb/A | 2 | NS | 21 | NA | 16 days | Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the tree and vines is prohibited. |
| | 6 lb/gal EC | 1.5 lb/A | 2 | NS | 21 | NA | 16 days | |
| | 32% WP (WSP) | 1.92 lb/A | NS | NS | 21 | NA | 16 days | Use prohibited in CA. Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops prohibited. |
| Currant, Date, Figs, Persimmon, pome fruits (apples, pears, and quince), Stone fruits (apricot, cherry, nectarine, peach, and plum/prune) | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 1.92 lb/A | 2 | NS | 21 | NA | 2 days | Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the tree and vines is prohibited. |
| | 6 lb/gal EC | 1.5 lb/A | 2 | NS | 21 | NA | 2 days | |
| | 32% WP (WSP) | 1.92 lb/A | NS | NS | 21 | NA | 2 days | Use prohibited in CA. Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops prohibited. |

| Site Application Type Application Timing Application Equipment | Formulation | Maximum Single Application Rate, ai | Maximum Number of Applications Per Season | Maximum Seasonal Rate, ai | Minimum Spray Interval (days) | Preharvest Interval, (days) | Reentry Interval (days) | Use Directions and Limitations ¹ |
|---|--------------------|-------------------------------------|---|---------------------------|-------------------------------|-----------------------------|-------------------------|--|
| Nut trees (almond, hazelnut, macadamia, pecan, pistachio, and walnut) | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) | 1.92 lb/A | 2 | NS | 21 | NA | 22 days | Use is restricted to crops which will not bear fruit within one year of application. Applications may be made in 50-400 gal of finished spray/A by ground. The grazing or feeding livestock on cover crops grown among the tree and vines is prohibited. |
| | 6 lb/gal EC | 1.5 lb/A | 2 | NS | 21 | NA | 22 days | |
| | | 32% WP (WSP) | 1.92 lb/A | NS | NS | 21 | NA | 22 days |
| Walnuts (interplanted with beans) | | | | | | | | |
| Broadcast foliar Ground | 32% WP (WSP) [SLN] | 2.46 lb/A | 2 | NS | 21 | NA | 9 days | For use on nonbearing walnuts interplanted with beans. Use limited to CA. Applications may be made in a minimum of 20 gal of water/A by ground and 5 gal of water by air. |
| Ornamental Crops | | | | | | | | |
| Ornamental Plants | | | | | | | | |
| Broadcast foliar Ground and aerial | 32% WP (WSP) | 2.5 lb/a max | | | | | | |

¹ The following rotational crop restrictions are specified on the labels for EPA Reg. Nos. 400-82, 400-89, 400-426, and 400-427: (i) planting leafy vegetables in rotation within 2 months after last application of propargite to cotton and corn; and (ii) planting any other food or feed crop in rotation within 6 months after last application of propargite unless the crop is a registered use for propargite.

The following rotational crop restrictions are specified on the labels for EPA Reg. Nos. 400-104 and 400-154: (i) planting leafy vegetables in rotation within 2 months after last application of propargite to cotton and corn; (ii) planting small grains in rotation within 82 days after last application of propargite to cotton and corn; (iii) planting any other food or feed crop in rotation within 6 months after last application of propargite unless the crop is a registered use for propargite.

The following rotational crop restriction is specified on the label for EPA Reg. No. 400-425: planting any food or feed crop in rotation within 6 months after last application of propargite unless the crop is a registered use for propargite.

The following rotational crop restriction is specified on the label for SLN No. CA920011: planting small grains in rotation within 60 days after last application of propargite.

NS = Not Specified

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Propargite

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|----------------------------------|----------------------|--|-------------|------------------------------|
| <u>PRODUCT CHEMISTRY</u> | | | | |
| New Guideline Number | Old Guideline Number | | | |
| 830.7050 | None | UV/Visable Absorption | ABC | Data Gap |
| <u>ECOLOGICAL EFFECTS</u> | | | | |
| 850.2100 | 71-1 | Avian Acute Oral Toxicity | ABC | 00052455 |
| 850.2200 | 71-2A | Avian Dietary Toxicity - Quail | ABC | 00113471 |
| 850.2200 | 71-2B | Avian Dietary Toxicity - Duck | ABC | 00052454 |
| 850.2300 | 71-4A | Avian Reproduction - Quail | ABC | 4104702 |
| 850.2300 | 71-4B | Avian Reproduction - Duck | ABC | 41041701 |
| 850.1075 | 72-1A | Fish Toxicity Bluegill | ABC | 00112368 |
| 850.1075 | 72-1D | Fish Acute Toxicity Test, Rainbow Trout (for typical end-use products) | ABC | 43759001 |
| 850.1010 | 72-2B | Invertebrate Toxicity - TEP | ABC | 43759002 |
| None | 72-3A | Estuarine/Marine Toxicity - Fish | ABC | 40514001 |
| None | 72-3B | Estuarine/Marine Toxicity - Mollusk | ABC | 00112395 |
| None | 72-3C | Estuarine/Marine Toxicity - Shrimp | ABC | 40431601 |
| None | 72-4A | Fish- Early Life Stage | ABC | 00126739 |
| None | 72-4B | Estuarine/Marine Invertebrate Life Cycle | ABC | 00126739 |
| 850.1400 | 72-4C | Early-life Stage Freshwater Fish | ABC | 001267389 |
| 850.1450 | 72-4D | Early-life Stage Estuarine Fish | ABC | Data Gap |
| 850.1500 | 72-5 | Fish Life Cycle Study | ABC | Data Gap |
| 850.3020 | 141-1 | Honey Bee Acute Contact Toxicity | ABC | 43185001 |
| 850.3030 | 141-2 | Honey Bee Toxicity of Residues on Foliage | ABC | Data Gap |
| <u>TOXICOLOGY</u> | | | | |
| 870.1100 | 81-1 | Acute Oral Toxicity-Rat | ABC | 42857001 |
| 870.3800 | 83-4 | 2-Generation Reproduction - Rat | ABC | 41325401 |
| 870.5140 | 84-2A | Gene Mutation (Ames Test) | ABC | 42885001, 42815201, 43502202 |
| 870.5375 | 84-2B | Structural Chromosomal Aberration | ABC | 40384603 |
| None | 84-4 | Other Genotoxic Effects | ABC | 40384602 |
| 850.4230 | 123-1 | Terrestrial Plant Testing | ABC | 43848801, 43848802 |
| 850.4400 | 123-2 | Aquatic Plant Acute Toxicity | ABC | 43448803, 43848807, 43414542 |

Data Supporting Guideline Requirements for the Reregistration of Propargite

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|----------------------------------|--------|---|-------------|--|
| <u>ENVIRONMENTAL FATE</u> | | | | |
| 835.2120 | 161-1 | Hydrolysis | ABC | 40358401 |
| 835.2240 | 161-2 | Photodegradation - Water | ABC | 40358402 |
| 835.2410 | 161-3 | Photodegradation - Soil | ABC | 40358402, 42319301, 42319307 |
| 835.2370 | 161-4 | Photodegradation - Air | ABC | Data Gap |
| 835.4100 | 162-1 | Aerobic Soil Metabolism | ABC | 41003601, 42786301, 43851401 |
| 835.4200 | 162-2 | Anaerobic Soil Metabolism | ABC | 41003602 |
| 835.4400 | 162-3 | Anaerobic Aquatic Metabolism | ABC | 42688801 |
| 835.1240 | 163-1 | Leaching/Adsorption/Desorption | ABC | 40431602, 41449202, 41449203, 41449204, 41449205, 41449206, 41449207, 42908401, 42908402 |
| 835.1410 | 163-2 | Laboratory Volatilization (from Soil) Study | ABC | Data Gap |
| None | 163-3 | Volatility lab | ABC | Data Gap |
| 835.6100 | 164-1 | Terrestrial Field Dissipation | ABC | 40969501, 41307301, 41325901, 41432501, 41731501, 41966001, 41966002 |
| 835.6200 | 164-2 | Aquatic Sediment Field Dissipation Study | ABC | Data Gap |
| 835.6400 | 164-4 | Combination Products and Tank Mixes Dissipation Study | ABC | Data Gap |
| None | 165-4 | Bioaccumulation in Fish | ABC | 40494001, 40916601 |
| None | 167-2 | Surface Water Monitoring | ABC | Data Gap |
| <u>RESIDUE CHEMISTRY</u> | | | | |
| 860.1300 | 171-4A | Nature of Residue - Plants | ABC | 00025749, 00029103, 00130618, 41006002, 41570701, 43738201, 41006001, 41117001, 42943601, 44730701 |
| 860.1300 | 171-4A | Nature of Residue - Plants - Plant Metabolism | ABC | 0025749, 41570701, 41117001, 00130618, 41006001, 41006002 |
| 860.1360 | 171-4M | Multi residue Method Testing | ABC | Data Gap |
| 860.1380 | 171-4E | Storage Stability | ABC | Data Gap |
| 860.1500 | 171-4K | Crop Field Trials | ABC | |
| | | Potato | | 00112347, 00112361, 42223502 |
| | | Dry beans | | 00064067, 41848602 |
| | | Bean succulent | | 00038033, 00064067 |

Data Supporting Guideline Requirements for the Reregistration of Propargite

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|-------------|--------|----------------------------|-------------|--|
| 860.1500 | 171-4K | Crop Field Trials | ABC | |
| | | Apples | | 00112384, 40615504, 42223501, 43602601 |
| | | Pears | | 00112345 |
| | | Grapefruit | | 00112347, 00112361, 00112397, 40615508 |
| | | Lemon | | 00112360, 00112408, 40615507 |
| | | Orange | | 00069174, 00112347, 00112360, 00112397, 40615506, 43695901 |
| | | Apricot | | 00112358, 44127202 |
| | | Nectarine | | 00112358, 40615509 |
| | | Peach | | 00112344, 00112345, 40615510, 44127201 |
| | | Plum | | 00067553, 00112345, 40615511, 44127204 |
| | | Almonds, nutmeat, and hull | | 00080225, 44698601, 40615503, 00112342, 00112355 |
| | | Walnuts | | 00112339, 00112345, 00138427 |
| 860.1500 | 171-4K | Crop Field Trials | ABC | |
| | | Corn, field/grain | | 00044638, 00079227, 00086708, 00112361, 00112401, 42005701, 44285701, 44285702, 40615512, 41197101, 41389001 |
| | | Corn, Sweet | | 00043251 |
| | | Sorghum, grain | | 00038032, 00038036, 42644401, 43847901, 40615513, 41831601 |
| | | Corn, forage and stover | | 00044638, 00079227, 00086708, 00112361, 00112401, 44285701, 44285702, 40615512 |
| | | Sorghum, forage an stover | | 00038032, 00038036 |
| | | Cranberry | | 00112400 |
| | | Fig | | 00037396 |
| | | Mint | | 00112361, 00138428 |
| | | Grape | | 00006678, 00048326, 00112345, 00112405, 40615501 |

Data Supporting Guideline Requirements for the Reregistration of Propargite

| REQUIREMENT | | | USE PATTERN | CITATION(S) |
|---------------------|--------|---|-------------|--|
| 860.1500 | 171-4K | Crop Field Trials | ABC | |
| | | Hops | | 00112355, 00112358, 00112398, 41848601, 41942401 |
| | | Peanut, nutmeat, and hay | | 00038650, 00044291, 00047994 |
| | | Strawberry | | 00112336, 00112355, 00112358, 44127203 |
| | | Tea | | PP#6H5100, 43905901, 44039201, 4472201 |
| 860.1520 | 171-4L | Magnitude of Residue in Processed Food/Feed | ABC | |
| | | Citrus | | 40615506 |
| | | Citrus | | 43802201 |
| | | Corn, field | | 43802201 |
| | | Fig | | 00037396 |
| | | Cottonseed | | 00030794, 00094938, 00112363, 00131893, 40615515 |
| | | Cotton gin | | Data Gap |
| | | Grape | | 00006678, 00112355, 43260801, 44861301, 40615501 |
| | | Hops | | 00112355, 00112358, 00112398, 41848601, 41942401 |
| | | Mint | | 00112361, 00138428 |
| | | Peanut | | 00038650, 43804001 |
| | | Plum | | 000112345, 43348701 |
| 860.1480 | 171-4J | Magnitude of Residue in Meat, Milk, Poultry, and Eggs | ABC | |
| | | Milk and the fat, meat, and meat byproducts of cattle goats, hog horses and sheep | | 00112360, 41862302, 41862304, 42011901 |
| | | Eggs and fat, meat, and meat byproducts of poultry | | 41862303, 41862304, 42011901 |
| 860.1850 | 165-1 | Confine/Field Accumulation in Rotational Crops | ABC | 43345501, 43799001, 44013801 |
| 860.1900 | 165-2 | Field Rotational Crops | ABC | 42846001, 42846002, 43345501 |
| <u>OTHER</u> | | | | |
| 840.1100 | 201-1 | Spray Droplet Size Spectrum | ABC | Data Gap |
| 840.1200 | 202-1 | Spay Drift Field Evaluation | ABC | Data Gap |

Appendix C: Technical Support Documents

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

The docket initially contained the risk assessments and related documents as of August 28, 2000. The Agency considered comments on the revised risk assessments and added the formal “Response to Comments” documents to the docket. 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/reregistration/propargite

Appendix D: Citations Considered To Be Part Of The Database Supporting the Interim Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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| 00030794 | Uniroyal Chemical (1973) Summary. (Unpublished study received June 16, 1980 under 400-104; prepared in cooperation with Morse Laboratories, Inc.; CDL:242671-A) |
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Appendix E: Generic Data Call-In

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

Appendix F: Product-Specific Data Call-In

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

Appendix G: EPA Batching of End Use Products for Meeting 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 propargite as the primary 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.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should 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 to-days standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, 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 Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Nine products were found which contain propargite as the active ingredient. These products have been placed into one batch and a “No Batch” category in accordance with the active and inert ingredients and type of formulation.

| Batch 1 | EPA Reg. No. | Percent active ingredient | Formulation Type |
|---------|--------------|---------------------------|------------------|
| | 400-82 | 32.0 | Solid |
| | 400-425 | 32.0 | Solid |
| | 400-426 | 32.0 | Solid |
| | 400-427 | 32.0 | Solid |

| No Batch | EPA Reg. No. | Percent active ingredient | Formulation Type |
|----------|--------------|---------------------------|------------------|
| | 400-89 | 69.2 | Liquid |
| | 400-185 | 69.2 | Liquid |
| | 400-83 | 57.0 | Liquid |
| | 400-95 | 90.6 | Liquid |
| | 400-104 | 73.6 | Liquid |

Appendix H: List of Registrants Sent this Data Call-In

Insert CRMS Page of Registrants to Recieve DCI Here

Appendix I: List of Available Documents and Electronically Available Forms

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

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

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

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

| | | |
|---------|---|---|
| 8570-37 | Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf |
|---------|---|---|

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
 - B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - C. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

- f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
- g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

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

Date of receipt
EPA identifying number
Product Manager assignment

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

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind"

codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents may not be available electronically. In cases where the document is not available electronically, contact the person listed on the respective Chemical Status Sheet.

- A. Health and Environmental Effects Science Chapters.
- B. Detailed Label Usage Information System (LUIS) Report.