United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA738-R-02-010
July 2002

# Interim Reregistration Eligibility Decision (IRED)

# DISULFOTON

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-02-009 July 2002

# EPA Disulfoton Facts

EPA has assessed the risks of disulfoton and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted , disulfoton's individual, aggregate risks are within acceptable levels. Disulfoton is also eligible for reregistration, once cumulative risks are considered.

EPA's next step is to consider the cumulative risks of the OP pesticides, which share a common mechanism of toxicity. The interim decision on disulfoton will not be final until these cumulative risks also are considered. Further risk mitigation may be warranted at that time.

Used on a variety of crops, disulfoton residues in food do not pose a risk concern. Drinking water risk estimates suggest concern for potential surface water exposure. However, these are conservative estimates based on screening level models. Because of the conservative nature of these estimates and because of some uncertainties in the water assessment, the Agency believes that drinking water risks are likely to be lower than the current modeled estimates, and not of concern. Therefore, to address the potential concern for drinking water, EPA is requiring confirmatory environmental fate data and surface water monitoring data for disulfoton and its degradates. Disulfoton's residential use as an insecticide for use on ornamental flowers and shrubs, including rose bushes, and outdoor potted plants poses risk concerns to residential handlers for a few scenarios. To address the scenarios of risk concern, the registrant has agreed to the following mitigation measures: limiting maximum application rate, prohibiting application with certain hand held devices, such as belly grinders, changes in packaging, including a requirement for child-resistant packaging, and deletion of certain uses, including all indoor uses and use in home vegetable gardens. With this mitigation limiting exposure through household use, disulfoton fits into its own "risk cup" and does not pose aggregate risk

**The OP Pilot Public Participation Process**

The organophosphates (OPs) are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review in implementing provisions of the Food Quality Protection Act (FQPA) of 1996.

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

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

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides. The Agency will make final decisions after considering the cumulative risks of the OPs. (Please see www.epa.gov/pesticides/cumulative.htm.)

concerns. Other mitigation measures are necessary to address worker and ecological risks for disulfoton, which are of concern. To mitigate worker risk, EPA is requiring closed mixing/loading systems for liquid formulations; closed loading and transfer for granular formulations; enclosed cabs plus a dust-mist respirator for all handlers using ground application equipment; enclosed cockpits and mechanical flaggers for aerial application; maximum personal protective equipment where closed cabs are not feasible; and increased re-entry intervals for foliar application to certain crops. To mitigate ecological risks, EPA is requiring reduced number of applications allowed per year; reduced maximum rates; phase out of certain uses; a 25-foot vegetative buffer between treated fields and permanent water bodies; and a precautionary bee statement on labels. These measures substantially reduce but do not fully mitigate worker and ecological risks. However, EPA believes that the benefits of continued disulfoton use on certain commodities outweigh the worker and ecological risk. For other commodities where benefits do not outweigh the risk, use will be phased out by June 2004.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs require decisions about their eligibility for reregistration under FIFRA. OPs with food, drinking water, residential, and any other non-occupational exposures must be reassessed to make sure they meet the new FFDCA safety standard, effected by the Food Quality Protection Act (FQPA) of 1996.

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

**Next Steps**

1. Numerous opportunities for public comment were offered as this decision was being developed. However, because some uses are being phased out, the disulfoton IRED is issued with a 30-day public comment period. (Please see www.epa.gov/pesticides/reregistration/status.htm or www.epa.gov/pesticides/op.

2. When EPA has considered the cumulative risks of the OP pesticides, the Agency will issue its final tolerance reassessment decision for disulfoton and may request further risk mitigation measures. The Agency will revoke 33 tolerances now, because there is either no registered use or because the technical registrant has requested, and EPA has approved, voluntary cancellation of use on the commodities associated with these tolerances. Two tolerances for disulfoton will be lowered now, and several tolerances will be modified to correct commodity definitions. No tolerances will be raised and no new tolerances will be established until cumulative risks have been considered for all the OPs.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 30 2002

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide disulfoton. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on March 10, 2000. Additionally, the Agency held a Technical Briefing on February 3, 2000, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee (TRAC), and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period officially commenced on March 10, 2000 and closed on May 9, 2000 due to unanticipated delays in posting to the Agency's web site.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of disulfoton. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of disulfoton and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for disulfoton will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Disulfoton," which was approved on March 29, 2002, contains the Agency's decision on the individual chemical disulfoton. The Agency has decided to provide a final 30-day opportunity for stakeholders to respond to the disulfoton interim risk management decision. On March 26, 2002, the Agency was informed of other information that may be used to refine post-application risks and will address this issue during this comment period. If substantive data or similar comments are received and indicate that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, appropriate modifications will be made at that time.

A Notice of Availability for this interim reregistration eligibility decision (IRED) document for disulfoton is being published in the *Federal Register*. To obtain a copy of the

IRED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the IRED and all supporting documents are available on the Internet at the following address: http:www.epa.gov/pesticides/op.

The IRED is based on the updated technical information found in the disulfoton public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for disulfoton, and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For disulfoton, a proposal was submitted by Bayer Corporation, the technical registrant. Additional comments were submitted by the American Landscape and Nursery Association, the California Asparagus Commission, the American Bird Conservancy, North Carolina Cooperative Extension Service, and numerous individual North Carolina Christmas tree growers.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the TRAC, a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

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

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

As part of the IRED, the Agency has determined that disulfoton will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of disulfoton may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this IRED document. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this IRED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this 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 disulfoton. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Christina Scheltema at (703) 308-2201. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Jane Mitchell at (703) 308-8061.

Sincerely,

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

# INTERIM REREGISTRATION ELIGIBILITY

# DECISION

# for

# DISULFOTON

LIST A

CASE 0102

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## DISULFOTON TEAM

**Office of Pesticide Programs:**

Health Effects Risk Assessment

David Anderson
Richard Griffin
Christina Jarvis
Alan Nielsen
John Punzi
Shanna Recore

Environmental Fate and Ecological Risk Assessment

Henry Craven
John Jordan
James Wolf

Endangered Species Assessment

Anne Stavola
Larry Turner
Henry Craven

Use, Benefits, and Alternatives

Colwell Cook
Anthony Gilbert
Nikhil Mallampalli
Istanbul Yusef

Registration Support

William Sproat
George LaRocca

Risk Management

Christina Scheltema
Michael Goodis

## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| a.i. | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| AR | Anticipated Residue |
| BCF | Bioconcentration Factor |
| CDPR | California Department of Pesticide Regulation |
| 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 |
| DWEC | Drinking Water Estimated Concentration |
| 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 |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| G | Granular Formulation |
| GENEEC | Tier I Surface Water Computer Model |
| GLN | Guideline Number |
| HDT | Highest Dose Tested |
| IPM | Integrated Pest Management |
| IR | Index Reservoir |
| IRED | Interim Reregistration Eligibility Decision |
| $LC_{50}$ | Median Lethal Concentration. Statistically derived concentration of a substance expected to causing death in 50% of test animals, 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. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LOAEL | Lowest Observed Adverse Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOQ | Limit of Quantitation |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MP | Manufacturing-Use Product |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies |

| | |
|---|---|
| | submitted. |
| N/A | Not Applicable |
| NASS | National Agricultural Statistical Service |
| NAWQA | USGS National Water Quality Assessment |
| NOEC | No Observable Effect Concentration |
| NOAEL | No Observed Adverse Effect Level |
| OP | Organophosphate |
| OPP | EPA Office of Pesticide Programs |
| PAD | Population Adjusted Dose |
| 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 |
| RAC | Raw Agriculture Commodity |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RQ | Risk Quotient |
| RUP | Restricted Use Pesticide |
| SCI-GROW | Tier I Ground Water Computer Model |
| SF | Safety Factor |
| SLN | Special Local Need (Registrations Under Section 24(c) of FIFRA) |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TRR | Total Radioactive Residue |
| UF | Uncertainty Factor |
| $\mu$g/g | Micrograms Per Gram |
| $\mu$g/L | Micrograms Per Liter |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| UV | Ultraviolet |
| WPS | Worker Protection Standard |

## EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA) has completed its review of public comments on the revised human health and environmental risk assessments for disulfoton and is issuing its interim risk management decision. The decisions outlined in this document do not include the final tolerance reassessment decision for disulfoton. Revocations, lowering tolerances, changing definitions and other actions will occur when the Interim Reregistration Eligibility Decision (IRED) is finalized. Raising or establishing new tolerances will be deferred until cumulative risks have been considered. Thirty-three tolerances will be proposed for revocation now, because either there are no currently registered uses or because the technical registrant has requested, and the Agency has approved, cancellation of the use on these commodities. Two tolerances will be lowered (coffee and peanuts), and several commodity definitions will be corrected. In addition, six tolerances for barley, wheat, and potatoes will be revoked consistent with the Agency's determination that uses on these commodities are inconsistent with FIFRA and must be phased out. The tolerances for barley grain and wheat grain will be lowered in the interim period before the phase out. The disulfoton IRED also provides that 19 tolerances must be established for meat, meat by-products, and meat fat for cattle, hogs, sheep, horses, and goats, for milk, and for cotton gin by-products, leaf lettuce, and aspirated grain fractions. As previously mentioned, the final tolerance reassessment, including establishing the nineteen new tolerances, will be deferred until after cumulative risks for all of the organophosphates pesticides are considered.

Disulfoton is an organophosphate insecticide used on a variety of crops. It was first registered in 1961 and is primarily used to control aphids in vegetable and field crops. Based on available pesticide usage information from 1987 through 1998, approximately 1.2 million pounds of disulfoton active ingredient (lbs ai) are used annually. However, according to Agency and registrant estimates, usage has been declining in recent years.

### *Overall Risk Summary*

The Agency's human health risk assessment for disulfoton indicates some risk concerns. Both acute and chronic risks from food are well below the Agency's level of concern. Drinking water risk estimates based on screening level models, from both ground and surface water exposures have been assessed and suggest concern for potential surface water exposure. Dietary exposure from ground water sources of drinking water are not of concern. There are also risk concerns for occupational handlers who mix, load, and apply disulfoton; for homeowner users; and for occupational workers who are exposed to disulfoton residues after it is applied to agricultural crops. The ecological risk assessment has identified chronic risk to birds and mammals that are of concern, as well as risk to aquatic and endangered species.

### *Dietary Risk*

Acute and chronic dietary (food) risks are less than 100% of the aPAD and cPAD for the general U.S. population and all population subgroups. Children (1-6 years), the most highly

exposed population group, are exposed to disulfoton at a level of 9.6% of the aPAD at the 99.9$^{th}$ exposure percentile and 3.5% of the cPAD. No mitigation measures are necessary to reduce dietary risks from food.

***Drinking Water Risk***

Surface water drinking water estimated concentrations (DWECs) were modeled using PRZM-EXAMS. Based on currently registered uses, the surface water DWECs for total disulfoton (parent + degradates) range from 8.0 ppb to 39.0 ppb for acute exposure, and from 2.0 to 16.7 ppb for chronic exposure. Therefore, some of the modeled DWEC values exceed the acute (23 ppb), short-term (14 ppb), and chronic (1.3 ppb) drinking water levels of comparison (DWLOC) and are of concern to the Agency.

Ground water DWECs for disulfoton were derived from a Tier I screening-level model (SCI-GROW), which estimates the maximum ground water concentrations from the application of a pesticide to crops. The estimated ground water DWEC is 1.2 ppb and does not exceed the Agency's level of concern for either acute, short-term or chronic exposures.

***Residential Risk***

Disulfoton is currently registered for residential use on small flower gardens, ornamental flowers and shrubs, including rose bushes and small trees, and outdoor potted plants. MOEs for residential uses of disulfoton range from 1.1 to 1900. For those scenarios with present risk concerns, the registrant has agreed to measures that will effectively mitigate risks; therefore, residential uses that are eligible for reregistration do not exceed the Agency's level of concern.

***Post-Application Residential Risk***

The Agency conducted a worse case residential, post-application risk assessment for disulfoton. Toddler hand-to-mouth exposure (oral exposure) assessed on the day of application results in an MOE of 230 which is not of concern. Therefore, the Agency does not have a concern for any post-application risks associated with the residential use of disulfoton and no risk mitigation is necessary.

***Aggregate Risk***

An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Based on the results of this aggregate assessment, the Agency made an interim determination that the human health risks from these combined exposures to disulfoton are within acceptable limits. Although combined disulfoton exposures from food, residential use, and surface water sources of drinking water appear to "fill" the aggregate risk cup, the drinking water exposure is based on screening-level modeling estimates. The Agency believes actual drinking water exposures are lower than predicted by the model, and has made an interim determination that disulfoton does "fit" within the dietary risk cup. As will be described later in

this IRED document, confirmatory water monitoring and environmental fate data will be required to verify this conclusion.

The acute and chronic aggregate risk assessment included only food and drinking water in contrast to the short-term aggregate assessment which included food, drinking water and residential exposures. The acute drinking water level of comparison (DWLOC) for children 1-6 years old, the most highly exposed population subgroup, is 23 ppb. The highest or acute surface water drinking water estimate concentration (DWEC) for total disulfoton (parent + degradates) is 39.0 ppb based on barley use and is greater than the DWLOC (23 ppb). The acute aggregate assessment therefore exceeds the Agency's level of concern. The short-term DWLOC is 14 ppb. The highest short-term surface water DWEC of 16.7 ppb is associated with the use on potatoes and is the only use which nominally exceeds the Agency's short-term level of concern. Lastly, the chronic DWLOC is 1.3 ppb and is of concern for all uses. Although surface water DWECs exceed the DWLOCs as indicated above, mitigation measures and additional fate and surface water data are expected to confirm that aggregate risks do not exceed the Agency's level of concern. Conversely, the acute ground water DWEC is 1.2 ppb for total disulfoton and does not exceed the Agency's level of concern for any aggregate scenario. Residential exposures do not contribute significantly to the aggregate assessment.

***Occupational Risk***

Occupational exposure to disulfoton is of concern to the Agency and mitigation measures are necessary. As part of the Agency's measures to mitigate occupational risks associated with the use of disulfoton, certain use sites are to be deleted or phased out. Among the uses to be discontinued are barley, potatoes, wheat, and ornamental trees, shrubs, flowers, and groundcover (field or nursery stock). In addition to personal protective equipment (PPE) and engineering controls for handlers, the Agency has considered reductions in the rate and frequency of applications. Despite these mitigation measures, residual risks are still of concern (MOE<100) for some occupational handler activities. The Agency has considered the benefits of these uses and identified measures necessary to mitigate these occupational risks of concern, which are summarized at the end of this executive summary.

Handler Risk

Occupational risks are of concern (i.e., MOEs < 100) for most mixer/loader and/or applicator (MLA) scenarios even when maximum PPE (i.e, double layer clothing, gloves, and a respirator) is used. MLA risks are also of concern for many scenarios with engineering controls, even at a level that provides protection from inhalation exposure (closed mixing/loading, enclosed cabs with air filtration or use of a dust/mist respirator). For MLAs wearing the maximum PPE described above and using the Agency's standard assumptions for acres treated per day, MOEs range from 1.1 to 61 for mixer/loaders, from 1.2 (commercially grown ornamental shrubs, trees, flowers, groundcover, or potted plants) to 69 for applicators, and from <1 (commercially grown ornamentals) to 9100 for mixers/loaders/applicators. For MLAs using the engineering controls described above and standard assumptions for acres treated per day,

MOEs range from 3.1 to 800 for mixer/loaders and from 1.8 to 160 for applicators.

Post-Application Risk

Post-application (re-entry) risks are of concern for workers performing tasks in areas that have received foliar applications of disulfoton. Restricted-entry intervals (REIs) are needed. The Agency acknowledges that additional dislodgeable foliar residue data could refine the post-application risk assessment and potentially reduce the REI for certain crops. Any data developed to refine this assessment would need to include residue data on both parent disulfoton and its toxicologically significant degradates. To mitigate post-application worker risks following foliar application of the liquid formulation, the following REIs are needed: (1) 26 days for asparagus; (2) 37 days for overhead sprinkler irrigation and groundboom applications, and 20 days for aerial applications to potatoes; (3) 16 days for wheat; (4) and 13 days for barley. For non-foliar application of the liquid formulation and for all granular formulations, the Worker Protection Standard designates the REI to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches which are adequate to mitigate post-application worker risks. If the ornamental use was eligible for reregistration, post-application risk is of concern and exposure data for activities such as transplanting or weeding would be required.

***Ecological Risk***

The Agency has ecological risk concerns regarding the acute risks of disulfoton to birds and mammals, and to freshwater and estuarine invertebrates; and chronic risk concerns to birds and mammals, freshwater invertebrates, marine and estuarine fish, and invertebrates. The ecological risk assessment for disulfoton also identified potential risk concerns for endangered species and nontarget plants. Risk assessments for both the liquid and granular formulations resulted in RQ values which exceed the various levels of concern (LOCs).

Birds and Mammals

The Agency has some acute and chronic risk concerns for birds and mammals potentially exposed to the liquid formulation. Acute RQs for birds range from 0.01 to 2.2, with the highest RQ associated with use on potatoes. Acute RQs for mammals range from <0.1 to 360, again with the highest RQ associated with potatoes. Chronic risk estimates for the liquid formulation range from 0.02 to 3.4 for birds and from 0.9 to 158 for mammals. Again, the highest RQ is associated with use on potatoes in the Pacific Northwest. For the remaining agricultural crops, the highest acute RQ is 0.7 for birds and 121 for mammals. The Agency also has a risk concern for endangered avian and mammalian species.

Risk concerns exist for the granular formulation, with potential concerns at the lowest application rate of 1 lb ai/A. Acute avian RQs range from 5 to 75,200 and mammalian RQs range from 0.3 to 257,300. The highest RQs for both birds and mammals are associated with the Christmas tree use at the current Section 3 registration at a label rate of 78 lbs ai/A. Although the registrant has agreed to substantially reduce the maximum application rate to 4.5 lbs ai/A for

the Christmas tree use, peak RQs remain of concern for birds (4,350) and mammals (14,900).

Aquatic Organisms

Acute risks are of concern for some aquatic organisms, potentially including endangered species. Acute RQs range from <0.01 to 0.21 for freshwater fish. Estuarine fish RQs range from <0.01 to 0.02 and are not of concern. For invertebrates, acute RQs range from <0.01 to 2.1 for freshwater invertebrates, and from <0.01 to 0.55 for estuarine invertebrates. Some of the acute values for invertebrates are of concern.

Chronic risks are of concern for freshwater invertebrates, but not for freshwater fish. The Agency has a greater chronic risk concern for freshwater invertebrates than for estuarine invertebrates. Chronic RQs range from <0.01 to 149 for freshwater invertebrates, and from <0.01 to 2.3 for estuarine invertebrates. For freshwater fish, chronic RQs range from <0.01 to 0.8, and for estuarine fish, chronic RQs range from <0.01 to 3.0.

The highest RQs of concern to both fish and invertebrates are associated with multiple aerial applications to potatoes, barley, and asparagus.

Endangered Species

Potential impacts on endangered aquatic species from several uses of disulfoton were addressed by the US Fish and Wildlife Service, which issued two formal Biological Opinions on disulfoton in 1983 and 1989. Because the disulfoton use pattern has changed significantly since EPA's last formal consultation with the US Fish and Wildlife Service, EPA conducted a screening assessment to determine if disulfoton use would result in potential exposure to endangered species. This analysis identified potential impacts for two bird species which appeared to occupy habitats in disulfoton areas where disulfoton is used: the Puerto Rico plain pigeon and the Mountain plover.

Further analysis and consultation with local fish and wildlife authorities showed that there is not a concern for these two species. Although the Mountain plover occupies habitat where disulfoton is used, it feeds only in fields with short vegetation. Disulfoton is used on barley late in the growing season, on tall plants that are near maturity. Further, disulfoton use on barley is being phased out. The Agency also requested and received technical assistance from the Fish and Wildlife Service in Puerto Rico, which revealed that the Puerto Rican plain pigeon does not utilize or otherwise occur in areas of Puerto Rico where coffee is produced. Therefore, because no adverse impacts to these species are expected, no mitigation is necessary.

***Regulatory Decision***

The Agency is issuing this IRED for disulfoton, as announced in a Notice of Availability published in the *Federal Register*. This IRED document includes guidance and requested time frames for making any necessary label changes for products containing disulfoton. The Agency

has decided to provide a final 30-day opportunity for stakeholders to respond to the disulfoton interim risk management decision. On March 26, 2002, the Agency was informed of other information that may be used to refine post-application risks and will address this issue during this comment period. If substantive data or similar comments are received and indicate that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, appropriate modifications will be made at that time. Note that neither the tolerance reassessment nor the reregistration eligibility decision for disulfoton can be considered final until the cumulative risks for all organophosphate pesticides are considered. The cumulative assessment may result in further risk mitigation measures for disulfoton.

***Summary of Mitigation Measures***

EPA believes that disulfoton is eligible for reregistration if the registrant takes the following actions, combined with the general mitigation measures previously described:

Dietary Risk

- No label changes are necessary, however certain confirmatory data listed in Section V are required.

Residential Risk

Only end-use products containing 2% active ingredient or less are eligible for reregistration. The following measures are necessary to mitigate residential risk:

- Limit maximum label rates for disulfoton to 0.3 lb ai/1000 $ft^2$ for use on flowerbeds; 0.01 lb ai/4 ft bush for use on shrubs; and 0.0013 lb ai/bush for use on rose bushes.

- Limit the maximum label rate for disulfoton packaged for application with a push type spreader to 0.3 lb ai/1000 $ft^2$. Products to be applied by this method do not need to be in child resistant packaging, and commercial use of this product is prohibited.

- Prohibit application of disulfoton with a belly grinder.

- Prohibit application to flower gardens and ornamental shrubs with a spoon, measuring scoop, shaker can, or by hand, unless the packaging and method of application of the end-use product conforms with the performance of a measuring cup and lid packaging currently manufactured for the Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granular product.

- Package all products marketed and labeled for hand application in child resistant packaging with a self-contained measuring device, which serves as the container lid and clearly measures the quantity to be applied. Products marketed and labeled for application with a push type spreader do not need to be in child resistant packaging, but

must be labeled "not for application by hand." Commercial use of the homeowner product is prohibited.

- Delete the following uses from all product labels: all indoor uses, use in greenhouses, and use on home vegetable gardens, including use on spinach and tomatoes.

Occupational Risk

*The following measures are necessary to mitigate handler risk:*

- Closed mixing/loading systems for liquid formulations by December 31, 2002;
- Closed loading systems for granular formulations by June 2004;
- Enclosed cabs plus a dust-mist respirator for all applicators using ground equipment;
- Enclosed cockpits for all aerial applicators;
- Mechanical flaggers for aerial application; or the use of global positioning system (GPS) equipment that negates the need for flaggers;
- When engineering controls are not feasible, handlers must wear maximum PPE (i.e., double layer clothing, chemical-resistant gloves and footwear, and a dust-mist respirator); and
- Application by open, handheld equipment, including belly grinders and bucket and spoon will be prohibited after June 2004. Where this is currently the application method of choice, growers will be allowed until June 2004 to transition to another method; and
- Phase out of use on barley, wheat, potatoes, and commercially grown ornamental trees, shrubs, flowers, and groundcovers (field or nursery stock) by June 2005.

*The following measures are necessary to mitigate risk to post-application workers:*

- For soil directed application of the liquid formulation *and for all granular formulations*, the Worker Protection Standard designates the REI to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches.
- For foliar application of the liquid formulation, a 26 day REI is necessary for asparagus. Longer REIs are also necessary for foliar application to barley (16 days), wheat (13 days), and potatoes (20 or 37 days depending upon the application method). The uses on barley, wheat, potatoes, and commercially grown ornamental field or nursery stock are to be phased out by June 2005.

Ecological Risks

The following measures are necessary to mitigate ecological risks. Disulfoton is eligible for reregistration provided that:

- A precautionary bee statement is added to all product labels for liquid formulations of disulfoton

- Use is prohibited within a level, well maintained 25 foot vegetative buffer between treated fields and all permanent water bodies. (Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for guidance.)

- No more than one application of disulfoton per calendar year for all crops, except for asparagus, barley, coffee, peanuts (North Carlina only), and potatoes, for which no more than two applications of disulfoton per calendar year are permitted.

- The maximum application rate for Christmas trees is reduced from 78 to 4.5 lbs ai/A nationally, the use is limited to fir species only, and disulfoton is soil incorporated, watered in, or applied to areas with permanent groundcover.

- Use on barley, wheat, potatoes, and commercially grown ornamentals (field or nursery stock) is phased out by June 2005.

Eligible Uses

- The following uses are eligible for reregistration, pending consideration of the cumulative assessment for the OPs: asparagus; beans (lima and snap); cabbage; cole crops (broccoli, Brussels sprouts, and cauliflower); lettuce; peppers; peanuts; cotton; clover and radish grown for seed; coffee trees; and Christmas trees.

Phase Outs

- The following uses will be phased out by June 2004: barley and wheat, commercially grown ornamentals, and potatoes.

## 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. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Disulfoton belongs to a group of pesticides called organophosphates (OPs), which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency's revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the interim reregistration eligibility decision (IRED) for disulfoton. This action is intended to be only the first phase in the reregistration process for disulfoton. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision (RED) for disulfoton. A preliminary cumulative risk assessment for the OPs was released in December, 2001.

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 Advisory Committee, which was composed of representatives from industry, environmental groups, and other interested parties.

In addition, the Agency published in the *Federal Register* on September 29, 2000, a Pesticide Registration Notice that presents EPA's approach for managing risks from OP

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

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 decision on interim reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices include Data Call-In (DCI) and other 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/op, and in the public docket.

## II. Chemical Overview

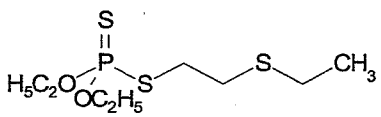
### A. Regulatory History

Disulfoton was first registered in 1961 for use as an insecticide. A Registration Standard, which describes the terms and conditions for continued registration of disulfoton, was issued for disulfoton in 1984. Disulfoton is currently registered for use on over 35 crops. There are 49 tolerances for disulfoton in the Code of Federal Regulations. At present, disulfoton is also registered for domestic outdoor uses on potted plants and ornamentals, including herbaceous plants, flowers, woody shrubs, and trees.

During the public participation process for the reregistration of disulfoton, Bayer Corporation, the technical registrant, proposed several changes to their disulfoton registrations. These changes were reflected in the revised disulfoton risk assessment, which was available for public comment, and later accepted by EPA as interim risk mitigation measures. These changes included use deletions, voluntary cancellations, rate reductions, and reduction in the number of applications of disulfoton allowed per year. In addition, various disulfoton end-use registrants voluntarily canceled products and/or deleted uses that were no longer supported by Bayer.

### B. Chemical Identification

Disulfoton:



- Common Name: Disulfoton
- Chemical Name: O,O-diethyl S-[2-ethylthio)ethyl] phosphorodithioate
- Chemical Family: Organophosphate
- Case Number: 0102
- OPP Chemical Code: 032501
- Empirical Formula: $C_8H_{19}O_2PS_3$
- Molecular Weight: 274.4 g/mole
- CAS Registry No.: 298-04-4

- Trade and other names: Di-Syston, Bayer Advanced Garden
- Basic Manufacturer: Bayer Corporation

## C. Use Profile

The following information is limited to the currently registered uses of disulfoton. Uses that have been deleted as part of the reregistration process are not included in this IRED document, except in discussions of risk mitigation in Section IV. Bayer, the sole technical registrant, has voluntarily canceled the following uses and deleted them from all disulfoton labels: berries, Bermuda grass, corn, all greenhouses, all home vegetable gardens, non-bearing fruit trees, oats, pecans, tomatoes, and triticale. These use deletions were effective on or before October 22, 2001. Bayer has voluntarily cancelled disulfoton use on dry beans, peas and lentils, poplars grown for pulp, sorghum, soybeans, and tobacco. A Federal Register Notice announcing this request was published on January 10, 2002, and these use deletions became effective on February 11, 2002.

On March 19, 2002, Bayer requested voluntary cancellation of the end-use product used to treat cotton seed (EPA Reg No 3125-173). Also, on March 28, 2002, the registrant requested voluntary cancellation of their end-use products of fertilizer spikes impregnated with disulfoton (EPA Reg Nos 46260-2, 46260-12, 46260-35, and 46260-36). A Federal Register Notice announcing the cancellation of the cotton seed treatment and impregnated fertilizer spike registrations is to be published.

**Type of Pesticide:** Insecticide

**Summary of Use Sites:**

Food and Feed Crops - asparagus, broccoli, Brussels sprouts, cabbage, Chinese cabbage, cauliflower, coffee, lettuce, pepper (bell, chili, and pimento), barley, succulent beans (lima and snap), cotton, peanuts, white/Irish potato, and wheat.

Non-Food Crops - clover grown for seed, radish grown for seed, commercially grown ornamental flowers/groundcover/herbaceous plants, ornamental shrubs and trees, ornamental woody shrubs and vines (field or nursery stock), and Christmas trees.

Residential - roses, flowers, and ornamental shrubs.

Public Health - none.

**Formulation Types Registered:**

Technical Grade/Manufacturer-Use Product (MP), liquid 68% active ingredient (ai); and solid 97.6% ai.

End-Use Product (EP), emulsifiable concentrate (EC) 23 - 85% ai; granular 1 - 15% ai; pellet/tableted 1 - 2% ai; and impregnated material 1% ai.

**Target Pests:** Invertebrates (insects and related organisms) consisting of aphids (asparagus, bird cherry-oat aphid, greenbug, green peach, lettuce root, root), beetle (Colorado potato, cottonwood leaf, elm leaf, flea, Mexican bean), billbugs (lawn), bugs (lace), borers, fly (Hessian), grasshoppers, leafhoppers, leafminer (birch, holly), mealybugs, midge (sorghum), mite (banks grass, red spider), moth (Nantucket pine tip, pine shoot, pine tip), psyllids (potato), scale (camellia, European elm, rhododendron, soft brown, soft, tea), thrips, webworm (mimosa), wireworm (southern potato), and whiteflies.

**Methods and Rates of Application:**

Equipment - aircraft; drip irrigation; high or low volume ground sprayer; tractor-drawn spreader; belly grinder; push-type spreader; measuring container; shaker can; soil injector equipment; sprayer; and sprinkler irrigation.

Methods - broadcast; chemigation, high volume spray (dilute); low volume spray (concentrate); seed treatment; soil band or broadcast treatment; soil in-furrow treatment (by drill, injection, and hill drop); soil incorporation treatment by irrigation; side dressing treatment; and top dressing treatment.

**Label Use Rates:** Maximum label use rates vary by crop. For most of the food and feed crops, the maximum label use rate is 1-2.5 lbs ai/acre/season. However, disulfoton is used at a rate of 3 lbs ai/acre (A) for potatoes, and 8.3 lbs ai/A for coffee. The highest rates are used on ornamental flowers, trees, and shrubs.

**Use Classification:** Both Restricted and Nonrestricted

### D. Estimated Usage of Disulfoton

This section summarizes the best estimates available for many of the pesticide uses of disulfoton, based on available pesticide usage information for 1987 through 1998, which is why some deleted uses are listed. A full listing of all uses of disulfoton, with the corresponding use and usage data for each site is in the "Quantitative Usage Analysis" document, which is available in the public docket and on the internet. 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 1.2 million pounds of disulfoton ai are used annually, according to Agency and registrant estimates; however, in recent years use has been declining.

Disulfoton is primarily used to control aphids in vegetable and field crops. Important regional uses of disulfoton include asparagus grown in California and Washington; Christmas trees (Fraser firs) grown primarily in the mountains of North Carolina; broccoli, Brussels sprouts, cabbage, cauliflower, and lettuce grown in the Salinas Valley of California; chili peppers grown in California; lima beans in Georgia; and radish grown for seed in Washington's Columbia River Basin.

**Table 1. Disulfoton Estimated Usage for Representative Sites**

| Crop | Lbs. Active Ingredient Applied (Wt. Avg.)[1] | Percent Crop Treated (Wt. Avg.)[2] | Percent Crop Treated (Likely Maximum)[3] |
|---|---|---|---|
| Asparagus | 37,000 | 40% | 55% National<br>80% CA, WA |
| Barley | 29,000 | 1% | 1% |
| Beans, dry* | 2,000 | <1% | 4% |
| Beans, lima and snap | 14,000 | 12% | 34% |
| Broccoli | 22,000 | 10% | 21% |
| Brussel sprouts | 1,000 | 20% | 40% |
| Cabbage | 7,000 | 6% | 9% |
| Cauliflower | 10,000 | 17% | 25% |
| Chili peppers | 4,000 | 25% | 40% |
| Cotton | 420,000 | 5% | 8% |
| Corn, field* | 36,000 | <1% | <1% |
| Corn, sweet* | 2,000 | <1% | 1% |
| Lima beans | 4,000 | 7% | 14% |
| Lettuce | 13,000 | 3% | 8% |
| Peanuts | 47,000 | 3% | 5% |
| Peas, green* | 1,000 | <1% | 7% |
| Potatoes | 120,000 | 4% | 7% |
| Sorghum* | 20,000 | <1% | 1% |
| Soybeans* | 26,000 | <1% | <1% |
| Tobacco* | 62,000 | 4% | 7% |
| Winter Wheat | 180,000 | 1% | 1% |

| Crop | Lbs. Active Ingredient Applied (Wt. Avg.)[1] | Percent Crop Treated (Wt. Avg.)[2] | Percent Crop Treated (Likely Maximum)[3] |
|---|---|---|---|
| Residential/Commercial Ornamentals | 11,000 | N/A | N/A |
| Horticultural Nurseries | 9,000 | N/A | N/A |
| Woodlands, including Christmas trees (national) | 80,000 | 2% | 2% |
| Christmas Trees (NC only) | 60,000 | 65% | 70% |

[1] Weighted Average is based on data for 1987-1998; with data from recent years weighted more heavily.
[2] Weighted average percent crop treated used in chronic dietary assessment.
[3] Maximum percent crop treated used in acute dietary assessment.
* Use on this crop has been voluntarily canceled; usage information reflects past use.
No data were available for the following crops: coffee, clover, popcorn, lentils, or triticale.

## III. Summary of Disulfoton Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of the human health and ecological risk assessments, and to better understand the conclusions reached in the assessments. Following is a list of EPA's revised human health and ecological risk assessments and supporting information that were used to formulate the findings and conclusions for the OP pesticide disulfoton. The listed documents may be found on the Agency's web page at www.epa.gov/pesticides/op and in the OPP public 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 4:00 pm.

### Human Health Risks

- *Risk Assessment and Reregistration Eligibility Decision (RED) Documents for Disulfoton (Revised Risk Assessment, Phase 4)*, February 10, 2000.
- *Disulfoton: Revised (3rd) Report of the Hazard Identification Assessment Review Committee,* April 10, 2001.
- *Review and Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds*, June 6, 2001.
- *Revised Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) Documents for Disulfoton*, May 31, 2001 and addendum, August 9, 2002.
- *Revised Occupational Exposure Assessment for the Reregistration Eligibility Decision Document for Disulfoton,* June 15, 2001.
- *Health Effects Division Toxicity Chapter for Reregistration Eligibility Decision (RED),* June 25, 2001.
- *Disulfoton: Aggregate Risk Assessment*, March 6, 2002.

### Environmental Fate and Ecological Effects

- *Reregistration Eligibility Document for Disulfoton*, September 5, 2000 and its addendum March 25, 2002.
- *[Review of ] The Interagency Study of the Impact of Pesticide Use on Ground-Water in North Carolina*, August 1, 2000.
- *Additional Information and Clarification for the Disulfoton RED [Review of California Surface Water Monitoring],* October 20, 2000.
- *Disulfoton Residues in Groundwater Found in the Virginia BMP Study,* November 20, 2001.
- *Endangered Species Addendum to EFED's Disulfoton Science Chapter,* January 24, 2002
- *Puerto Rican Plain Pigeon and Disulfoton*, April 24, 2002
- *Disulfoton: Summary of Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment,* February 25, 2002.

**Benefits and Alternatives Analysis**

- *Asparagus Benefits Assessment for Disulfoton,* September 11, 2001.
- *Benefits of Disulfoton on Selected Vegetable Crops and Cotton,* September 27, 2001.
- *Benefits Assessment for Disulfoton Use on Potatoes and Radish Seed,* September 28, 2001.
- *Use of Disulfoton on Bell and Pimento Peppers,* November 3, 2001.
- *Cursory Assessment of Disulfoton Use in Coffee in Puerto Rico*, November 26, 2001.
- *Response to Questions Concerning Disulfoton Posed by Special Review and Reregistration Division [Regarding Ornamentals]*, December 17, 2001.
- *Analysis of Disulfoton Use on Fraser Fir Christmas Trees in Western North Carolina*, July 9, 2002.

## A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for disulfoton in January, 1999 for public comment. Based on the comments received and additional information, the Agency revised the risk assessments and presented this information at a Technical Briefing on February 3, 2000. This was followed by another opportunity for public comment on risk management for this pesticide. In response to comments and studies submitted during the public comment periods, the following major revisions were made to the risk assessments:

- Refinement of the acute dietary risk assessment to use probabilistic (Monte Carlo) techniques;

- Incorporation of data from FDA's Surveillance Monitoring Program and USDA's Pesticide Data Program (PDP) into the dietary risk assessment;

- Incorporation of data from the Occupational and Residential Re-Entry Task Force into the occupational and residential risk assessments;

- Incorporation of residential exposure monitoring and toxicology data on the 1% granular home use product;

- Incorporation of data from an acute delayed neurotoxicity study in hens;

- Incorporation of recent label changes into the water, occupational, residential, and environmental assessments;

- Incorporation of new information and methodologies into the water assessment, such as the index reservoir and percent crop area factor;

- An assessment of the impacts of disulfoton on endangered species; and

- An assessment of benefits and alternatives on the remaining currently registered agricultural uses that are subject to reregistration.

### 1. Dietary Risk from Food

#### a. Toxicity

The Agency has reviewed all toxicity studies submitted, and has determined that the toxicity database is substantially complete, and that it supports an IRED for all currently registered uses. Only the developmental neurotoxicity study is outstanding, which is scheduled to be submitted to the Agency by November 2004. Further details on the toxicity of disulfoton can be found in the April 10, 2001 Hazard Identification Assessment Review Committee (HIARC) Report for Disulfoton. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

The Agency has also considered the toxicity of the metabolites of disulfoton found in plants and animals, as well as the degradates found in the environment. Of the metabolites and degradates identified, the following are of toxicological concern: disulfoton sulfoxide, disulfoton sulfone, disulfoton oxygen analogue (demeton-S), disulfoton oxygen analogue sulfoxide, and disulfoton oxygen analogue sulfone. Therefore, the Agency included these compounds in the dietary and drinking water risk assessments for disulfoton, and in the reassessment of disulfoton tolerances. Because toxicology data are not available for the metabolites and degradates for the purposes of assessing risks, the Agency assumes that the degradates are as toxic as the parent. Therefore, toxicological endpoints for the parent were used to assess the risk of the parent and degradates.

#### b. FQPA Safety Factor

The FQPA Safety Factor (SF) was removed (reduced to 1X) for disulfoton because:

- The database of toxicity studies necessary to assess the applicability of the FQPA safety factor is complete, including an acceptable two-generation reproduction study in rats, acceptable prenatal developmental toxicity studies in rats and rabbits, an acute delayed neurotoxicity study in hens, and neurotoxicity studies in rats.

- These studies show no evidence of either neurotoxicity or increased susceptibility of fetuses or offspring in prenatal or postnatal studies in rabbits or rats.

- Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment.

- The assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

In summary, the Agency has determined that the 1X FQPA SF is applicable for all populations potentially exposed to disulfoton.

### c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA SF (i.e., RfD ÷ FQPA SF). In the case of disulfoton, the FQPA SF is 1X; therefore, both the acute and chronic PADs are identical to the corresponding acute and chronic RfDs. The Agency applied the conventional uncertainty factor (UF) of 100X to account for both interspecies extrapolation (10X) and intraspecies variability (10X). These UFs were applied to the No Observed Adverse Effect Level (NOAEL) selected for risk assessment. The acute PAD (aPAD) is 0.0025 mg/kg/day, and the chronic PAD (cPAD) is 0.00013 mg/kg/day. Table 2 below summarizes the toxicological endpoints used in the disulfoton dietary risk assessment.

**Table 2. Summary of Toxicological Endpoints for the Dietary Risk Assessment**

| Exposure Duration and Route | Toxicology Endpoint and Dose | Toxicology Study Used | UF/ FQPA SF | PAD (mg/kg/day) |
|---|---|---|---|---|
| Acute Dietary (one day) | NOAEL = 0.25 mg/kg/day; LOAEL = 0.75 mg/kg/day, based on muscle fasciculation, plasma and red blood cell cholinesterase inhibition | acute neurotoxicity study in rats, MRID 42755801 | 100/1 | 0.0025 |
| Chronic Dietary | NOAEL = 0.013 mg/kg/day; LOAEL = 0.094 mg/kg/day, based on plasma, red blood cell, and corneal cholinesterase inhibition; and brain cholinesterase inhibition in females only | 1-year toxicity study in dogs, MRID 44248002 | 100/1 | 0.00013 |

NOAEL: no observed adverse effect level
LOAEL: lowest observed adverse effect level

### d. Exposure Assumptions

The Agency's dietary (food) risk assessment for disulfoton uses the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Extensive monitoring data have been generated for disulfoton by the USDA Pesticide Data Program (PDP) and the U.S. Food and Drug Administration (FDA). However, only FDA data were used in the dietary risk assessment, because the PDP data do not include all of the cholinesterase-inhibiting metabolites of toxicological concern. However, the available PDP data support the FDA findings. Of the hundreds of samples analyzed by FDA between 1992 and 1998, no residues were detected except for the following: broccoli with 2 detects in 309

samples; cabbage with 5 detects in 510 samples; lettuce with 4 detects in 866 samples; and potatoes with 6 detects in 1133 samples. Residue values for non-detects were assumed to be equal to one-half the limit of quantitation (LOQ). Therefore, for the acute dietary risk assessment, the entire distribution for each food item of single day food consumption was combined with anticipated residues estimated from FDA monitoring data or field trial data generated by the registrant. For the chronic dietary risk assessment, the three-day average consumption for the U.S. and sub-populations was combined with average residues in commodities to determine average exposure. The Agency uses the estimated maximum percent crop treated for acute risk assessments and the average estimated percent crop treated for chronic risk assessments.

### e. Acute Dietary (Food) Risk

For disulfoton, a dietary risk estimate that is less than 100% of the aPAD is not of concern to the Agency. The Agency conducted a probabilistic (Monte Carlo) analysis which estimated a dietary exposure of 9.6% of the aPAD at the 99.9$^{th}$ exposure percentile for the most highly exposed subpopulation (children 1 - 6 years). The acute dietary (food) risk for disulfoton is less than 100% of the aPAD for all subpopulations, and is therefore not of concern to the Agency. Results of the Agency's acute dietary risk assessment for food are summarized in Table 3.

**Table 3. Acute Dietary Risk Estimates**

| Population | 99.9$^{th}$ percentile | |
|---|---|---|
| | Exposure (mg/kg/day) | % aPAD |
| US population (total) | 0.000176 | 7.0 |
| All infants (<1 yr) | 0.000218 | 8.7 |
| Children (1-6 yr) | 0.000239 | 9.6 |

### f. Chronic Dietary (Food) Risk

For disulfoton, a dietary (food) risk estimate that is less than 100% of the cPAD is not of concern to the Agency. The chronic dietary exposure is estimated to be 3.5% of the cPAD for the most highly exposed subgroup (children 1-6 years). The chronic dietary (food) risk for disulfoton is less than 100% of the cPAD for all subpopulations, and is therefore not of concern to the Agency. Results of the Agency's chronic dietary risk assessment for food are summarized in Table 4.

**Table 4. Chronic Dietary Risk Estimates**

| Population | Average Exposure (mg/kg/day) | % cPAD |
|---|---|---|
| US population (total) | 0.000003 | 2.3 |
| All infants (<1 yr) | 0.000001 | 0.9 |
| Children (1-6 yr) | 0.000005 | 3.5 |

### 2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. The Agency considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available. EPA assessed the potential of disulfoton to reach surface or ground water sources of drinking water based on available ground and surface water monitoring data, laboratory and field studies, and Agency models. Limited surface and ground water monitoring data were available for disulfoton; however, because most monitoring did not include the degradates of concern and because the monitoring data were not considered to be nationally representative, the Agency used modeling to predict the potential concentration of total disulfoton (parent + degradates) in drinking water.

The available laboratory and field data for disulfoton indicate that both parent disulfoton and the following degradates may be found in surface and ground water: disulfoton sulfonic acid, disulfoton oxygen analogue sulfonic acid, disulfoton sulfone, disulfoton oxygen analogue sulfone, disulfoton sulfoxide, and disulfoton oxygen analogue sulfoxide. Data for disulfoton and other OPs suggest that the sulfoxide and sulfone degradates are more mobile and persistent than the parent. For parent disulfoton, the estimated upper 90$^{th}$ percentile upper bound on the mean half-life of the aerobic soil metabolism was 6.12 days (non first order decay). The aerobic soil metabolism half-life is greater than 17 days for disulfoton sulfoxide and greater than 150 days for disulfoton sulfone. The 90$^{th}$ percent upper bound on the mean half life for total disulfoton residues is 259 days.

No aerobic or anaerobic aquatic metabolism data are available for disulfoton or its degradates, which are necessary to fully understand the environmental fate. Hence, as part of this IRED, the Agency is requiring aerobic and anaerobic aquatic metabolism data (OPPTS Guidelines 835.4300 and 835.4400) and mobility, adsorption, and desorption data (OPPTS Guideline 835.1240) for the disulfoton parent and sulfoxide and sulfone degradates. These studies are confirmatory data.

As part of the cumulative assessment for all OPs, the Agency contacted nearly all 50 states to determine whether any ground or surface water monitoring had been conducted for OP pesticides over the last ten years. A total of ten states (i.e., Hawaii, Kansas, Kentucky, Maryland, Michigan, Nebraska, North Carolina, West Virginia, Wisconsin, and Wyoming) conducted monitoring for disulfoton parent, but no detections were reported. Only one state,

North Carolina, conducted monitoring for disulfoton and its sulfone and sulfoxide degradates.

The results of the Agency's drinking water analysis are summarized here. Details of this analysis, are found in the following supporting technical documents: *Reregistration Eligibility Document for Disulfoton*, September 5, 2000, and its addendum, March 25, 2002; *Disulfoton: Aggregate Risk Assessment*, March 6, 2002; *[Review of ] The Interagency Study of the Impact of Pesticide Use on Ground-Water in North Carolina*, August 1, 2000; *Additional Information and Clarification for the Disulfoton RED [Review of California Surface Water Monitoring]*, October 20, 2000; *Disulfoton Residues in Groundwater Found in the Virginia BMP Study*, November 20, 2001; and *Disulfoton: Summary of Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment*, February 25, 2002. All of these documents are available in the public docket and on the internet.

### a. Surface Water

*Monitoring*

There are limited surface water monitoring data for disulfoton. The available data show few detections, including the US Geological Survey (USGS) National Assessment of Water Quality (NAWQA) data and a Virginia Tech Best Management Practice monitoring study. The NAWQA data up to 1998 included 5196 samples, with 29 samples detecting parent disulfoton ranging from < 0.017 ppb to 0.06 ppb. The USGS NAWQA study is ongoing; however, the most recent NAWQA data have not yet been released and is therefore not available to EPA. The Virginia Tech monitoring study was conducted to evaluate the effectiveness of Best Management Practices in a 3616-acre watershed in Westmoreland County, Virginia. Approximately half of the watershed is in agriculture and the other half is forested. From the study, three samples detected parent disulfoton in 2 of the 8 monitoring sites with values ranging from 0.37 to 6.11 ppb. As stated above, a major limitation of the surface water monitoring data, including the NAWQA and Virginia Tech data, is that the analysis did not include the sulfoxide and sulfone degradates. The importance of which is that the Agency is concerned that the sulfoxide and sulfone degradates may be more mobile and persistent than the parent.

The California Department of Pesticide Regulation (CDPR) also maintains a database of surface water monitoring data collected in the state. This database contains the results of studies conducted by a number of agencies and researchers and therefore, may have been included or reported elsewhere (e.g., STORET, NAWQA). The CDPR database contains results of surface water samples collected during 1991 to 1999, from ten counties, which were analyzed for a number of pesticides, including disulfoton (parent only). Of the 860 samples collected and analyzed, two resulted in detections of parent disulfoton residues, both of which were 0.06 ppb. Although CDPR also keeps records of all agriculture pesticide use in California, it is not clear which usage contributed to these detections.

A pilot reservoir monitoring program was initiated jointly by EPA's Office of Pesticide Programs and Office of Ground Water and Drinking Water, and by USGS NAWQA to assess

pesticide concentrations in raw and finished drinking water. Disulfoton and its sulfone and sulfoxide degradates were included in this study. Parent disulfoton was not detected, but the sulfone degradate was detected (0.013 ppb) in 1 of 316 samples, and the sulfoxide degradate was also detected (0.006 ppb) in 1 of 316 samples. This pilot study shows that the degradates can be found in surface water sources of drinking water. No detections of disulfoton or its degradates were found in finished drinking water samples. Please refer to the following internet address for additional information on the pilot reservoir monitoring program: http://www.epa.gov/pesticides/cumulative/pra-op/iii_e_3-f.pdf.

The interpretation of the monitoring data is limited by the lack of correlation between sampling dates and the use patterns of the pesticide within the study's drainage basin. Additionally, the sample locations were not associated with actual drinking water intakes for surface water. Limitations for the monitoring studies include the use of different limits of detection between studies, lack of information concerning disulfoton use around sampling sites, and lack of data concerning the hydrogeology of the study sites.

***Modeling***

Surface water drinking water estimated concentrations (DWECs) were derived from the Tier II PRZM-EXAMS model with the Index Reservoir and percent cropped area (PCA), which is a screening-level model designed to provide high-end estimates of potential pesticide exposure. The following surface water modeling scenarios were chosen for disulfoton to represent high run-off sites:

- barley in the Southern Piedmont of Virginia
- cotton in the Southern Mississippi Valley Silty Uplands of Mississippi
- potatoes in New England and Eastern New York Upland of Maine
- spring wheat in the Rolling Till Prairie of South Dakota.

The maximum registered application rates for the respective crops were used for the modeled scenarios. These scenarios represent major uses and generally reflect the highest use rates and highest number of pounds that are annually applied, and were chosen because they were expected to represent the upper $10^{th}$ percentile of potential runoff from sites where the representative crop is grown. Disulfoton use on Christmas trees was not specifically modeled due to lack of an appropriate scenario. However, surface and groundwater monitoring conducted by the North Carolina Department of Agriculture showed no detections of disulfoton or its sulfoxide or sulfone degradates.

Also, as part of DWEC calculation, the values were adjusted by the PCA, which is a factor that represents the maximum percent of the area within the watershed that is planted and treated in the crop(s) under evaluation. For the crops that are treated with disulfoton, the PCAs used to estimate the DWECs are 20% for cotton and 56% for wheat. For all other crops, the default PCA of 87% was used. Better estimates of the PCA for these crops would reduce the uncertainty associated with the DWECs.

Based on current labels, the DWECs for disulfoton (parent only) in surface water range from 2.8 to 15.5 ppb for acute exposure, and from 0.2 to 1.6 ppb for chronic exposure. The DWECs for total disulfoton (parent + degradates) range from 8.0 to 39.0 ppb for acute exposure, and from 2.0 to 16.7 ppb for chronic exposure. Table 5 summarizes the modeled DWEC for the crop scenarios previously mentioned.

**Table 5. Surface Water Concentrations of Disulfoton Residues (Parent + Degradates)**

| Crop Scenario (PCA) | Application Rate and Method | Number of Applications per Season | Concentration (ppb) | |
|---|---|---|---|---|
| | | | Peak (Acute Risk) | Annual Average (Short-Term or Chronic Risk) |
| Barley (0.87) | 1.0 lb ai/A foliar | 2 | 15.51 parent<br>34.53 total | 1.61 parent<br>7.62 total |
| Barley (0.87) | 1.0 lb ai/A granular, soil applied | 2 | 14.88 parent<br>39.05 total | 1.22 parent<br>10.01 total |
| Cotton (0.20) | 1.0 lb ai/A ground and soil | 1 | 7.21 parent<br>12.59 total | 0.40 parent<br>1.96 total |
| Potatoes (0.87) Western States | 3.0 lb ai/A ground and soil | 1 | 6.89 parent<br>12.53 total | 0.46 parent<br>4.77 total |
| Potatoes (0.87) East of Rockies | 1.0 lb ai/A foliar | 3 | 13.09 parent<br>34.37 total | 1.09 parent<br>16.72 total |
| Spring Wheat (0.56) | 0.75 lb ai/A foliar | 1 | 2.79 parent<br>8.02 total | 0.24 parent<br>2.39 total |

### b. Ground Water

*Monitoring*

Limited ground water monitoring data from a study in Virginia and another in Wisconsin are available for disulfoton. The same Best Management Practices study in Westmoreland County, Virginia that was conducted to evaluate surface water was also conducted for ground water. The ground water component was started in 1986 and ended in June 1997. Monthly samples were taken from eight ground water monitoring wells and were analyzed for a number of pesticides, including disulfoton (parent only). The study resulted in a total of six detections of disulfoton parent at levels ranging from 0.04 to 2.87 ppb in 5 of the 8 wells. The mean of all the disulfoton detections is 0.39 ppb.

The Wisconsin study showed detections of disulfoton parent in 14 of 29 samples in 25 wells. The concentration of disulfoton detected ranged from 4 to 100 ppb. The high concentrations of disulfoton detected in the Wisconsin groundwater monitoring study were unexpected, given the low mobility and persistence of disulfoton in the environment. EPA

concludes that these detections may have occurred at a highly vulnerable site, which is not typical of the entire disulfoton use area. The Wisconsin study also had quality assurance and quality control issues, and no detections of disulfoton were reported in follow up sampling. However, this lack of detections does not discount previous detections because groundwater is a dynamic system. Because groundwater is constantly moving and undergoing biotic and/or abiotic interactions, pesticides and other contaminants are not always detected. Although the Wisconsin values can not be ignored, they are not appropriate for use in a national ground water assessment.

Neither the Virginia nor the Wisconsin studies included analysis for the sulfoxide and sulfone degradates. Mississippi and Texas also monitored for both disulfoton and degradates in ground water, but found no detections. Also, no detections of disulfoton parent were found in 3,000 ground water samples in the NAWQA database.

Another ground water monitoring study was conducted by the North Carolina Department of Agriculture under the direction of the North Carolina Pesticide Board to determine if labeled uses of pesticide products, including disulfoton, were impacting the ground water resources of North Carolina. In phase I of the study, 55 wells representing the major drinking water aquifers of the state were sampled; and in phase II, 97 monitoring wells were installed adjacent to and down-gradient from areas where pesticides were applied. These monitoring well sites were selected based on the vulnerability of ground water to risk of contamination from use of pesticides. Monitoring of disulfoton residues were conducted in the five counties where disulfoton use was reported. There were no detections of disulfoton residues, including the sulfone and sulfoxide degradates, in any of the samples collected in the study.

***Modeling***

Groundwater DWECs for disulfoton and its degradates were estimated using the Tier I SCI-GROW screening-level model. The Agency used a scenario where disulfoton was applied to potatoes once per season at a rate of 3 lb ai/A to generate a high-end to bounding estimate of disulfoton concentration in ground water. The resultant DWEC of disulfoton parent in groundwater was 0.02 ppb, and the DWEC of total disulfoton residues (parent + degradates) was 1.2 ppb.

The SCI-GROW model used various environmental fate parameters as inputs, including the half-life of total disulfoton residues and an average $K_{oc}$ value of 551 mL/g for parent disulfoton. The $K_{oc}$ value is an estimate of the mobility of a chemical in soil. Because the degradates are persistent, and because the Agency does not have adequate data to fully understand the environmental fate of the degradates, EPA assumed a 259 day half-life derived from the 90$^{th}$ percentile upper confidence limit of the mean aerobic soil half-life as an input in the SCI-GROW model. In comparison, the 90$^{th}$ percentile upper confidence limit of the mean aerobic soil half-life for parent alone is 6.12 days. Provided the confirmatory fate data demonstrate that the mobility of the degradates is less than the parent, the DWECs predicted by

the SCI-GROW model would not be underestimates.

### 3. Residential and Occupational Risk

Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational or residential exposure comes to a NOAEL.

Occupational workers, such as individual farmers or custom applicators, can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Risk for all of these potentially exposed populations is also measured by an MOE. For disulfoton, MOEs greater than 100 are not of concern to the Agency for both residential and occupational exposure.

The occupational and residential risk assessments are summarized herein; for more details, see the following documents: *Risk Assessment and Reregistration Eligibility Decision (RED) Documents for Disulfoton (Revised Risk Assessment, Phase 4)*, February 10, 2000; *Disulfoton: Revised (3rd) Report of the Hazard Identification Assessment Review Committee,* April 10, 2001; *Revised Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) Documents for Disulfoton,* May 31, 2001 and addendum, August 9, 2002; *Review and Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds*, June 6, 2001; *Revised Occupational Exposure Assessment for the Reregistration Eligibility Decision Document for Disulfoton,* June 15, 2001; *Health Effects Division Toxicity Chapter for Reregistration Eligibility Decision (RED),* June 25, 2001; and *Disulfoton: Aggregate Risk Assessment*, March 6, 2002. All of these documents are available in the public docket and on the internet.

#### a. Toxicity

All risk calculations are based on the most current toxicity information available for disulfoton. The toxicological endpoints and other factors used in the residential and occupational risk assessments for disulfoton are listed in Table 6.

**Table 6. Toxicological Endpoints for Residential and Occupational Risk Assessment**

| Route and Duration of Exposure | Toxicological Endpoint and Dose | Study | Percent Absorption |
|---|---|---|---|
| Dermal Short-Term (one day to one month) | NOAEL = 0.5 mg/kg/day, LOAEL = 1.0 mg/kg/day, based on plasma and brain cholinesterase inhibition after 3 days of dosing | 3-day rat dermal study on 1% granular product (MRID 45239602) | N/A |
| Incidental Ingestion by Children, Short Term (one day to one month) | NOAEL = 0.03 mg/kg/day, LOAEL = 0.06 mg/kg/day, based on plasma, red blood cell, and brain cholinesterase inhibition in female rats | Special 6-month dietary cholinesterase study in rats (MRID 43058401) | N/A |
| Dermal Intermediate-Term (one month to several months) | NOAEL = 0.03 mg/kg/day; LOAEL = 0.06 mg/kg/day, based on plasma, red blood cell, and brain cholinesterase inhibition in female rats | Special 6-month dietary study in rats to measure cholinesterase inhibition (MRID 43058401), supported by 2-generation reproductive toxicity study | 36† |
| Inhalation (any time duration) | NOAEL = 0.045 mg/kg/day LOAEL = 0.39 mg/kg/day, based on plasma, red blood cell, and brain cholinesterase inhibition | 90-day inhalation toxicity study in the rat (MRID 41224301) | N/A |

†A dermal absorption factor of 36% (relative to oral absorption) is used in route-to-route extrapolation, and was derived from a dermal absorption study in rats.

When the revised human health risk assessment was conducted for disulfoton, EPA used a period of 1 to 7 days to assess short-term exposure, and a period from 7 days to several months to assess intermediate term exposure. Consequently, both short- and intermediate-term exposure and risk were assessed for disulfoton. On June 6, 2001, the Agency revised its approach and now uses a short-term exposure duration of 1 day to 1 month, and an intermediate-term exposure duration of 1 to 6 months. Because disulfoton applications are generally made only pre-plant or at-plant, and specify only one application per year, it is reasonable to believe that handlers will not treat crops with disulfoton for a duration of more than one month; hence intermediate (1-6 months) and also chronic (> 6 months) occupational exposures to disulfoton are not expected to occur. Even though a few sites allow more than one application per crop or per year (i.e., asparagus, barley, potatoes, wheat), current labels specify discrete time intervals between applications, thus it is expected that commercial applicators would not be exposed for more than 14 days and therefore would not receive intermediate or long-term (chronic) exposures.

In the February 2000 human health risk assessment, EPA used a NOAEL of 0.5 mg/kg/day from a 21-day dermal toxicity study in rabbits to assess risk to occupational and residential handlers from short-term exposure. Subsequently, the technical registrant submitted data from a 3-day dermal toxicity study in the rat, and that study's NOAEL of 0.4 mg/kg/day was chosen to assess risk from short-term exposure. The rat is considered to be a more sensitive species than the rabbit to the toxicological effects of disulfoton. Although the 3-day dermal

toxicity study in the rat is acceptable to assess residential exposure, because residential exposure is expected to be less than 3 days, it may underestimate short-term (one day to one month) exposure to commercial handlers, who could be exposed for up to 14 days. Therefore, a 21-day dermal study in the rat is required as part of the IRED as confirmatory data to better characterize risk to commercial handlers. Until the 21-day study is received, the dermal short-term occupational assessment for commercial handlers will be based on the 3-day study, which may underestimate potential risk, but is more appropriate to use than the available six-month oral rat study, which will most likely overestimate exposure to commercial handlers.

The results of the acute toxicity studies with disulfoton are listed in Table 7. Disulfoton is classified as Toxicity Category I for all acute endpoints.

**Table 7. Acute Toxicity Categories for Disulfoton**

| Guideline Number | Study | MRID Number | Results | Toxicity Category |
|---|---|---|---|---|
| 81-1 | acute oral | 139595 | $LD_{50}$ = Male: 6.2 mg/kg<br>$LD_{50}$ = Female: 1.9 mg/kg | I |
| 81-2 | acute dermal | 139595 | $LD_{50}$ = Male: 15.9 mg/kg<br>$LD_{50}$ = Female: 3.6 mg/kg | I |
| 81-3 | acute inhalation | 147754 | $LC_{50}$ = Male: 0.06 mg/L<br>$LC_{50}$ = Female: 0.89 mg/L | I |
| 81-4 | eye irritation | Waived | Data requirement waived because disulfoton was too toxic to test; EPA assumed results | severe eye irritant |
| 81-5 | dermal irritation | Waived | | severe skin irritant |
| 81-6 | dermal sensitization | Waived | | severe sensitizer |

### b. Residential Risk Assessment

***Residential Uses of Disulfoton***

Current residential uses of disulfoton include small flower gardens, ornamental flowers and shrubs, including rose bushes and small trees, and outdoor potted plants. Bayer, the technical registrant, is only supporting a 1% granular homeowner product for reregistration: Bayer Advanced 2-in-1 Systemic Rose and Flower Care (EPA Reg. No. 3125-152), which is packaged in small (2 or 5 lb) containers and labeled for spot treatment only. Bayer voluntarily canceled Di-Syston Systemic Insecticide for Vegetables (EPA Reg. No. 3125-126), effective October 23, 2000, and has deleted all indoor uses, including greenhouse use. However, at the present time, other registrants are producing and selling various granular formulations (1-2% ai) registered for a variety of indoor and outdoor residential uses. Therefore, the Agency has evaluated potential exposure and risk from residential uses of disulfoton.

At present, disulfoton can be applied by hand to potted plants, ornamentals, flowers, and rose bushes. When disulfoton is applied by hand, granular product is typically distributed at the base of the plant or shrub to be treated using a measuring cup, shaker can, or spoon, followed by soil incorporation or watering. Disulfoton can also be applied by belly grinder or push-type spreader when treatment is made prior to planting. Application rates for products containing disulfoton labeled for residential garden use were converted to units of pounds ai per area treated to simplify the residential exposure assessment.

***Residential Applicator Assessment***

For homeowner exposure assessments, the Agency does not consider personal protective equipment (PPE). Homeowners often lack access to PPE and do not possess expertise in the proper use of PPE. Also, PPE requirements for homeowners are difficult to enforce. As a result, homeowner assessments are completed using a single scenario based on the use of short-sleeved shirts, short pants, and shoes and socks, which are common homeowner attire during the pesticide application season. In addition, only short-term exposures were assessed, as the Agency does not believe homeowners who apply disulfoton will be exposed for more than 30 days. The exposure scenarios included the following:

- Loading/Applying Granulars with a Belly Grinder,
- Loading/Applying Granulars with a Push Type Spreader,
- Loading/Applying Granulars with a Spoon, Shaker Can, Measuring Scoop, or by Hand,
- Loading/Applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care by Hand Using a Measuring Cup/Lid, and
- Applying Insecticidal Spikes.

The residential exposure assessment was conducted using chemical-specific exposure monitoring data for the 1% granular product (MRID 45333401) and generic exposure monitoring data from three sources: push-type spreader study conducted by the Outdoor Residential Exposure Task Force (ORETF); proprietary exposure monitoring data for another granular pesticide; and generic exposure monitoring data from Pesticide Handlers Exposure Data (PHED). EPA assumed that home gardeners could treat as many as 25 shrubs, 50 rose bushes, or 20 potted plants in a given day. The Agency also assumed that the area of a garden treated with disulfoton would be 1000 $ft^2$. As indicated in Table 6, the residential risk assessment was based on a dermal short-term NOAEL of 0.5 mg/kg/day and an inhalation NOAEL of 0.045 mg/kg/day.

Residential risk for each scenario is expressed as a MOE, and is summarized in Table 8. For disulfoton, residential risks with MOEs less than 100 are of concern. Combined (dermal + inhalation) residential MOEs for currently registered residential uses of disulfoton range from

1.1 to 1900.

**Table 8. Homeowner Short-Term Risks from Disulfoton**

| Exposure Scenario | Crop Type | Amount Handled/ Day | Maximum Application Rate | Dermal MOE | Inhalation MOE | Combined MOE |
|---|---|---|---|---|---|---|
| Loading/ applying granulars using a belly grinder | Flower Gardens (pre-planting) | 1,000 $ft^2$ | 0.3 lb ai/1000 $ft^2$ | 1.1 | 170 | 1.1 |
| Loading/ applying granulars using a push-type spreader | Flower Gardens | 1,000 $ft^2$ | 0.3 lb ai/1,000 $ft^2$ | 172 | 1.2E4 | 170 |
| | Ornamental Shrubs/ Small Trees | 25 shrubs | 0.01 lb ai/4 ft shrub | 210 | 1.4E4 | 200 |
| | Roses | 50 bushes | 0.00126 lb ai/bush | 820 | 5.5E4 | 810 |
| Loading/ applying granulars using a spoon, measuring scoop, shaker can, or by hand | Flower Gardens | 1,000 $ft^2$ | 0.3 lb ai/1,000 $ft^2$ | 34 | 2.3E5 | 34 |
| | Ornamental Shrubs/ Small Trees | 25 shrubs | 0.01 lb ai/4 ft shrub | 41 | 2.8E5 | 41 |
| | Outdoor Potted Plants | 20 pots | 0.00034 lb ai/6" pot | 1500 | 1.0E7 | 1500 |
| | Roses | 50 bushes | 0.00126 lb ai/bush | 160 | 1.1E6 | 160 |
| Loading/ applying Bayer Advanced. Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granulars using a measuring cup/lid | Flowerbeds | 1000 $ft^2$ | 0.21 lb ai/1000 $ft^2$ | 5600 | 1.2E3 | 960 |
| | Shrubs | 25 shrubs | 0.01 lb ai/4 ft shrub | 1500 | 9.7E2 | 490 |
| | Roses | 50 bushes | 0.0013 lb ai/bush | 5900 | 3.7E3 | 1900 |
| Applying insecticidal spikes | Roses/Trees | No Data | No Data | No Data | No Data | No Data |

***Residential Post-Application Assessment***

Disulfoton can be used on flower gardens, roses, bushes, trees, and other ornamentals where exposure to adults and children may occur after the granular is applied. Potential post-application exposure can occur during transplanting garden flowers, ornamental shrubs, and trees. Potential exposure can also occur from non-harvest activities, such as weeding and from incidental soil ingestion by toddlers from hand-to-mouth exposure.

The Agency assessed post-application exposure to toddlers, because this is expected to be a worst-case scenario for which EPA has data. EPA used surrogate data to assess exposure and assumed that 20% of the amount of disulfoton applied is found in the uppermost 1 centimeter of soil on the day of application. Soil ingestion was assumed to be 100 mg/day for a 15 kg child. EPA assumed that 1% granular disulfoton was applied at the maximum rate of 13 lbs ai/A (to flowerbeds) and soil incorporated. Using these conservative assumptions, the Agency estimated a MOE of 230 for a toddler from hand-to-mouth exposure on the day of treatment. Because the MOE is greater than 100, EPA does not have a risk concern for toddler hand-to-mouth or any other residential post-application exposure to disulfoton.

### c. Aggregate Risk

Aggregate risk considers the combined exposures from food, drinking water, residential and other non-occupational uses of a pesticide. For disulfoton, the aggregate risk considers food, drinking water, and residential exposures. There are no other disulfoton non-occupational exposures, such as use on golf courses, which would contribute to aggregate risk. Based on these sources of exposure, acute, chronic, and short-term aggregate exposure and risk assessments were conducted for disulfoton. Results of the aggregate risk assessment are summarized here, and are discussed extensively in the document *Disulfoton: Aggregate Risk Assessment*, March 6, 2002, which is available in the public docket and on the internet.

To determine the maximum contribution of disulfoton from water in the diet, the Agency first looks at how much of the overall risk is contributed by food and residential use, and then determines a drinking water level of comparison (DWLOC) to determine whether modeled or monitored water concentrations exceed this value. The Agency uses the DWLOC as a surrogate measure of risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with other sources of ambient exposure, such as residential use, does not exceed a level of concern. The DWLOC is then compared with the DWEC to determine whether there is a potential concern for aggregate exposure and risk. When the DWEC is less than the DWLOC, the Agency can make a determination of safety for aggregate exposure. When the DWEC is greater than the DWLOC, the Agency may not be able to make a determination of safety. EPA may also require additional data concerning potential water contamination. However, in certain situations where the DWEC is not significantly greater than the DWLOC, EPA may be able to conclude that existing uses do not present a risk concern, depending on the nature and conservatism of the assessment used. On December 3, 2001, EPA released its preliminary assessment of cumulative risks of OP pesticides, which included a probabilistic drinking water assessment for OP pesticides that may allow EPA to refine the nature of the risk. The preliminary results of that assessment suggest that risk from drinking water exposure to disulfoton and other OP pesticides may in fact be lower than the modeled estimates.

Acute and chronic aggregate risk for disulfoton included only food and drinking water sources of exposure. Short-term aggregate risk included food, drinking water, and residential exposure. A comparison of DWLOCs with the DWECs is given in Table 9. Only the DWLOCs

associated with children 1-6 years old are presented in Table 9, because this is the most highly exposed population subgroup, which results in the lowest and most protective DWLOC for acute, chronic, and short-term sources of exposure. As indicated in Table 9, the peak (acute) surface water DWECs are less than the acute DWLOC for all crop scenarios and are not of concern, except for disulfoton use on barley and potatoes (east of the Rockies). The average surface water DWECs are greater than the chronic DWLOC for all scenarios and are of potential concern. Also, the average surface water DWECs are less than the short-term DWLOC for all scenarios and are not of concern, except for disulfoton use on potatoes (east of the Rockies). For purposes of comparison, EPA included a conservative, high-end scenario for cotton with a PCA of 87% to represent the remaining minor crops. The peak surface water DWEC for this alternate cotton scenario is comparable to the highest peak surface water DWEC of the scenarios listed in Table 9; therefore, the peak DWEC of 39.0 ppb should be used to evaluate drinking water risks for all registered crops. Also, the ground water DWEC is less than the DWLOCs for all exposures, and is therefore not of concern.

**Table 9. Aggregate Comparison of DWLOCs with DWECs**

| Crops | Application Type | DWECs (ppb)* | | | DWLOCs (ppb) (Children 1-6 yrs) | | |
|---|---|---|---|---|---|---|---|
| | | Surface Water | | Ground Water | | | |
| | | Peak | Avg** | | Acute | Chronic | Short-Term |
| Barley | foliar (liquid) | 34.5 | 7.6 | 1.2 | 23 | 1.3 | 14 |
| | soil (granular) | 39.0 | 10.0 | | | | |
| Cotton | soil (granular) | 12.6 | 2.0 | | | | |
| Potatoes | soil (granular) | 12.5 | 4.8 | | | | |
| | foliar (liquid) East of Rockies | 34.4 | 16.7 | | | | |
| Wheat | foliar (liquid) | 8.0 | 2.4 | | | | |

* DWECs include disulfoton parent and degradates

** Average DWECs are compared to both chronic and short-term DWLOCs

### d. Occupational Risk Assessment

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of disulfoton include: individual farmers or growers who mix, load, and/or apply pesticides, *and* professional or custom agricultural applicators. Risk to potentially exposed workers is measured by a Margin of Exposure (MOE). For disulfoton, occupational MOEs greater than 100 are not of risk concern to the Agency.

*Occupational Exposure*

EPA assessed occupational exposure to disulfoton using the PHED Version 1.1; ORETF data; and proprietary data, including chemical-specific data submitted by the technical registrant for disulfoton. In addition, standard default assumptions about average body weight, work day, and area treated daily were used to calculate risk estimates. Application rates used in this assessment are derived directly from current disulfoton labels. Worker exposure and risk estimates are based on the best data currently available to the Agency. The quality of the data used for each scenario assessed is discussed in the occupational and residential exposure assessment for disulfoton, which is available on the internet and in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. The current labels specify application rates of 3.75 to 7.5 grams product per foot of height for a tree or shrub; 2.5 oz product per inch of trunk diameter measured 4 feet from the ground for trees; and 5 lb product per 1000 ft of row for field grown plants. For purposes of risk assessment, the Agency has converted the rates on ornamentals to 37 lb ai/A for trees, 109 lb ai/A for shrubs, and 29 lb ai/A for field grown ornamental flowers and groundcover. The Agency typically uses values for acres treated per day that are thought to represent 8 hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures in a tiered approach to determine the level of personal protective equipment necessary to obtain appropriate MOEs. The lowest level (baseline) of personal protective equipment (PPE) includes long sleeve shirts, long pants, shoes, and socks. A single layer of PPE includes the addition of chemical-resistant gloves to the standard attire of long sleeves, long pants, shoes, and socks. A respirator may also be added if there is a concern for inhalation exposure. If MOEs at that level of PPE are less than 100, increasing levels of PPE are applied (i.e., coveralls are added to provide a double layer of protective clothing). If MOEs are still less than 100 with a double layer of PPE, then engineering controls are applied. The typical disulfoton label specifies maximum PPE for agricultural products. The types of protection, including PPE and engineering controls that were used to calculate occupational exposure from disulfoton include the following:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline clothing, plus chemical-resistant gloves, with or without a dust/mist respirator.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, plus chemical-resistant gloves, with and without a dust/mist respirator.
- Engineering Controls: Closed mixing/loading systems for liquids (mechanical closed mixing/loading or transfer systems); Closed loading systems for granulars (Smartbox® or LockNLoad®);

Enclosed Cockpits or Enclosed Cabs with or without inhalation protection (air filtration).

Disulfoton is not expected to be used on an intermediate (greater than one month) or long-term basis; therefore, the occupational exposure assessment is based on the redefined short-term duration (one day to one month). The Agency considers the tasks performed by a pesticide worker, pesticide formulation, application method, application rate, and area treated per day in assessing occupational exposure. EPA considers both direct and indirect (or secondary) exposure and risk that may result from the use of the pesticide, such as handlers not directly involved in mixing/loading or applying the chemical.

***Handler Risk***

Inhalation and dermal exposure to disulfoton can result from occupational use. The Agency assessed dermal and inhalation risks (MOEs) for each crop currently registered for disulfoton. For disulfoton, occupational MOEs greater than 100 are not of risk concern to the Agency.

As summarized in Table 10, occupational risks are of concern (i.e., MOEs < 100) for all scenarios, even with the use of maximum PPE (i.e, double layer clothing, gloves, and a respirator). Handler risks are of concern for many scenarios with engineering controls, even at a level that provides protection from inhalation exposure (closed mixing/loading, enclosed cabs, with air filtration or dust/mist respirator). Engineering controls with inhalation protection are considered to be the maximum feasible risk mitigation. For handlers wearing the maximum PPE and using the standard assumptions for acres treated per day, MOEs range from 1.1 to 61 for mixer/loaders, from 1.2 to 69 for applicators, and from <1 to 9100 for mixers/loaders/applicators. For handlers using engineering controls and using the standard assumptions for acres treated per day, MOEs range from 3.1 to 800 for mixer/loaders and from 1.8 to 160 for applicators. The route of exposure that significantly contributes to the risk (risk driver) depends upon the formulation used, the worker activity, and the level of protective equipment or engineering controls.

The Agency is also aware that disulfoton is applied to Christmas trees (Fraser fir) in North Carolina with a motorcycle or all-terrain vehicle equipped with a spreader. However, no data are available to assess this scenario. To assess occupational risks associated with this type of equipment, EPA has included this scenario under the assessment for a tractor drawn spreader. Because EPA believes that use of the tractor drawn spreader data results in an overestimate of actual exposure, the Agency is requiring confirmatory exposure data for the motorcycle or all-terrain vehicle spreader as part of this IRED.

**Table 10. Occupational Risk Summary for Disulfoton**

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| Asparagus (SLN only) | Mixing/loading liquid formulation for aerial application | 1 lb/A & 350A | 0.034 | 2.8 | 3.9 | 3.3 | 5.1 | 4.6 | 11 |
| | Applying sprays with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 17 |
| | Flagging for aerial spray applications | | 6.7 | PPE Not Applicable | | 7.2 No Gloves | 9.3 No Gloves | 24 | 340 |
| | Mixing/loading liquid formulation for groundboom application | 1 lb/A & 80A | 0.15 | 12 | 17 | 14 | 22 | 20 | 46 |
| | Applying sprays with groundboom equipment | | 20 | 20 | 28 | 23 | 35 | 33 | 80 |
| Barley | Mixing/loading liquid formulation for aerial application | 1 lb/A & 1200 A | 0.01 | 0.8 | 1.1 | 0.96 | 1.5 | 1.3 | 3.1 |
| | Applying sprays with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 5.1 |
| | Flagging for aerial spray applications | 1 lb/A & 1200A | 2 | PPE Not Applicable | | 2.1 No Gloves | 2.7 No Gloves | 7.1 | 98 |
| | | 1 lb/A & 350A | 6.7 | PPE Not Applicable | | 7.2 No Gloves | 9.3 No Gloves | 24 | 340 |
| | Loading granular formulation for aerial application | 1 lb/A & 1200A | 1.1 | 1.1 | 2.7 | 1.3 | 4.1 | Not Feasible | 53 |
| | Applying granular with aircraft | 1 lb/A & 1200 A | No Data to Complete Assessment | | | | | Not Feasible | 1.8 |
| | Flagging for aerial granular application | 1 lb/A & 1200 A | 6.5 | PPE Not Applicable | | 8.9 No Gloves | 15 No Gloves | 17 | 330 |
| | Mixing/loading liquid formulation for groundboom application | 1 lb/A & 200A | 0.06 | 5.8 | 8.9 | 4.8 | 6.8 | 8 | 18 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Applying sprays with groundboom equipment | | 7.9 | 7.9 | 11 | 9.1 | 14 | 13 | 32 |
| | Loading granular formulations for ground application | 1 lb/A & 200A | 6.4 | 6.8 | 16 | 7.9 | 24 | Not Feasible | 320 |
| | Applying granules with tractor-drawn spreader | | 7.5 | 8.5 | 18 | 10 | 25 | 11 | 39 |
| Wheat | Mixing/loading liquid formulation for aerial application | 0.75 lb/A & 1200A | 0.013 | 1.1 | 1.5 | 1.3 | 2 | 1.8 | 4.1 |
| | Applying sprays with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 6.8 |
| | Flagging for aerial spray applications | 0.75 lb/A & 1200A | 2.6 | PPE Not Applicable | | 2.8 N o Gloves | 3.6 No Gloves | 9.5 | 130 |
| | | 0.75 lb/A & 350A | 9 | PPE Not Applicable | | 9.6 No Gloves | 12 No Gloves | 32 | 450 |
| | Loading granular formulation for aerial application | 1 lb/A & 1200A | 1.1 | 1.1 | 2.7 | 1.3 | 4.1 | Not Feasible | 53 |
| | Applying granular with aircraft | 1 lb/A & 1200A | No Data to Complete Assessment | | | | | Not Feasible | 1.8 |
| | Flagging for aerial granular application | 1 lb/A & 1200A | 6.5 | PPE Not Applicable | | 8.9 No Gloves | 15 No Gloves | 17 | 330 |
| | | 1 lb/A & 350A | 5.6 | PPE Not Applicable | | 7.7 No Gloves | 13 No Gloves | 15 | 280 |
| | Mixing/loading liquid formulation for groundboom application | 1 lb/A & 200A | 0.06 | 4.8 | 6.8 | 5.8 | 8.9 | 8 | 18 |
| | Applying sprays with groundboom equipment | | 7.9 | 7.9 | 11 | 9.1 | 14 | 13 | 32 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Loading granular formulations for ground application | 1 lb/A & 200A | 6.4 | 6.8 | 16 | 7.9 | 24 | Not Feasible | 320 |
| | Applying granules with tractor-drawn spreader | | 7.5 | 8.5 | 18 | 10 | 25 | 11 | 39 |
| Potatoes (foliar) | Mixing/loading liquid formulation for aerial application | 0.5 lb/A & 350A | 0.069 | 5.5 | 7.8 | 6.6 | 10 | 9.1 | 21 |
| | Applying sprays with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 35 |
| | Flagging for aerial spray applications | | 13 | Not Applicable | | 14 No Gloves | 19 No Gloves | 49 | 670 |
| | Mixing/loading/applying liquid formulation through overhead drip irrigation (chemigation) (OR, WA, ID, UT) | 3 lb/A & 350A | 0.011 | 0.92 | 1.3 | 1.1 | 1.7 | 1.5 | 3.5 |
| | Mixing/loading liquid formulation for groundboom application | 0.5 lb/A & 80A | 0.3 | 24 | 34 | 29 | 44 | 40 | 92 |
| | Applying sprays with groundboom equipment | | 39 | 39 | 56 | 46 | 69 | 66 | 160 |
| Potatoes (soil-directed) | Mixing/loading liquid formulation for groundboom application | 3 lb/A & 80A | 0.05 | 4 | 5.7 | 4.8 | 7.4 | 6.6 | 15 |
| | Applying sprays with groundboom equipment | | 6.6 | 6.6 | 9.3 | 7.6 | 12 | 11 | 27 |
| | Loading granular formulations for ground application | 3 lb/A & 80A | 5.3 | 5.7 | 14 | 6.5 | 20 | Not Feasible | 270 |
| | Applying granules with tractor-drawn spreader | | 6.3 | 7.1 | 15 | 8.3 | 21 | 9.4 | 32 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Loading granular formulations for aerial application | 3 lb ai/A & 350A | 1.2 | 1.3 | 3.1 | 1.5 | 4.6 | Not Feasible | 61 |
| | Applying granular with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 2.1 |
| | Flagging for aerial granular applications | | 7.5 | PPE Not Applicable | | 10 No Gloves | 17 No Gloves | 19 | 370 |
| Cotton (SLN) | Mixing/loading liquid formulation for aerial application | 0.2 lb/A & 1200A | 0.05 | 4 | 5.7 | 4.8 | 7.4 | 6.6 | 15 |
| | Applying sprays with aircraft | | No Data to Complete Assessment | | | | | Not Feasible | 25 |
| | Flagging for aerial spray applications | 0.2 lb/A & 1200A | 34 | PPE Not Applicable | | 36 No Gloves | 46 No Gloves | 120 | 1700 |
| | | 0.2 lb/A & 350A | 9.8 | PPE Not Applicable | | 11 No Gloves | 14 No Gloves | 35 | 490 |
| Cotton | Mixing/loading liquid formulation for groundboom application | 1 lb/A & 200A | 0.06 | 4.8 | 6.8 | 5.8 | 8.9 | 8 | 18 |
| | Applying sprays with groundboom equipment | | 7.9 | 7.9 | 11 | 9.1 | 14 | 13 | 32 |
| | Loading granular formulations for ground application | 1 lb/A & 200A | 6.4 | 6.8 | 16 | 7.9 | 24 | Not Feasible | 320 |
| | Applying granules with tractor-drawn spreader | | 7.5 | 8.5 | 18 | 10 | 25 | 11 | 39 |
| Cabbage | Mixing/loading/applying liquid through chemigation | 2 lbs & 350A | 0.017 | 1.4 | 1.9 | 1.6 | 2.5 | 2.3 | 5.3 |
| | Mixing/loading liquid formulation for groundboom application | 2 lb/A & 80A | 0.075 | 6 | 8.5 | 7.2 | 11 | 10 | 23 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Applying sprays with groundboom equipment | | 9.8 | 9.8 | 14 | 11 | 17 | 17 | 40 |
| | Loading granular formulations for ground application | 1.5 lb/A & 80A | 11 | 11 | 27 | 13 | 41 | Not Feasible | 530 |
| | Applying granules with tractor-drawn spreader | | 13 | 14 | 30 | 17 | 42 | 19 | 64 |
| Lettuce | Mixing/loading/applying liquid through chemigation | 2 lbs & 350A | 0.017 | 1.4 | 1.9 | 1.6 | 2.5 | 2.3 | 5.3 |
| | Mixing/loading liquid formulation for groundboom application | 2 lb/A & 80A | 0.075 | 6 | 8.5 | 7.2 | 11 | 10 | 23 |
| | Applying sprays with groundboom equipment | | 9.8 | 9.8 | 14 | 11 | 17 | 17 | 40 |
| Cole Crops (Broccoli, Brussels Sprouts, and Cauliflower) | Mixing/loading/applying liquid through chemigation | 1 lb & 350A | 0.034 | 2.8 | 3.9 | 3.3 | 5.1 | 4.6 | 11 |
| | Mixing/loading liquid formulation for groundboom application | 1 lb/A & 80A | 0.15 | 12 | 17 | 14 | 22 | 20 | 46 |
| | Applying sprays with groundboom equipment | | 20 | 20 | 28 | 23 | 35 | 33 | 80 |
| | Loading granular formulations for ground application | 1 lb/A & 80A | 16 | 17 | 41 | 20 | 61 | Not Feasible | 800 |
| | Applying granules with tractor-drawn spreader | | 19 | 21 | 44 | 25 | 64 | 28 | 96 |
| Beans (snap and lima) | Mixing/loading liquid formulation for groundboom application | 2 lb/A & 80A | 0.075 | 6 | 8.5 | 7.2 | 11 | 10 | 23 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Applying sprays with groundboom equipment | | 9.8 | 9.8 | 14 | 11 | 17 | 17 | 40 |
| | Loading granular formulations for ground application | 1 lb/A & 80A | 16 | 17 | 41 | 20 | 61 | Not Feasible | 800 |
| | Applying granules with tractor-drawn spreader | | 19 | 21 | 44 | 25 | 64 | 28 | 96 |
| Clover grown for seed (SLN) | Loading granular formulations for ground application | 1 lb/A & 80A | 16 | 17 | 41 | 20 | 61 | Not Feasible | 800 |
| | Applying granules with tractor-drawn spreader | | 19 | 21 | 44 | 25 | 64 | 28 | 96 |
| Peppers, Radish grown for seed (SLN) | Mixing/loading liquid formulation for groundboom application | 2 lb/A & 80A | 0.075 | 6 | 8.5 | 7.2 | 11 | 10 | 23 |
| | Applying sprays with groundboom equipment | | 9.8 | 9.8 | 14 | 11 | 17 | 17 | 40 |
| | Loading granular formulations for ground application | 2 lb/A & 80A | 8 | 8.5 | 20 | 9.8 | 30 | Not Feasible | 400 |
| | Applying granules with tractor-drawn spreader | | 9.4 | 11 | 22 | 12 | 32 | 14 | 48 |
| Peanuts | Loading granular formulations for ground application | 2 lb/A & 80A | 8 | 8.5 | 20 | 9.8 | 30 | Not Feasible | 400 |
| | Applying granules with tractor-drawn spreader | | 9.4 | 11 | 22 | 12 | 32 | 14 | 48 |
| | Loading granular formulations for ground application | 1 lb/A & 80A | 16 | 17 | 41 | 20 | 61 | Not Feasible | 800 |
| | Applying granules with tractor-drawn spreader | | 19 | 21 | 44 | 25 | 64 | 28 | 96 |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| Field Grown Ornamental Shrubs | Loading granular formulations for ground application | 109 lb/A & 40A | 0.29 | 0.31 | 0.75 | 0.36 | 1.1 | Not Feasible | 15 |
| | Applying granules with tractor-drawn spreader | | 0.35 | 0.39 | 0.81 | 0.46 | 1.2 | 0.52 | 1.8 |
| | Loading/Applying with Push Type Spreader | 109 lb/A & 5A | 0.15 | 0.21 | 0.27 | 0.33 | 0.51 | Not Feasible | |
| | Loading/Applying with Bellygrinder | 109 lb/A & 1A | 0.03 | 0.032 | 0.034 | 0.05 | 0.055 | Not Feasible | |
| | Loading/Applying with Pump Feed Backpack Spreader | 109 lb/A & 10A | No Data | 0.57 Apron | 1.7 Apron | No Data to Complete Assessment | | Not Feasible | |
| | | 109 lb/A & 5A | No Data | 1.1 Apron | 3.3 Apron | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Gravity Feed Backpack Spreader | 109 lb/A & 10A | No Data | 0.029 | 0.046 | No Data to Complete Assessment | | Not Feasible | |
| | | 109 lb/A & 5A | No Data | 0.059 | 0.092 | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | 109 lb/A & 10A | No Data | 0.013 | 0.015 | No Data to Complete Assessment | | Not Feasible | |
| | | 109 lb/A & 5A | No Data | 0.026 | 0.031 | No Data to Complete Assessment | | Not Feasible | |
| Field Grown Ornamental Trees | Loading granular formulations for ground application | 37 lb/A & 40A | 0.87 | 0.92 | 2.2 | 1.1 | 3.3 | | 43 |
| | Applying granules with tractor-drawn spreader | | 1 | 1.2 | 2.4 | 1.3 | 3.4 | 1.5 | 5.2 |
| | Loading/Applying with Push Type Spreader | 37 lb/A & 5A | 0.44 | 0.62 | 0.8 | 0.98 | 1.5 | Not Feasible | |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Loading/Applying with Bellygrinder | 37 lb/A & 1A | 0.088 | 0.095 | 0.1 | 0.15 | 0.16 | Not Feasible | |
| | Loading/Applying with Pump Feed Backpack Spreader | 37 lb/A & 10A | No Data | 1.7 Apron | 4.9 Apron | No Data to Complete Assessment | | Not Feasible | |
| | | 37 lb/A & 5A | No Data | 3.3 Apron | 9.8 Apron | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Gravity Feed Backpack Spreader | 37 lb/A & 10A | No Data | 0.087 | 0.14 | No Data to Complete Assessment | | Not Feasible | |
| | | 37 lb/A & 5A | No Data | 0.17 | 0.27 | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | 37 lb/A & 10A | No Data | 0.038 | 0.045 | No Data to Complete Assessment | | Not Feasible | |
| | | 37 lb/A & 5A | No Data | 0.076 | 0.09 | No Data to Complete Assessment | | Not Feasible | |
| Field Grown Ornamental Flowers and Groundcover | Loading granular formulations for ground application | 29 lb/A & 40A | 1.1 | 1.2 | 2.8 | 1.4 | 4.2 | Not Feasible | 55 |
| | Applying granules with tractor-drawn spreader | | 1.3 | 1.5 | 3.1 | 1.7 | 4.4 | 2 | 6.6 |
| | Loading/Applying with Push Type Spreader | 29 lb/A & 5A | 0.56 | 0.8 | 1 | 1.2 | 1.9 | Not Feasible | |
| | Loading/Applying with Bellygrinder | 29 lb/A & 1A | 0.11 | 0.12 | 0.13 | 0.19 | 0.21 | Not Feasible | |
| | Loading/Applying with Pump Feed Backpack Spreader | 29 lb/A & 10A | No Data | 2.1 Apron | 6.2 Apron | No Data to Complete Assessment | | Not Feasible | |
| | | 29 lb/A & 5A | No Data | 4.3 Apron | 12 Apron | No Data to Complete Assessment | | Not Feasible | |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | Loading/Applying with Gravity Feed Backpack Spreader | 29 lb/A & 10A | No Data | 0.11 | 0.17 | No Data to Complete Assessment | | Not Feasible | |
| | | 29 lb/A & 5A | No Data | 0.22 | 0.35 | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | 29 lb/A & 10A | No Data | 0.048 | 0.057 | No Data to Complete Assessment | | Not Feasible | |
| | | 29 lb/A & 5A | No Data | 0.097 | 0.11 | No Data to Complete Assessment | | Not Feasible | |
| Field Grown Flowers & Groundcover (lower rate) | Loading granular formulations for ground application | 11 lb/A & 40A | 2.9 | 3.1 | 7.4 | 3.6 | 11 | Not Feasible | 150 |
| | Applying granules with tractor-drawn spreader | | 3.4 | 3.9 | 8.1 | 4.5 | 12 | 5.2 | 18 |
| | Loading/Applying with Push Type Spreader | 11 lb/A & 5A | 1.5 | 2.1 | 2.7 | 3.3 | 5 | Not Feasible | |
| | Loading/Applying with Bellygrinder | 11 lb/A & 1A | 0.3 | 0.32 | 0.34 | 0.5 | 0.55 | Not Feasible | |
| | Loading/Applying with Pump Feed Backpack Spreader | 11 lb/A & 10A | No Data | 5.6 Apron | 16 Apron | No Data to Complete Assessment | | Not Feasible | |
| | | 11 lb/A & 5A | No Data | 11 Apron | 33 Apron | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Gravity Feed Backpack Spreader | 11 lb/A & 10A | No Data | 0.29 | 0.46 | No Data to Complete Assessment | | Not Feasible | |
| | | 11 lb/A & 5A | No Data | 0.58 | 0.91 | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | 11 lb/A & 10A | No Data | 0.13 | 0.15 | No Data to Complete Assessment | | Not Feasible | |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | | 11 lb/A & 5A | No Data | 0.25 | 0.3 | No Data to Complete Assessment | | Not Feasible | |
| Potted Ornamentals | Loading/Applying with Pump Feed Backpack Spreader | 0.2 lb ai/day | No Data | 3100 Apron | 9100 Apron | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Gravity Feed Backpack Spreader | | No Data | 160 | 250 | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | | No Data | 70 | 83 | No Data to Complete Assessment | | Not Feasible | |
| Christmas Trees | Loading granular formulations for ground application | 78 lb/A & 50A | 0.33 | 0.35 | 0.84 | 0.4 | 1.3 | Not Feasible | 16 |
| | Applying granules with tractor-drawn spreader | | 0.39 | 0.44 | 0.91 | 0.51 | 1.3 | 0.58 | 2 |
| | Loading/Applying with Push Type Spreader | 78 lb/A & 5A | 0.21 | 0.3 | 0.38 | 0.46 | 0.71 | Not Feasible | |
| | Loading/Applying with Bellygrinder | 78 lb/A & 1A | 0.042 | 0.045 | 0.048 | 0.07 | 0.077 | Not Feasible | |
| | Loading/Applying with Pump Feed Backpack Spreader | 78 lb/A & 10A | No Data | 0.79 Apron | 2.3 Apron | No Data to Complete Assessment | | Not Feasible | |
| | | 78 lb/A & 5A | No Data | 1.6 Apron | 4.6 Apron | No Data to Complete Assessment | | Not Feasible | |
| | Loading/Applying with Gravity Feed Backpack Spreader | 78 lb/A & 10A | No Data | 0.041 | 0.064 | No Data to Complete Assessment | | Not Feasible | |
| | | 78 lb/A & 5A | No Data | 0.082 | 0.13 | No Data to Complete Assessment | | Not Feasible | Not Feasible |
| | Loading/Applying with Scoop and Bucket | 78 lb/A & 10A | No Data | 0.018 | 0.021 | No Data to Complete Assessment | | Not Feasible | Not Feasible |

| Crop | Handler Scenario | Application Rate & Area Treated | Total Short-Term MOE (UF=100) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Minimum PPE (Gloves) | | Maximum PPE (Gloves + Double Layers) | | Engineering Controls | |
| | | | | No Respirator | Respirator | No Respirator | Respirator | No Inhalation Protection | Inhalation Protection |
| | | 78 lb/A & 5A | No Data | 0.036 | 0.043 | No Data to Complete Assessment | | Not Feasible | Not Feasible |
| Christmas Trees (SLN) | Loading granular formulations for ground application | 4.5 lb/A & 50A | 5.7 | 6 | 15 | 7 | 22 | Not Feasible | 280 |
| | Applying granules with tractor-drawn spreader | | 6.7 | 7.6 | 16 | 8.9 | 23 | 10 | 34 |
| | Loading/Applying with Push Type Spreader | 4.5 lb/A & 5A | 3.6 | 5.1 | 6.6 | 8 | 12 | Not Feasible | |
| | Loading/Applying with Scoop and Bucket | 4.5 lb/A & 10A | No Data | 0.31 | 0.37 | No Data to Complete Assessment | | Not Feasible | |
| | | 4.5 lb/A & 5A | No Data | 0.62 | 0.74 | No Data to Complete Assessment | | Not Feasible | |
| Coffee Trees | Loading granular formulations for ground application | 8.3 lb/A & 80A | 1.9 | 2 | 4.9 | 2.4 | 7.3 | Not Feasible | 96 |
| | Applying granules with tractor-drawn spreader | | 2.3 | 2.6 | 5.3 | 3 | 7.7 | 3.4 | 12 |
| | Loading/Applying with Scoop and Bucket | 8.3 lb/A & 10A | No Data | 0.17 | 0.2 | No Data to Complete Assessment | | Not Feasible | |
| | | 8.3 lb/A & 5A | No Data | 0.34 | 0.4 | No Data to Complete Assessment | | Not Feasible | |

*Post-Application Risks*

The Agency also assessed post-application risks to workers who may be exposed to disulfoton when they enter previously treated fields, because their skin may contact treated surfaces. Exposures are directly related to the kind of tasks performed. EPA estimates the amount of pesticide exposure to post-application workers over time based on various studies. The Agency evaluates this information to determine the number of days following application that must elapse before the pesticide residues dissipate to a level where worker MOEs equal or exceed 100 while wearing baseline attire. Baseline attire is defined as long-sleeved shirt, long pants, shoes and socks. Based on the results of the post-application worker assessment, the Agency establishes restricted entry intervals (REIs) before workers may enter treated areas. At present, the Worker Protection Standard designates the disulfoton REI to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches.

The Agency completed a post-application exposure assessment for disulfoton for the following scenarios: irrigating, scouting, thinning, and weeding immature or low-foliage crops (i.e., asparagus, barley, cotton, potatoes and wheat). The short-term dermal NOAEL of 0.5 mg/kg/day based on a 3-day dermal toxicity study in rats (Table 6) was used to assess potential dermal exposure to workers re-entering treated fields. The post-application assessment is also based on 8 hours of worker daily exposure and the default transfer coefficients (Tcs) shown in Table 11. Although three chemical-specific dislodgeable foliar residue (DFR) studies were conducted for disulfoton, EPA has determined that none of these studies are sufficient for use in the post-application assessment. Therefore, EPA roughly estimated the exposure and risk to post-application workers and handlers using an assumption that 20% of the initial application remained as a DFR immediately following application, and the residue degraded into nontoxic by-products at a rate of 10% per day.

For post-application risks to disulfoton, an MOE of 100 or greater is not of concern to the Agency, and REIs for the assessed crops are determined when the MOE reaches 100. Table 11 summarizes the occupational post-application risks following foliar applications of disulfoton. In summary, for foliar applications of disulfoton, EPA has a post-application risk concern for all crops except cotton.

**Table 11. Occupational Post-Application Risks from Foliar Applications of Disulfoton**

| Crop | Application Rate (lb ai/A) | Tasks of Concern | Timing of Application | Transfer Coefficient | MOE | Days After Treatment |
|---|---|---|---|---|---|---|
| Asparagus | 1.0 | Irrigating, scouting, thinning, weeding immature or low foliage plants | fern stage (3 per year; 120 DTH) | 300 | 6.5 | 1 |
| | | | | | 101 | 26 |
| Barley | 1.0 | | after tillering (30 DTH) | 100 | 20 | 1 |
| | | | | | 105 | 16 |
| Cotton (SLN) | 0.2 | | Before boll opens (30 DTH) | 100 | 108 | 1 |

| Crop | Application Rate (lb ai/A) | Tasks of Concern | Timing of Application | Transfer Coefficient | MOE | Days After Treatment |
|---|---|---|---|---|---|---|
| Potatoes (East of Rockies) | 0.5 | | When pest appears (3 per season; 30 DTH) | 300 | 14 | 1 |
| | | | | | 107 | 20 |
| Potatoes (OR, ID, UT, WA only) | 3.0 | | As needed (1 per season; 60 DTH) | 300 | 2.4 | 1 |
| | | | | | 51 | 30 |
| | | | | | 100 | 37 |
| Wheat | 0.75 | | Post-plant (after tillering; 30 DTH) | 100 | 29 | 1 |
| | | | | | 102 | 13 |
| Wheat (SLN) | 1.0 | | Two per season (30 DTH) | 100 | 20 | 1 |
| | | | | | 105 | 16 |

DTH - Days to harvest

### e. Incident Reports

***Human Incident Reports***

The Agency also reviews any incident data that may be available and applicable. There have been a significant number of occupational poisoning incidents associated with disulfoton, resulting in adverse health effects. Poison Control Center data from 1985 to 1992 indicate that disulfoton ranked third highest among OPs for the percent of individuals hospitalized for occupational poisoning, with 27 individuals hospitalized following exposure to disulfoton alone and 28 individuals hospitalized following exposure to multiple chemicals, including disulfoton. Data from the California Department of Pesticide Regulation show that disulfoton ranked 11$^{th}$ highest in the number of worker poisonings, with 0.22 poisonings per 1000 pesticide applications from 1982 to 1989.

***Pet Incident Reports***

Recent incidents of accidental pet poisonings (dogs) have been reported through the National Pesticide Information Center, NPIC (formerly the National Pesticide Telecommunication Network, NPTN). These incidences have been associated with the 1 and 2% granular products used by homeowners. According to the American Society for the Prevention of Cruelty to Animals, disulfoton is the second most common pesticide associated with veterinary poisonings. Because of its high toxicity, only a small amount is required to poison a cat, dog, or other domestic animal.

## 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 document, *Reregistration Eligibility Decision for Disulfoton*, September 5, 2000 and its addendum March 25, 2002; and *Endangered Species Addendum to EFED's Disulfoton Science Chapter,* January 24, 2002, which are available in the public docket and on the internet.

### 1. Environmental Fate and Transport

In soil, disulfoton is not expected to undergo significant hydrolysis or volatilization. Disulfoton parent photochemically degrades rapidly by sunlight on soil, and in water where light can penetrate. Disulfoton is metabolized or oxidized in soil to the corresponding sulfoxide and sulfone degradates, and the half-life of disulfoton parent in soil is less than 6 days. Field dissipation studies confirm that disulfoton does not persist in the environment. Disulfoton is not considered mobile under convective-dispersive processes, but it has been detected in groundwater monitoring conducted in highly vulnerable areas. The mobility of disulfoton, which can be represented as a $K_{oc}$, ranged from 383 to 888 mL/g carbon with a mean $K_{oc}$ of 551.

Disulfoton's major degradates, disulfoton sulfone and sulfoxide, are more persistent and mobile than the parent. Two aerobic soil metabolism studies showed an average half life of 166 days. In a field study, as much as 35% of the applied disulfoton remained in soil as disulfoton sulfone after 367 days. Thus the sulfone and sulfoxide degradates appear to be much more persistent than parent in soil. The other degradates were either not identified or occurred at much lower concentrations. The Agency is concerned that the sulfoxide and sulfone degradates have a high potential to reach ground and surface water. In field testing, degradates were detected at a depth of 18 inches, indicating potential mobility. The Agency has limited data regarding the persistence of the degradates and lacks the absorption/desorption data necessary to confirm the mobility of the degradates. EPA does not have data on the aerobic or anaerobic aquatic metabolism of disulfoton and its degradates, nor does it have data on the mobility and leaching potential of the degradates. Thus, these data are necessary to confirm the findings in the disulfoton IRED.

### 2. Ecological Risk Assessment

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of disulfoton products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the toxicity endpoint values, such as the median lethal dose ($LD_{50}$) or the median lethal concentration ($LC_{50}$). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicates whether a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. In general, the higher the RQ the greater the concern. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 12.

**Table 12. LOCs and Associated Risk Presumptions**

| IF... | THEN the Agency presumes... |
|---|---|
| *Mammals and Birds* | |
| The acute RQ > LOC of 0.5, | Acute risk |
| The acute RQ >LOC of 0.2, | Risk that may be mitigated through restricted use |
| The acute RQ > LOC of 0.1, | Acute effects may occur in Endangered species |
| The chronic RQ > LOC of 1 | Chronic risk *and*<br>Chronic effects may occur in Endangered species |
| *Fish and Aquatic Invertebrates* | |
| The acute RQ > LOC of 0.5 | Acute risk |
| The acute RQ > LOC of 0.1 | Risk that may be mitigated through restricted use |
| The acute RQ >LOC of 0.05 | Acute effects may occur in Endangered species |
| The chronic RQ > LOC of 1 | Chronic risk *and*<br>Chronic effects may occur in Endangered species |
| *Plants* | |
| The RQ > LOC of 1 | Acute risk and endangered plants may be affected |

### a. Ecological Hazard Profile

The Agency has a robust toxicity database for disulfoton and the two primary degradates, disulfoton sulfoxide and disulfoton sulfone. Data for birds showed disulfoton to be highly to very highly toxic for acute oral gavage testing, and highly toxic for subacute dietary testing. Additionally, the major degradates are moderately to highly toxic to avian species on a dietary basis. The effects in avian reproduction testing included decreased adult and hatchling body weight. The results of small mammal acute oral studies indicated that disulfoton and the sulfone degradate are very highly toxic. Rat reproductive toxicity studies demonstrated decreased litter size, lowered pup survival, and decreased pup weight. Acute contact studies on honey bees showed disulfoton to be moderately toxic to honey bees, while disulfoton sulfone and sulfoxide are very highly toxic.

The laboratory data for freshwater fish indicate that disulfoton is slightly to very highly toxic in acute tests. The two major degradates, disulfoton sulfone and sulfoxide are slightly to highly toxic to freshwater fish on an acute basis. In a fish early life stage test on fresh water fish, disulfoton impacted the growth of fry. For freshwater invertebrates, the results indicate that disulfoton and its degradates are very highly toxic in acute tests, and affects survival, growth, and the number of young/adult in chronic tests. Disulfoton is highly toxic to estuarine fish in acute tests, and in chronic tests, disulfoton impacts the reproduction, as well as larval growth and survival. In testing with estuarine/marine invertebrates, disulfoton is highly to very highly toxic in acute tests, and production and survival of young were adversely affected in chronic tests.

### b. Risk to Birds and Mammals

EPA uses models to estimate exposure of animals to disulfoton. For terrestrial birds and mammals, the Agency estimates peak and average concentrations of pesticide residues over time on various wildlife food items. Acute risk to birds and mammals, including endangered species, were predicted for both the granular and liquid formulations. The Agency estimated chronic risk to birds and mammals from the liquid formulation only, because of the uncertainty in calculating fate and exposure of the active ingredient as the granules dissipate.

The Agency's assessment suggests the potential for the liquid formulation to cause acute and chronic effects to birds and mammals for uses other than soil injection and in-furrow applications. An analysis of the use patterns other than soil injection and in-furrow application indicate that the least risk is from the Texas 24(c) use on cotton and the greatest is from chemigation to potatoes in the Pacific Northwest. Based on peak exposure estimates, the acute RQs for birds range from 0.01 to 2.2 and for mammals from 0.05 to 360. Chronic RQs are calculated from both peak and average concentrations over time. Therefore, chronic RQs for birds range from 0.02 (average for granivores) to 19 (peak for herbivores feeding on short grass). However, the latter RQ declines to 3.4 when based on the average residue value for herbivores feeding on short grass. Using the same scenarios, chronic RQs range from 0.9 (average for granivores) to 900 (peak for herbivores feeding on short grass) with a decrease in the latter value to 158 for average residues in short grass. In summary, except for soil injection and in-furrow applications, all use patterns are of concern to the Agency for acute and chronic effects to birds and mammals, including endangered species.

Birds and mammals may be exposed to granular pesticides by ingesting granules when foraging for food or grit. They also may be further exposed by other routes, such as walking on exposed granules or drinking water contaminated by granules. The Agency's assessment suggests potential for the granular formulation to cause acute risk to birds from a single application at or above the lowest application rate of 1.0 lb ai/A, even when the material is incorporated. The acute RQs for small birds range from 0.1 for the in-furrow, 1 lb ai/A rate on cotton to approximately 75,200 for 78 lb ai/A, unincorporated spot treatment to Christmas trees. For the same use patterns, small mammal acute RQs range from 0.3 to 257,300. However, at a lower application rate of 4.5 lb ai/A to Christmas trees, the highest avian and mammalian RQs are reduced to 4,350 and 14,900, respectively. When the Christmas tree use is excluded, RQs for birds range from 0.1 to 346, and RQs for mammals range from 0.3 to 1184. The highest RQs are associated with use of disulfoton on some commercially grown ornamentals.

The North Carolina Christmas Tree community has submitted numerous testimonials emphasizing the ever increasing numbers and diversity of wildlife, including game animals, such as turkey rearing young amidst the trees, song birds, rodents, and foxes. Although this information is intended to suggest there is little or no negative population impact from disulfoton use in combination with other pesticides or cultural practices as well, documented surveys or research is needed for the Agency to corroborate these conclusions. Although it is not clear whether there are population effects, the risk assessments suggests that there is acute risk to

nontarget birds and mammals exposed to disulfoton.

### c. Risk to Insects

Disulfoton is moderately toxic to honey bees and its sulfoxide and sulfone degradates are highly toxic to bees. A 24-hour residual study on the liquid formulation indicated no toxicity to honey bees following exposure to alfalfa that had been treated 3 hours earlier at a rate of 1.0 lb ai/A. However, there is some uncertainty as to the risk from higher application rates associated with aerial and foliar applications, and from later exposure and longer time periods to the more toxic degradates.

### d. Risk to Aquatic Animals

To assess potential risk to aquatic animals, the Agency uses a computer model to generate EECs of disulfoton in surface water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the index reservoir and percent crop area factor. The index reservoir and percent crop area factor represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EECs used to assess exposure to aquatic animals are not the same as the DWEC values used to assess human dietary exposure from drinking water sources.

#### *Freshwater Fish*

The acute risk level of concern (LOC) to freshwater fish is not exceeded for any use patterns, with RQs ranging from <0.01 to 0.21. When disulfoton is applied at rates greater than or equal to 1.0 lb ai/A, the LOC for restricted use is exceeded. Also, the endangered species LOC is exceeded from either a single, unincorporated application at rates greater than or equal to 0.75 lb ai/A or 2 or more unincorporated applications at 0.2 lbs ai/A. The RQs for chronic risk to freshwater fish are less than or equal to 0.8, and therefore do not exceed the acute LOC. These RQs do not preclude possible fish kills from the use of disulfoton. There are three incident reports of fish kills associated with disulfoton use. However, only one of the three reported fish kills was attributed solely to disulfoton, whereas use of disulfoton and other pesticides were associated with the other two reported fish kills.

#### *Freshwater Invertebrates*

The freshwater invertebrate acute risk is of concern for some disulfoton uses with RQs ranging from <0.01 to 2.1. Similarly, chronic risk is of concern for nearly all modeled sites and application regimes with RQs ranging from <0.01 to 149. For both acute and chronic risks to invertebrates, the highest RQ is based on multiple applications to barley and asparagus. Risks to endangered species are of concern for all uses, except those where disulfoton is applied by soil injection.

The North Carolina Christmas tree industry provided information that has contributed to a refinement of the Agency's risk assessment for aquatic organisms from Christmas tree farming. Specifically, this information indicate limited and localized potential exposure from use of the granular formulation on Christmas trees, and that any estuarine exposure is precluded. Moreover, because the primary aquatic sites adjacent to tree farms are streams and not ponds, disulfoton residues in these streams will be lower and of shorter duration than those that would have been predicted if standard models had been used. In addition, two rapid assessment macro invertebrate surveys of streams in the Western region of North Carolina indicate that when conservation measures associated with Christmas tree farming are implemented, there may be only slight, short-term impact to aquatic macro invertebrates from disulfoton use.

***Estuarine/Marine Fish***

The acute risk to estuarine and marine fish is low with RQs for all modeled crops are less than 0.05. However, there is some uncertainty to these risk estimates due to the limitations of the pond scenario to predict exposure to marine/estuarine organisms, and that the only species tested (i.e., Sheepshead minnow) probably does not represent the true range of sensitivity of marine or estuarine fish.

Modeling and the results of the fish full life-cycle test indicate that only some of the uses on barley and asparagus, if located adjacent to estuaries, may be of chronic risk concern with RQs ranging from 2 to 3. All other modeled uses had RQs less than or equal to 1 and are not of concern. In addition to the previously stated uncertainties, other uncertainties concerning chronic risk are the duration adult fish must be exposed to disulfoton for their reproductive systems to be affected, and when in their reproductive cycle is the impact occurring. For example, even if adults are affected after an exposure of only a week, disulfoton residues may dissipate from an area within several days resulting in little or no chronic risk. Therefore, there is some uncertainty in acute and chronic risk to estuarine and marine fish.

***Estuarine/Marine Invertebrates***

Similar to the risks to estuarine fish, the same uncertainties associated with exposure apply to estuarine invertebrates. Most of the modeled scenarios do not exceed the acute or restricted use criteria for marine and estuarine invertebrates. The RQs range from <0.01 to 0.55, with the highest RQ reflecting multiple applications of the liquid formulation to barley and asparagus. Although nearly all uses result in endangered species risk concerns, currently there are no marine or estuarine invertebrates listed as endangered. The modeled crop scenarios do not show the potential for chronic risk to marine and estuarine invertebrates, except for some uses on cotton, barley, and asparagus, which have RQs between 1.2 and 2.3.

**e. Risk to Plants**

EPA was unable to conduct a risk assessment for nontarget plants due to a lack of test data. Nontarget plant testing was not required in the Registration Standard because disulfoton is

not a herbicide. However, because of phytotoxicity statements on the current Di-Syston 8EC label, the Agency is concerned about potential risk to nontarget plants. Given that disulfoton is applied to growing crops, it is unlikely to result in significant nontarget risks to plants. Confirmatory data are needed to determine the extent of any risk that may exist. To address this concern, Tier I plant toxicity data are required (OPPTS Guidelines 850.4100 and 850.4150).

### f. Risks to Endangered Species

Disulfoton was included in the formal Section 7 consultation with the US Fish and Wildlife Service (USFWS) under the Endangered Species Act for the 1983 cluster reviews for corn, cotton, soybean and sorghum. The Biological Opinion, which is the formal USFWS response, stated that these uses of disulfoton would jeopardize the continued existence of the valley elderberry longhorn beetle, delta green ground beetle, and the Everglade snail kite.

Disulfoton was also included in the reinitiated Biological Opinion of 1989 from the USFWS. In this opinion, the Service found jeopardy to two amphibian species, fifteen species of freshwater fish, and one bird species from the uses on crops and forests. Terrestrial insects were not considered in this opinion. Reasonable and Prudent Alternatives (RPAs) were given for each jeopardized species. Reasonable and Prudent Measures (RPMs) were also given for 35 non-jeopardized species to minimize incidental take of these species. However, the consultations and findings expressed in the two USFWS Opinions 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 RPAs and 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 disulfoton use to Federally listed threatened and endangered species. At that time, the Agency will also consider any regulatory changes recommended in the IRED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to disulfoton at levels of concern.

Recently, the Agency completed a comprehensive preliminary assessment for potential risk to endangered birds and mammals from disulfoton use. Because risks to aquatic species were addressed in the 1989 Biological Opinion, they were not addressed in this assessment. To conduct this assessment, the Agency used information from the Agency's OPP Endangered

Species database, which compares the USDA's Agriculture Census information on crop and county overlap with USFWS information on the location of endangered species to the county level. The results of this assessment are described in detail in the following documents: *Endangered Species Addendum to EFED's Disulfoton Science Chapter,* dated January 24, 2002, and *Puerto Rican Plain Pigeon and Disulfoton*, dated April 23, 2002. This document is available in the public docket and on the internet. This comparison included the use sites and regions identified below, because they comprise the majority of soil surface or foliar use of disulfoton that could potentially affect endangered species that are exposed to such applications. For purposes of endangered and threatened species evaluations, risks below EPA's criteria of concern are considered to be a "no effect." Therefore, a finding of "no concern for risk" is equivalent to a "no effect" for the species.

- Asparagus-- foliar application of liquid in CA and WA
- Barley -- foliar application of liquid in CO, ID, MT and WA
- Christmas trees -- spot broadcast of granular in NC
- Coffee -- spot broadcast of granular in Puerto Rico
- Cotton -- in-furrow application of granular and liquid in LA, MO, OK, NC and SC
- Potatoes -- foliar application of liquid in ID and WA
- Wheat -- foliar application of liquid in KY

The results of a screen of this information and other correspondence are as follows:

- Puerto Rico has no endangered mammals; however, two endangered ground feeding birds, the Yellow shouldered blackbird and Puerto Rican plain pigeon, could potentially consume granules as grit. The Agency's screening level analysis indicated that the Puerto Rican plain pigeon once lived in municipalities where coffee was grown. This is no longer the case. At present, neither of these avian species utilize coffee plantations for habitat or occur near coffee plantations. Therefore, there is no concern for risk for these two species.

- Concerning disulfoton use on barley, only the Mountain plover (a species that is not currently listed as endangered, but is proposed to be listed) would be potentially at risk from ingesting soil invertebrates in soil that has been sprayed directly or received wash off from the foliage. However, the residues would likely be lower on these soil invertebrates than what would be required to cause an adverse effect in the Mountain plover. Like other plovers, the Mountain plover prefers unvegetated, open areas; therefore, if the barley is taller than 3 inches before it is sprayed, there is little likelihood the bird would utilize the field. Since disulfoton is not used until later in the growing season, after the plants are taller, it is exceedingly unlikely that Mountain plovers will be utilizing the treated fields. Therefore, there is no concern for risk to Mountain plovers. There are 14 counties in Colorado and 17 counties in Montana where both barley is grown and the bird may occur.

- There is no county overlap between asparagus grown in Washington and California, and endangered species.

- Carnivorous birds (i.e., owls and eagles) and mammals (i.e., Black-footed ferret, grizzly, Gray wolf and Red wolf) are not at risk, based on secondary poisoning studies on representatives from these two classes. Therefore, there is no concern for risk to these species.

- Bats would not be at risk as they would only be feeding on flying insects from dusk to dawn. Assuming spraying does not occur at those times, bats would not be at risk. Also, bats would not be exposed to granules.

- Concerning Christmas trees grown in North Carolina, in addition to some of the organisms stated above, there are several birds and mammals which, although they could be in or around the vicinity of Christmas tree plantations, are not considered at risk especially from granules. Specifically, because the Wood stork feeds on fish, and the Piping plover resides on sand bars and feeds on aquatic invertebrates, there is no concern for risk to these species.

- Concerning Christmas trees grown in North Carolina, because disulfoton is systemic, there is a slight potential for low, undetermined dietary exposure to the Northern flying squirrel and the Red-cockaded woodpecker. In addition to lichens and fungi, the squirrel consumes insects, buds, and seeds. However as the squirrel is a cavity nester, it prefers deciduous trees to conifers in the same proximity. Its habitat is taller trees, because it has adapted to gliding. The woodpecker requires old living pine trees (at least 60 years) in which to make cavities, and they feed on insects found under the bark in conifers where the trunk is larger and more accessible than in Christmas trees. Therefore, disulfoton use poses no concern for risk to these species.

- Concerning use sites other than Christmas trees and coffee, the following are forest dwellers and/or are not associated with agricultural sites: Northern Idaho Ground squirrel; Marbled murrelet (feeds on fish); Woodland caribou; Brown pelican (feeds on fish); Red-cockaded woodpecker; Carolina northern flying squirrel; Preble's meadow jumping mouse (resides in high elevation meadows); and Wood stork (feeds on fish). Hence, disulfoton use poses no concern for risk to these species.

- Concerning the use sites other than Christmas trees and coffee, disulfoton poses no concern for risk to the following species: the Whooping crane feeds on aquatic invertebrates; the Black capped vireo resides in scrub areas and feeds on flying insects; and the Piping plover resides principally on sand bars and feeds on aquatic invertebrates.

### g. Ecological Incident Reports

Several reports of wildlife poisonings are associated with disulfoton. These poisoning

incidents are summarized in Table 13.

**Table 13. Chronological List of Ecological Incidents for Disulfoton**

| Date | Misuse? | Incident Description |
|---|---|---|
| 6/12/95 | unknown | Johnston County, NC: Fish kill occurred in commercial fish pond. Crop fields nearby treated with pesticides. Water, soil and vegetation samples analyzed for a variety of pesticides. Disulfoton, as well as several other pesticides, was found at 0.2-2.5 ppm in vegetation samples. Possible certainty index for disulfoton. (Incident Report No. I003826-002). |
| 6/14/94 | unknown | Arapahoe, CO: Fish kill following application of Di-Syston EC to wheat just before heavy rain. Water samples contained disulfoton sulfoxide at 29.5-48.7 ppb and disulfoton sulfone at 0.0199-0.214 ppb. (Incident Report No. I001167-001). |
| 1/24/94 | unknown | Puerto Rico: 6 grackles fell dead from a tree in a yard of private residence. Dead heron and owl also found in vicinity. Use site and method not reported. Birds had depressed acetyl cholinesterase. Analysis of GI contents of a grackles showed disulfoton at 2.37 ppm wet weight. Highly probable certainty index for disulfoton. (Incident Report No. I003966-004). |
| 6/18/93 | No | Young County,TX: 18 Swainsons hawks dead, 1 severely disabled in a cotton field. Cotton seed had been treated with disulfoton prior to planting, ~10 days before the birds were discovered. No additional applications of OP or carbamate pesticides made in vicinity of field. Autopsies showed no trauma or disease. Lab analysis showed insect material in GI tracts; this material contained disulfoton (~7 ppm); no other OP or carbamate insecticides were present. Hawks fed on insects, which had been feeding on the young cotton plants, which contained disulfoton residues. (L. Lyon, Div. of Environmental Contaminants, U.S. Fish and Wildlife Service, Arlington, VA.) |
| 6/22/91 | unknown | Onslow County, NC: Fish kill in pond at private residence. Pond received runoff from neighboring tobacco field; pondwater analysis showed disulfoton and several other pesticides, including endosulfan. Disulfoton sulfoxide found in water at 0.32 ppb. Endosulfan had highest concentration (1.2 $\mu$g/L), and is toxic to fish, but disulfoton cannot be ruled out as a possible cause of death. No tissue analysis. Possible certainty index for disulfoton. (Incident Report No. B0000216-025). |
| 4/26/91 | unknown | Sussex County, DE: 9 American robins dead following application of granular disulfoton at tree nursery. Corn and soybeans also in vicinity. No laboratory analysis. Probable certainty index for disulfoton. (Incident Report No. I000116-003). |

## C. Alternatives and Benefits

### 1. Alternatives

Only a limited number of alternative pesticides are available for controlling aphids on agricultural crops. Some pesticides, such as lambda-cyhalothrin have some potential as a disulfoton alternative; however, they also act on beneficial, predatory insects as well as targeted insect pests, and can not be used in Integrated Pest Management (IPM) Programs. Disulfoton can be used in IPM programs because its systemic activity does not target beneficial insects. In addition, lambda-cyhalothrin is a member of the chemical group synthetic pyrethroids, which are prone to resistance problems. Imidacloprid is a potential alternative when used at-plant for

short-lived crops, but this chemical loses its efficacy after 4-5 weeks. Also, imidacloprid is currently more expensive than disulfoton. Other alternatives are other OPs which are also under review. Alternatives for crops representing primary uses are summarized in Table 14.

**Table 14. Registered Alternatives to Disulfoton for Agricultural Crops***

| Crop/Target Pest | Alternative Pesticide (Chemical Class) |
|---|---|
| Asparagus/European Asparagus Aphid | Chlorpyrifos and dimethoate (OPs) |
| Barley/Russian Wheat Aphid, other aphids and thrips | Imidacloprid (Chloronicotinyl), Lambda cyhalothrin (Synthetic pyrethroid, Section 3 registration pending) |
| Cotton/Thrips | Phorate, Aldicarb (OPs) |
| Lima Beans/Thrips | Acephate (OP) |
| Snap Beans/Potato Leafhopper, Thrips | Carbaryl (carbamate), acephate, methomyl, or dimethoate (OPs) |
| Broccoli, Cabbage, Cauliflower & Brussel Sprouts/Cabbage Aphid, other aphids | Chlorpyrifos, Dimethoate, Oxydemeton-methyl (OPs), Imidacloprid (Chloronicotinyl) |
| Bell and Chili Peppers/Green Peach Aphid, Symphylan | Chlorpyrifos, Diazinon, Dimethoate, Malathion, Oxydemeton-methyl (OPs), Imidacloprid (Chloronicotinyl), Pyrethroids |
| Lettuce/Lettuce Root Aphid | Imidacloprid (Chloronicotinyl) |
| Potatoes/Green Peach Aphid, Potato Aphid | Methamidophos, Dimethoate, Malathion (OPs), Pymetrozine (Triazine), Imidacloprid, Thiomethoxam (Chloronicotinyls) |
| Radish (grown for seed)/Cabbage Aphid, Turnip Aphid | Pirimicarb (Carbamate), Chlorpyrifos (OP), Pymetrozine (Triazine) |
| Wheat/Russian Wheat Aphid | Chlorpyrifos, Dimethoate, Malathion, Phorate (OPs), Endosulfan (chlorinated hydrocarbon), Imidacloprid (Chloronicotinyl), Lambda-cyhalothrin (Synthetic pyrethroid), Methomyl (carbamate), Pyrethrins |
| Ornamentals, including shrubs, trees, flowers, groundcover, and potted plants (field or nursery stock) | Imidacloprid, Hexythiazox, Bifenazate, Abamectin, Acephate, Chlorpyrifos (OP), Bifenthrin |
| Coffee Trees/Leafminer | Aldicarb, Azadirachtin (no residual activity) |
| Christmas Trees (Firs) | Chlorpyrifos (OP) |

* Not all alternatives are efficacious; see the following text for details.

### 2. Benefits

The Agency has assessed the benefits of a number of registered uses of disulfoton, including asparagus, barley and wheat, snap and lima beans, cabbage, cole crops, cotton, lettuce, peanuts, peppers, potatoes, radish grown for seed, coffee, ornamentals, and Christmas trees. Because occupation risks were low for disulfoton use on clover grown for seed, benefits

information associated with this use was not collected. A summary of the Agency's benefits findings is presented below; for more information, see the following documents: *Asparagus Benefits Assessment for Disulfoton*, September 11, 2001; *Benefits of Disulfoton on Selected Vegetable Crops and Cotton,* September 27, 2001; *Benefits Assessment for Disulfoton Use on Potatoes and Radish Seed*, September 28, 2001; *Use of Disulfoton on Bell and Pimento Peppers,* November 3, 2001; *Cursory Assessment of Disulfoton Use in Coffee in Puerto Rico,* November 26, 2001; *Response to Questions Concerning Disulfoton Posed by Special Review and Reregistration Division [Regarding Ornamentals]*, December 17, 2001; and *Cursory Analysis of Disulfoton Use on Fraser Fir Christmas Trees in Western North Carolina*, July 9, 2002. All of these documents are available in the public docket and on the internet.

***Asparagus***

Liquid disulfoton is used on asparagus in Arizona, California, North Carolina, Oregon, and Washington. These states have Special Local Need (SLN) registrations under FIFRA Section 24(c). Most disulfoton use on asparagus is in California and Washington; these two states account for 96% of use on this crop. In Washington, 50% of the asparagus crop is treated with disulfoton, and in California, 70% of the crop is treated. Growers in these states have a critical need for Di-Syston 8E. The target pest is the European asparagus aphid, which severely damages asparagus plants and weakens the crowns. Asparagus is a high value perennial crop grown for 10 years or more. The asparagus plants rely on energy produced by vegetative growth and stored in the root crowns to produce the shoots that are harvested the following year. Registered pesticide alternatives are chlorpyrifos and dimethoate, but secondary aphid flare ups occur with chlorpyrifos, and both chlorpyrifos and dimethoate have a short residual half-life. Therefore, none of these alternatives is considered viable. Disulfoton is long lived and spares beneficial insects, preventing secondary flare ups of insect pests.

Disulfoton is applied once or twice a year during the fern stage (after harvest) at a rate of 2 lb ai/A. At this point in the asparagus life cycle, there are no activities (other than pest control) requiring the presence of workers in the fields. Vegetation is up to 5 feet high and wide at this stage of the life cycle, so the rows are virtually impassible. Growers have difficulty getting application equipment into the fields and aerial application is the most feasible method of pesticide application at this stage. The liquid formulation is needed because of its translaminar action; liquid is quickly taken up by foliage where it penetrates the outermost cell layers and spreads out, providing aphid control. Even though the granular also has systemic action, it is not taken up by asparagus roots quickly enough to control aphids. Therefore, the granular formulation is not registered for use on asparagus.

In Washington, 98% of disulfoton used on asparagus is applied aerially for the reason stated above. In California, 65% of disulfoton is applied aerially. The remaining 35% of disulfoton used on asparagus in California is applied by groundboom to the field edges to stave off aphid infestation. Based on the 1977 Agriculture Census from the USDA National Agricultural Statistics Service (NASS), the overall average asparagus farm size in California is 219 acres. Also, for asparagus farms in Washington, no farm is greater than 300 acres, and the

average asparagus farm size is 62 acres. Other sources indicate that the maximum area that can be aerially treated in a day is about 75-150 acres in Washington, and about 150-200 acres in California.

***Barley and Wheat***

Liquid disulfoton is applied by air for late-season control of aphids on barley and wheat as the seed head nears maturity. Nationally, < 1% of crop is treated for both barley and wheat, with most use on malting barley in the states of Idaho, Montana, Colorado, Wyoming, and Washington. Disulfoton use on wheat is limited to a few states, where Kentucky is reported to have the greatest use. The potential alternative for aphid control on these crops is lambda cyhalothrin (Warrior®), which is scheduled for a FIFRA Section 3 registration in 2002. Warrior® is already available in some states as a FIFRA Section 18 registration. There are concerns that, because Warrior® is a pyrethroid, aphids may develop resistence, and a secondary control for resistance management may be needed.

Nearly 50% of all barley produced in the US is marketed as malting barley, which receives a premium price over regular barley. Disulfoton is used primarily on malting barley to control aphids, especially the Russian wheat aphid, to ensure plumpness and fullness of the barley grain. Aphid infestations in barley fields are localized and sporadic, and require immediate control to prevent spreading. Aphid damage to malting barley can result in up to a 50% loss in crop revenue. Approximately 3% of all acres planted in barley experience aphid infestation. In these cases, the liquid formulation of disulfoton is generally applied aerially to localized pockets of aphid infestation. Imidacloprid is registered for late-season control aphids in malting barley, but does not appear to be as effective as disulfoton in controlling aphids by foliar application. However, lambda cyhalothrin (Warrior®), which is expected to be available as a Section 3 registration within the next year, is considered to be the product of choice, because it is recognized as a safer alternative to disulfoton, especially for aerial application due to drift concerns to nearby inhabited areas and adjacent fields. Disulfoton use has been declining in recent years due to the use of Warrior® as the primary tool for aphid control in the states where it is currently used under FIFRA Section 18 registrations.

Disulfoton is used on wheat to control the Barley Yellow Dwarf Virus, which is transmitted by aphids. Ground applications of the liquid are used late-season. In Kentucky, the state with the greatest use, most disulfoton is applied by custom applicators. Lambda cyhalothrin is the main alternative for wheat, which may be more expensive than disulfoton. Other registered alternatives include chlorpyrifos, malathion, methomyl, and pyrethrins.

***Beans, Lima and Snap***

Growers use both liquid and granular formulations of disulfoton for lima and snap beans. Most use on lima beans is in Georgia, with 20-30% of crop treated. Disulfoton is applied at-plant to control thrips. Acephate is currently the only viable alternative for lima beans, and foliar application would be used to control thrips.

Use on snap beans is sporadic in states that produce snap beans and use is declining. Disulfoton is applied at-plant to control potato leaf hopper, an intermittent pest that does not require control every year. Some processing companies will not purchase snap beans treated with a systemic insecticide unless a pest problem requiring such treatment is substantiated by extension agents. Alternatives to disulfoton on snap beans include acephate, carbaryl, methomyl, or dimethoate.

***Cabbage***

Both the liquid and granular formulations are registered for use on cabbage for aphid control. The liquid formulation is shank injected, and the granular formulation is applied as a soil incorporated band or side-dressing. According to USDA NASS data for 2000, 3,400 lb ai of disulfoton was applied that year, with 3% of all cabbage grown nationally being treated with disulfoton. In California, from 1997 to 1999, an average of 3,117 lbs ai of disulfoton was applied to cabbage, primarily in Ventura County. The major advantage of disulfoton over imidacloprid is its long residual activity, which protects cabbage plants for the entire season.

***Cole Crops (Broccoli, Brussels Sprouts, Cauliflower)***

Both the liquid and granular formulations of disulfoton are registered for use on cole crops. The liquid formulation is used exclusively in California's Salinas Valley, whereas the granular formulation is used nationally, wherever cole crops are grown. Liquid disulfoton is applied by shank injection, and is used as a rescue remedy to control cabbage and green peach aphids. Within the Salinas Valley, Monterey County appears to be where the predominant use of the liquid formulation of disulfoton is used. Usage data from 1997 to 1999 for Monterey County, California indicate that as much as 60% of broccoli, 87% of Brussels sprouts, and 52% of cauliflower that was grown was treated with disulfoton. Nationally, less than 3% of the crop was treated in 2000.

Registered alternatives to disulfoton on cole crops include imidacloprid and the OP pesticides oxydemeton-methyl, dimethoate, and chlorpyrifos. Currently, imidacloprid is applied at-plant, but it does not control the cabbage aphid throughout the entire growing season due to its limited period of residual effectiveness. Imidacloprid is not effective as a foliar application. Chlorpyrifos is toxic to beneficial insects and also causes phytotoxicity at the high rates required to control the cabbage aphid.

***Cotton***

Liquid disulfoton is used as a safener to protect cotton seedlings from the effects of the herbicide clomazone (Command®), which is the herbicide of choice to control velvet leaf, primrose, morning glory, and wild poinsettia. The liquid formulation is preferred, because it appears to be both a better safener and more effective than the granular formulation at protecting the cotton seedlings against thrips. Alternatives include phorate and aldicarb. However, phorate, which is applied as a granular formulation, is not as efficacious against thrips. Aldicarb

is very effective against thrips, but does not act as a safener.

Use of disulfoton in cotton has been declining and this decline has been attributed to the introduction of genetically modified glyphosate tolerant (RoundUp-Ready®) cotton. However, the percentage of acreage that can be planted with glyphosate tolerant cotton is limited. Therefore, disulfoton is still important in areas that use clomazone for weed control. Most use is in Louisiana, Missouri, Mississippi, and Texas, with some use in Alabama, Arkansas, Georgia, Florida, Tennessee, the Carolinas, and Virginia.

***Lettuce***

Only the liquid formulation of disulfoton is registered for use on lettuce. Disulfoton is applied preplanting or at planting by banding, sometimes in combination with fertilizer or herbicide. Most iceberg lettuce (96%) and leaf lettuce (97%) grown in the United States is produced in California and Arizona. California treated about 2-3% of the iceberg and 1% of the leaf lettuce acreage with disulfoton in 1999. USDA reported no use of disulfoton in Arizona for the year 2000.

Disulfoton use on lettuce in California is mostly limited to the Salinas Valley, which includes Monterey County. Approximately 59% of the total amount of disulfoton that is used on head lettuce is used in Monterey County, and 57% of the total amount of disulfoton that is used on leaf lettuce is also used in Monterey County. Disulfoton is used in this area primarily to control the lettuce root aphid, which is harbored in Lombardy poplars, a popular ornamental, when other methods fail. California has been actively removing Lombardy poplar trees so that the lettuce root aphid does not have an alternate host. If disulfoton is not used, the main pesticide alternative is imidacloprid, which has short residual activity and therefore does not provide adequate control.

***Peanuts***

Only the granular formulation is registered on peanuts. Thrips are the main target pest, but disulfoton is also used for aphid control. In the year 2000, disulfoton was used in Alabama, Georgia, North Carolina, and Oklahoma. Disulfoton is applied in-furrow or as a soil incorporated side-dressing to control thrips and aphids. Since the time the risk assessment was prepared, Bayer, the technical registrant, had reduced the maximum application rate for the Section 3 registration from 2 lbs ai/A to 1 lb ai/A. Disulfoton is applied once a year at a rate of 1 lb ai/A, except in North Carolina where an SLN registration permits two applications for a seasonal maximum of 2 lbs ai/A.

***Peppers***

Disulfoton is used on chili, bell, and pimento peppers to control the green peach aphid and the garden symphylan, a non-insect pest. Most disulfoton use on peppers is in California and New Mexico. Aphids, especially the green peach aphid, transmit mosaic viruses which kill

pepper plants. The green peach aphid has developed insecticide resistance and is difficult to manage. The green peach aphid prefers shade-grown plants, such as those in the Salinas Valley.

Both liquid and granular formulations are registered for use on peppers. The liquid formulation is registered only in California as a Section 24(c) SLN registration. The liquid is shank injected when the plants are 4-5 weeks old and the aphids have exceeded the economic threshold. There is a FIFRA Section 3 registration for the granular, which is used outside California.

Registered alternatives to disulfoton on peppers include imidacloprid, chlorpyrifos, diazinon, dimethoate, malathion, oxydemeton methyl, and pyrethrins. Neither diazinon nor malathion is effective against the green peach aphid. Dimethoate is an inexpensive, frequently used alternative, but it is no longer effective for aphid control in some areas of California and New Mexico. Chlorpyrifos harms beneficial insects and has been shown to cause phytotoxicity at the rates necessary for aphid control. Although oxydemeton methyl is registered, it is not recommended for use on cole crops. Use of imidacloprid is increasing, but it does not provide effective control in some parts of California. Pyrethroids are not often used because they are not compatible with integrated pest management (IPM) programs.

***Potatoes***

Both the liquid and granular formulations of disulfoton are registered for use on potatoes to control aphids. Based on 1987-1998 usage data, an average of approximately 58,000 acres of potatoes were treated annually, with an average of 4% of the nations potato acreage treated with disulfoton. The liquid is used mainly in the Pacific Northwest (PNW) (i.e., Oregon, Idaho, Washington, and Utah), where it is predominantly applied either aerially or by chemigation (sprinkler irrigation) as an alternative to methamidophos (Monitor®). The liquid is used for late-season aphids control in sensitive areas where growers cannot aerially apply Monitor®. The granular formulation appears to be used mostly outside the PNW, where it is applied to the soil and incorporated.

As mentioned above, the liquid formulation is applied in the PNW by overhead sprinkler irrigation to control aphids. According to the National Potato Council, growers apply disulfoton by chemigation (sprinkler irrigation) when methamidophos (Monitor®), the product of choice, cannot be aerially applied, due to weather conditions or lack of availability of aerial applicators, or for potatoes that are grown next to sensitive areas, where aerial application is an issue. However, the Agency believes that there are a number of other alternative products that are available to control aphids that can be chemigated, such as pymetrozine (Fulfill) and thiamethoxam (Actara), which seem promising, although growers are learning how to use these new chemistries. Further, methamidophos is labeled for application by chemigation. Imidacloprid can also be applied at-plant for control of early to mid season aphid and Colorado potato beetle infestations.

Although growers may view disulfoton as the only cost-effective, reliable, and consistent

aphid material that can be chemigated, the Agency believes the available alternatives are adequate to achieve effective aphid control. Both pymetrozine and thiomethoxam can be applied by chemigation and are effective at late-season aphid control. Further, pymetrozine is less expensive than disulfoton. The average cost of post-emergence foliar treatment for potatoes is about $16.00 per acre for disulfoton and $13.00 per acre for pymetrozine. No data were available for thiomethoxam. Because these two chemicals are relatively new, they have yet to be widely used or accepted by growers; however, efficacy field trials show promising results for aphid control.

In summary, the Agency does not believe that disulfoton is critical to potato growers, because use of disulfoton on potatoes is declining and new, effective alternatives that can be applied by chemigation, the application method that is most critical to growers in the PNW, are now available.

***Radish Grown for Seed***

Both the liquid and granular formulations are registered for use on radish grown for seed in Washington only through a 24(c) SLN registration. As part of this registration, disulfoton use is limited to the Columbia River Basin in Washington to control cabbage and turnip aphids, which cause premature plant death and crop loss. Both formulations are applied to the soil and are either shank injected or soil incorporated. In the year 2000, only about 635 acres total of this crop was produced. Even though it is a minor crop, it is an economically important crop for producers in the Columbia River Basin.

The only registered alternatives available to growers are pirimicarb, chlorpyrifos, and pymetrozine. Pirimicarb is used solely to control late-season aphid infestations; chlorpyrifos cannot be used during bloom when aphids can occur; and pymetrozine is more expensive than disulfoton and does not provide good lower canopy control. Also, disulfoton is also advantageous because it allows predatory and parasitic insects to develop in the seed radish fields.

***Coffee Trees***

Granular disulfoton is registered in Puerto Rico to control leafminers, which can cause up to a 40% reduction in yield in the coffee crop, valued at approximately $30 million. In the year 2000, about 15% of acreage planted in coffee was treated with disulfoton. The current application rate of 8.3 lbs a.i./A is supported by efficacy data. Government sponsored custom applicators broadcast disulfoton by hand, with a bucket and spoon. Growers and agricultural extension staff appear to be receptive to alternative application methods involving closed systems. At present, the only viable alternative is aldicarb. Azadirachtin, a registered alternative, does not have the residual activity needed to control leafminers.

*Christmas Trees*

Disulfoton is used on Christmas trees, on Fraser, Balsam, and other firs, in 16 states including Oregon, Michigan, Washington, Ohio, and Wisconsin. The greatest use is in western North Carolina, where 1,600 growers produced 34 million trees on 24,000 acres in 1996. Two-thirds of North Carolina Christmas tree farms are small, with 10 acres or less in production.

Disulfoton is used to control balsam twig aphid and spruce spider mite, widespread and perennial pests. Disulfoton is used in conjunction with chlorpyrifos and esfenvalerate. Disulfoton is applied at bud break in early spring, followed by foliar applications of chlorpyrifos and esfenvalerate. Disulfoton and esfenvalerate may be alternated if resistance management becomes an issue. Chlorpyrifos and esfenvalerate must be foliarly-applied by a commercial applicator by mist blower or high-powered hose sprayer. Further, the chlorpyrifos foliar spray is phytotoxic in some situations. Foliar applications are problematic, because they are usually uneven, which significantly affects efficacy. Esfenvalerate has the advantage of also controlling balsam wooly adelgid to a limited extent, but the disadvantage of allowing spider mite populations to increase. Disulfoton control of both balsam twig aphid and spruce spider mite is systemic, conserving beneficial insect predators.

Christmas trees are a perennial crop with a 6-10 year growth cycle. The target pests can cause significant cosmetic damage in the last year or two before harvest, leading to a significant decrease in crop value and/or crop loss. Value was $78 million in 1996 and $122 million in 1999. Fraser firs represented 27% of all US grown Christmas trees sold in 1999. Impacts are greatest near harvest when trees may be downgraded for cosmetic damage. Without disulfoton, a significant amount of loss from downgrading and extra application costs would be sustained over the region annually. Disulfoton is important in resistance management and conserving beneficial insects. Disulfoton is an important component of the Fraser fir integrated pest management (IPM) program developed by the North Carolina Agricultural Extension Service and North Carolina State University. The Agency concludes that disulfoton use on Christmas trees, especially Fraser firs grown in the mountains of western North Carolina, is critical to growers.

*Commercially Grown Ornamentals*

The granular formulation is registered for use on shrubs, trees, flowers, and ground covers (field or nursery stock) to control a variety of pests, including aphids, thrips, lacebugs, and mites. The current label rate is up to 7.5 grams per foot of shrub height or 2.5 oz per trunk diameter of trees, which is extrapolated to 109 lbs ai/A. The nursery industry claims to need a minimum rate of 13 lbs ai/A; however, EPA can not substantiate this rate for all uses. Available data show use of ≤6 lbs ai/A in California and 13 lbs ai/A on hollies and birches in New York, with 2% of the production area treated. Disulfoton is applied by broadcast or soil injection. According to preliminary data from a USDA NASS floriculture survey, very little disulfoton is used on ornamentals. Of 4,000 operations surveyed, only 22 operations reported using disulfoton. After extensive research and contacting all major stakeholders, including the

American Nursery and Landscape Association, Rutgers's IR4, and state departments of agriculture, EPA has found only small pockets of use. Further, many agricultural extension agents who work with ornamentals do not recommend the use of disulfoton. Alternatives are available, including imidacloprid, abamectin, acephate, bifenthrin, and chlorpyrifos. Therefore, the Agency concludes that on a national basis, there is not a critical need for disulfoton use on ornamentals grown for field or nursery stock.

## IV. Interim Risk Management and Reregistration Decision

### A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient disulfoton, as well as a disulfoton-specific dietary risk assessment that has not considered the cumulative effects of OPs as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient disulfoton, EPA has sufficient information on the human health and ecological effects of disulfoton to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that products containing disulfoton are eligible for reregistration provided that (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures, including the phase out of disulfoton use on barley, wheat, potatoes, and ornamentals by June 2005; (iii) cumulative risks considered for the OPs support a final reregistration eligibility decision; and tolerances are issued (if appropriate) for commodities lacking tolerances as identified in the tolerance summary.

As part of the Agency's ongoing process to review and take the necessary risk reduction measures as required by FQPA, on December 4, 2001, EPA released the preliminary cumulative risk assessment for OP pesticides for public comment. That assessment is based on evaluation of the potential exposure of 31 total OP pesticides from eating food, drinking water, and residential sources. The assessment also takes into account EPA's past regulatory actions on various pesticides, such as eliminating uses. Continuing the effort to ensure transparency of decision processes, EPA conducted a technical briefing and presented the assessment to the Scientific Advisory Panel for peer review and comment. The Agency intends to release a revised cumulative risk assessment during the summer of 2002.

Although the Agency has not yet considered its final cumulative risk assessment for the OPs, the Agency is issuing this interim decision now in order to identify risk reduction measures that are necessary to support continued use of disulfoton. Based on its current evaluation of disulfoton alone, the Agency has determined that disulfoton 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 disulfoton.

At the time that the cumulative assessment is considered, the Agency will address any

outstanding risk concerns. For disulfoton, if all changes outlined in this document are incorporated into the labels, then all currently identified risks will be mitigated. But, because this is an IRED, the Agency may take further actions, if warranted, to finalize the RED for disulfoton after considering the cumulative risk of the OP class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each OP pesticide in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the OPs in as timely a manner as possible.

Because the Agency has not yet considered the cumulative risks for the OPs, this IRED does not fully satisfy the reassessment requirement for existing disulfoton food residue tolerances as called for by FQPA. When the Agency has considered cumulative risks, disulfoton tolerances will be reassessed in that light. At that time, the Agency will reassess disulfoton along with the other OP pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this IRED and requesting mitigation measures now for the individual chemical disulfoton, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of an assessment required under the FQPA. This decision does not preclude the Agency from making further FIFRA or FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future. If the Agency determines, before finalizing the RED, that any of the determinations described in this IRED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this IRED.

Label changes for disulfoton are described in Section V. Appendix B identifies the generic data the Agency reviewed as part of its IRED of disulfoton, and lists the studies that the Agency found acceptable.

### B. Summary of Phase 5 Comments

When making its IRED for disulfoton, the Agency took into account all comments received during Phase 5 of the OP Public Participation Process. Comments were received from the technical registrant, Bayer Corporation; the American Landscape and Nursery Association; the California Asparagus Commission; the American Bird Conservancy; North Carolina Cooperative Extension Service; and from numerous individual North Carolina Christmas tree growers. A brief summary of the comments is provided below. All of the submitted comments in their entirety are available in the public docket, and the Agency's response to the comments is also available in the docket and on the internet..

A number of Christmas tree growers in North Carolina provided comments relating to their use practices, farm sizes, the number of acres they treat with disulfoton, the frequency of their applications, the number of workers involved in disulfoton application activities, and the length of time it takes to make the pesticide applications. The Agency has validated much of this

information and used it to revise the risk assessments for disulfoton.

The North Carolina Cooperative Extension Service commented on both the worker and ecological risks assessments for disulfoton and provided extensive information on disulfoton use, cultural practices, and impacts of disulfoton on stream fauna. EPA has considered this information in both the revised risk assessment and the regulatory decision for disulfoton.

The American Nursery and Landscape Association commented on pest management issues in the nursery industry. Disulfoton allows nurserymen to use less pesticide overall because disulfoton is compatible with Integrated Pest Management (IPM). The American Nursery and Landscape Association urges EPA to allow time for development of data to refine the worker risk assessment. The California Asparagus Commission commented on the use of disulfoton in asparagus and provided information about cultural practices. EPA has considered information on integrated crop management, cultural practices, and feasibility of various mitigation measures in its interim regulatory decision for disulfoton.

The American Bird Conservancy recommended elimination of all aerial applications as well as foliar sprays by ground equipment in wheat and sorghum. The American Bird Conservancy also recommended use of a less friable non-clay based granular formulation. EPA has considered these suggestions in the risk mitigation strategy for disulfoton.

Bayer Corporation, the technical registrant, provided comments that focused on further refining assessed risks and potential risk mitigation measures for disulfoton. Bayer's efforts to reduce risks include repackaging the liquid formulation into a closed mixing/loading system, reformulating and repackaging the 1% granular home use product. EPA has considered all of this new information in the revised risk assessment for disulfoton.

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

EPA has determined that dietary risk from exposure to disulfoton is within its own "risk cup." In other words, if disulfoton did not share a common mechanism of toxicity with other

chemicals, EPA would be able to conclude today that the tolerances for disulfoton meet the FQPA safety standards, provided the risk mitigation measures outlined in this document are adopted and additional data needs are addressed. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Based on the results of this aggregate assessment, the Agency has determined that the human health risks from these combined exposures are considered to be within acceptable levels. While the screening-level modeling estimates indicate that disulfoton may in fact fill its aggregate risk cup, the Agency has determined that actual drinking water exposures are likely lower than predicted by the model, and has made an interim determination that disulfoton does "fit" within the dietary risk cup. However, EPA will seek additional data to help refine and confirm this assessment. Except for those tolerances that are to be lowered or revoked, the current disulfoton tolerances will remain in effect and unchanged until a full reassessment of the cumulative risk from all OP pesticides is considered later this year.

### b. Tolerance Summary

Tolerances for residues of disulfoton in/on plant commodities [40 CFR §180.183] are presently expressed in terms of the combined residues of disulfoton and its cholinesterase-inhibiting metabolites, calculated as demeton. The tolerance expression for disulfoton should be modified to include the combined residues of parent, the sulfoxide and sulfone degradates, and the oxygen analogues of the sulfoxide and sulfone degradates. Specifically, tolerances should be modified to include the combined residues of O,O-diethyl S-[2-(ethylthio)-ethyl]phosphoro-dithioate; O,O-diethyl S-[2-(ethylthio)-ethyl]phosphorothioate; O,O-diethyl S-[2-(ethylsulfinyl)-ethyl] phosphorodithioate; O,O-diethyl S-[2-(ethylsulfinyl)-ethyl]phosphorothioate; O,O-diethyl S-[2-(ethylsulfonyl)-ethyl]phosphorodithioate; and O,O-diethyl S-[2-(ethylsulfonyl)-ethyl]phosphorothioate. The Agency is changing the tolerance expression to include all degradates of toxicological concern.

The Agency will commence proceedings to revoke and modify the existing tolerances, and correct commodity definitions. The establishment of a new tolerance or raising tolerances will be deferred, pending consideration of cumulative risk for the OPs. "Reassessed" does not imply that all of the tolerances have been reassessed as required by FQPA, since these tolerances may only be reassessed once the cumulative risk assessment of all OP pesticides is considered, as required by the statute. Rather, this IRED provides reassessed tolerances for disulfoton in/on various commodities, supported by all of the submitted residue data, only for the single OP chemical disulfoton. EPA will finalize these tolerances after considering the cumulative risks for all OP pesticides.

The Agency's tolerance summary is provided in Table 15. This table lists several tolerances associated with uses that are no longer registered, as announced in several FIFRA 6(f)(1) Notices of Receipt of Requests from the registrant for cancellation and/or use deletion, which EPA approved. Therefore, the associated tolerances should be revoked. This table also

lists uses that are to be phased out and the associated tolerances that are to be revoked after 2004. Last, this table lists livestock tolerances that must be established following consideration of the cumulative assessment for all OPs. Livestock feeding studies for disulfoton indicate that residues transfer from feed to meat and milk; therefore, tolerances should be established for livestock commodities, pending consideration of the cumulative assessment for all OPs.

**Table 15. Tolerance Summary for Disulfoton**

| Commodity | Current Tolerance (ppm) | Reassessed[1] Tolerance (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Tolerances Listed Under 40 CFR §180.183(a)(1) Raw Agricultural Commodities | | | |
| Barley, grain | 0.75 | 0.20 | Available data for wheat support lowering barley tolerance. Wheat data may be translated to barley. EPA expects to revoke tolerance after the use is phased out; however, tolerance should be lowered in the interim. |
| Barley, straw | 5.0 | 5.0 | EPA expects to revoke after the use is phased out. |
| Beans, dry | 0.75 | Revoke | Use on dry beans deleted; therefore, tolerance should be revoked. |
| Beans, lima | 0.75 | 0.75 | *[Bean, succulent]* |
| Beans, snap | 0.75 | 0.75 | |
| Beans, vines | 5.0 | Revoke | *[Cowpea, forage]* Use on cowpeas was deleted; therefore, tolerance should be revoked. |
| Beets, sugar, roots | 0.5 | Revoke | No registered uses on sugar beets; therefore, associated tolerances should be revoked. |
| Beets, sugar, tops | 2.0 | Revoke | |
| Broccoli | 0.75 | 0.75 | |
| Brussels sprouts | 0.75 | 0.75 | |
| Cabbage | 0.75 | 0.75 | |
| Cattle, meat | - | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Cattle, meat byproducts | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Cattle, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Cauliflower | 0.75 | 0.75 | |
| Coffee beans | 0.3 | 0.2 | *[Coffee, bean, green]* Available data support lowering the tolerance. |

| Commodity | Current Tolerance (ppm) | Reassessed[1] Tolerance (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Corn, field, fodder | 5.0 | Revoke | Use on corn deleted; therefore associated tolerances should be revoked. |
| Corn, field, forage | 5.0 | Revoke | |
| Corn, grain | 0.3 | Revoke | |
| Corn, pop | 0.3 | Revoke | |
| Corn, pop, fodder | 5.0 | Revoke | |
| Corn, pop, forage | 5.0 | Revoke | |
| Corn, sweet, fodder | 5.0 | Revoke | |
| Corn, sweet, forage | 5.0 | Revoke | |
| Corn, sweet, grain (K+CWHR[2]) | 0.3 | Revoke | |
| Cottonseed | 0.75 | 0.75 | *[Cotton, undelinted seed]* |
| Goats, meat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Goats, meat byproducts | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Goats, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Hog, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Hog, meat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Hog, meat byproducts | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Hog, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Hops | 0.5 | Revoke | No registered uses on hops; therefore tolerance should be revoked. |
| Horse, meat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Horse, meat byproducts | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |

| Commodity | Current Tolerance (ppm) | Reassessed[1] Tolerance (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Horse, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Lettuce | 0.75 | 0.75 head | *[Lettuce, head]* |
| | | TBD leaf[3] | *[Lettuce, leaf]* Tolerance to be raised for leaf lettuce, pending completion of additional field trial data and the outcome of the OP cumulative assessment. |
| Milk | -- | 0.01 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Oats, fodder, green | 5.0 | Revoke | Use on oats deleted; therefore, associated tolerances should be revoked. |
| Oats, grain | 0.75 | Revoke | |
| Oats, straw | 5.0 | Revoke | |
| Peanuts | 0.75 | 0.10 | Available data for peanuts support lowering tolerance. *[Peanut]* |
| Peas | 0.75 | Revoke | Use on peas deleted; therefore, associated tolerances should be revoked. |
| Peas, vines | 5.0 | Revoke | |
| Pecans | 0.75 | Revoke | Use on pecans deleted; therefore, associated tolerances should be revoked. |
| Peppers | 0.1 | 0.10 | *[Pepper, bell]* *[Pepper, nonbell]* |
| Pineapples | 0.75 | Revoke | No registered uses on pineapple; therefore, tolerance should be revoked. |
| Potatoes | 0.75 | 0.50 | *[Potato]* Available data for potatoes support lowering tolerance. EPA expects to revoke tolerance after the use is phased out; however, tolerance should be lowered in the interim. |
| Rice | 0.75 | Revoke | No registered uses on rice; therefore, tolerance was revoked. |
| Rice, straw | 5.0 | Revoke | |
| Sheep, meat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Sheep, meat byproducts | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |

| Commodity | Current Tolerance (ppm) | Reassessed[1] Tolerance (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Sheep, fat | -- | 0.05 | Tolerance should be proposed based on LOQ, pending outcome of OP cumulative assessment. |
| Sorghum, fodder | 5.0 | Revoke | Use on sorghum deleted; therefore, associated tolerances should be revoked. |
| Sorghum, forage | 5.0 | Revoke | |
| Sorghum, grain | 0.75 | Revoke | |
| Soybeans | 0.1 | Revoke | Use on soybeans deleted; therefore, associated tolerances should be revoked. |
| Soybeans, forage | 0.25 | Revoke | |
| Soybeans, hay | 0.25 | Revoke | |
| Spinach | 0.75 | Revoke | No registered use on spinach; therefore, tolerance should be revoked. |
| Sugarcane | 0.3 | Revoke | No registered use on sugarcane; therefore, tolerance should be revoked. |
| Tomatoes | 0.75 | Revoke | Use on tomatoes deleted; therefore, tolerance should be revoked. |
| Wheat, fodder, green | 5.0 | 5.0 | *[Wheat, forage]* EPA expects to revoke tolerance after the use is phased out. |
| Wheat, grain | 0.3 | 0.2 | Available data support lowering tolerance. EPA expects to revoke tolerance after the use is phased out; however, tolerance should be lowered in the interim. |
| Wheat, straw | 5.0 | 5.0 | EPA expects to revoke tolerance after the use is phased out. |
| Tolerances Listed Under 40 CFR §180.183(a)(2) Livestock Feed Items | | | |
| Sugar beet pulp | 5 | Revoke | No registered use on sugar beets; therefore, tolerance should be revoked. |
| Pineapple bran | 5 | Revoke | No registered use on pineapple; therefore, tolerance should be revoked. |
| Aspirated grain fractions | -- | 0.3 | Based on wheat tolerance and concentration factor from processing study. EPA expects to establish a temporary tolerance, which will be revoked following the phase out of the use on wheat and barley, pending the outcome of the OP cumulative assessment. |
| Cotton, gin byproducts | -- | TBD[4] | Animal feed item; tolerance to be determined pending completion of field trial study and outcome of OP cumulative assessment. |
| Tolerances Listed Under 40 CFR §180.183(c) Regional Registrations | | | |

| Commodity | Current Tolerance (ppm) | Reassessed[1] Tolerance (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Asparagus | 0.10 | 0.10 | |

[1] "Reassessed" does not imply that the tolerances have been reassessed as required by FQPA; tolerances may only be reassessed once the cumulative risk assessment of all OP pesticides is considered.
[2] K+ CWHR, kernel plus cob with husks removed.
[3] TBD, to be determined pending completion of outstanding field trial data (OPPTS GDLN 860.1500) and pending the outcome of the cumulative assessment. Available data support a separate, higher tolerance for leaf lettuce.
[4] TBD, to be determined. Field trial data (OPPTS GDLN 860.1500) are now required for cotton gin byproducts.

***Raw Agricultural Commodities, 40 CFR § 180.183(a)(1)***

The following tolerances should be revoked because there is no longer a registered use on these commodities:

- Sugar Beets, all tolerances
- Hops
- Spinach
- Pineapples, all tolerances
- Rice, all tolerances
- Sugarcane

The following tolerances should be revoked because the technical registrant has requested, and EPA has approved, voluntary cancellation of disulfoton use on these commodities:

- Beans, dry
- Beans, vines
- Corn, all tolerances
- Oats, all tolerances
- Peas, all tolerances
- Pecans
- Sorghum, all tolerances
- Soybeans, all tolerances
- Tomatoes

The following tolerances will be lowered based on available residue data:

- Barley, grain
- Coffee beans
- Peanuts
- Potatoes
- Wheat, grain

In addition, the Agency expects to propose revocation of tolerances on barley, potatoes, and wheat because these uses are being phased out. The revocation will allow sufficient time for legally treated commodities to clear the channels of trade.

***Livestock Feed Items, 40 CFR §180.183(a)(2)***

A tolerance must be established for residues of aspirated grain fractions. The concentration factors for wheat aspirated grain fractions was 1.35x. The reassessed tolerance for wheat grain is 0.2 ppm. Multiplying concentration factors by the reassessed tolerances gives 0.3 ppm for aspirated grain fractions of wheat.

As explained in the Agency's definition of livestock feed commodities (OPPTS Guideline 860.1000, Table 1), tolerances are required for cotton gin byproducts. The appropriate tolerance levels for these commodities will be determined when adequate field trial data (OPPTS GDLN 860.1500) have been submitted and evaluated.

A tolerance of 0.05 ppm, the level of quantification, would address potential residues on meat, fat, and meat byproducts of cattle, hogs, horses, sheep, and goats. A tolerance of 0.01 ppm, the level of quantification, should be established for milk.

***Residue Analytical Methods***

Adequate methods are available for data collection and tolerance enforcement for plant and livestock commodities. The Pesticide Analytical Manual (PAM) Vol. II lists the enforcement methods for demeton, paper chromatography and colorimetric methods, as Method I. A gas chromatography (GC) method (Method II) with potassium chloride thermionic detection is listed for the determination of disulfoton, its oxygen analogue, and their sulfoxides and sulfones in/on plant commodities. The GC enforcement Method in PAM calculates residues in terms of disulfoton, whereas the tolerance expression states that residues are calculated as demeton. The majority of data used for tolerance reassessment were collected using the enforcement GC method (or modification thereof). Therefore, the tolerance expression will be revised to state that residues are to be calculated as disulfoton. This revision will also make the tolerance expression compatible with the Codex expression.

Multiresidue methods are also available for disulfoton. PAM Volume I, Appendix I indicates that disulfoton, its sulfoxide and sulfone, demeton-S (disulfoton oxygen analogue), and its sulfoxide and sulfone are completely recovered (>80%) using Multiresidue Method Section 302. Disulfoton is partially recovered (50-74%) and metabolites disulfoton sulfone and demeton-S are not recovered using Multiresidue Method §303. Disulfoton is not recovered using §304.

### c. Endocrine Disruptor Effects

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

Screening Program (EDSP).

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

## D. Regulatory Rationale

EPA has determined that label amendments are necessary in order for disulfoton products to be eligible for reregistration. Provided the following risk mitigation measures are incorporated in their entirety into labels for disulfoton-containing products, the Agency finds that certain currently registered uses of disulfoton are eligible for reregistration, pending consideration of cumulative risks of OP pesticides. The regulatory rationale for each of the mitigation measures is discussed below. Where labeling revisions are warranted, specific language is set forth in the summary table of Section V.

### 1. Human Health Risk Mitigation

#### a. Dietary Mitigation

Dietary risk from food sources alone are not of concern. Screening level modeling estimates indicate that aggregate disulfoton exposure from food and drinking water may fill the risk cup; however, the Agency has determined that drinking water exposures are likely lower than predicted. Therefore, the Agency has made an interim determination that no additional mitigation are necessary at this time. EPA will require additional data to refine the drinking water modeling values and confirm this interim conclusion.

*Acute (Food)*

The acute dietary (food) risk estimate is less than 100% of the aPAD for the general population and all population subgroups. Children (1-6 years), the most highly exposed population group, are exposed to disulfoton at a level of 9.6% of the aPAD (0.0025 mg/kg/day) at the 99.9$^{th}$ exposure percentile. The acute dietary (food) risk estimate is not of concern; therefore, no additional mitigation measures are necessary to reduce these risks.

*Chronic (Food)*

The chronic dietary (food) risk estimate is less than 100% of the cPAD for the general population and all population subgroups. Children (1-6 years), the most highly exposed population group, are exposed to disulfoton at a level of 3.5% of the cPAD (0.00013 mg/kg/day). The chronic dietary (food) risk estimate is not of concern; therefore, no additional mitigation measures are necessary to reduce these risks.

***Drinking Water - Surface***

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

Based on model predictions of currently registered uses, the DWECs for disulfoton (parent only) in surface water range from 2.8 to 15.5 ppb for acute exposure, and from 0.2 to 1.6 ppb for chronic exposure. The DWECs for total disulfoton (parent + degradates) range from 8.0 ppb to 39.0 ppb for acute exposure, and from 2.0 to 16.7 ppb for chronic exposure and are summarized in Table 5.

As part of the Agency's measures to mitigate occupational risks associated with the use of disulfoton (discussed later in this section), certain use sites are to be phased out or discontinued. Among the uses to be discontinued are barley, potatoes, and wheat. However, disulfoton use on these crops and cotton were selected to assess overall drinking water exposures from surface water sources. Excluding the crop scenarios for barley, potatoes, and wheat would result in cotton use as being the only remaining drinking water crop scenario from which to assess drinking water risks. However, disulfoton is used on many other crops, such as asparagus, beans, broccoli, brussels sprouts, cabbage, cauliflower, chilli peppers, lentils, lettuce, peanuts, and peas. These use sites were not specifically modeled, because the barley, cotton, potatoes, and wheat crop scenarios were selected to be representative of all sites vulnerable to runoff. Thus, to represent the use of disulfoton on all the use sites subject to reregistration, it is appropriate to use the DWEC model estimates from the original barley, cotton, potatoes, and wheat crops scenarios to assess drinking water risks from surface water sources.

For disulfoton, the fate of the parent compound and its degradates once in surface water and sediments, and the likely concentrations therein, cannot be modeled with a high degree of certainty, since aerobic and anaerobic aquatic degradation data are not available. Because there are no studies for individual degradates, a 259 day half-life was used for a model input, which is the upper 90% confidence bound on the mean of total residue half-lives in aerobic soil metabolism studies. The assessment could be refined if studies for the individual degradates were conducted and model inputs could be derived from these studies. In addition, the aerobic soil metabolism half-life is used to estimate the aerobic aquatic half-life when aerobic aquatic data are not available, and has also contributed to the uncertainty of the water assessment.

In addition, the water model scenarios on disulfoton use on barley and potatoes, which result in the highest DWECs, include the default PCA value of 87%. This factor translates to 87% of the modeled drainage basin is planted with crops which are treated with disulfoton. This

default value may be an overestimate, since some of the disulfoton use areas are highly mixed agricultural regions where other crops that are not treated with disulfoton are also grown or areas where no crops are grown and disulfoton is not applied.

Because modeling without complete fate data was employed to develop DWEC values to assess drinking water risks for disulfoton, the Agency has some level of uncertainty of whether actual concentrations of disulfoton in surface water sources of drinking water would be as high as the model predictions. Therefore, to confirm these estimates, aerobic and anaerobic aquatic metabolism, and mobility, leaching, absorption and desorption studies (OPPTS Guidelines 835.4300, 835.4400, and 835.1240) on both the parent and degradates are required.

For many chemicals where there are uncertainties in the modeling estimates, the Agency also relies on actual monitoring data to confirm these estimates. Thus, for disulfoton, the Agency is also requiring confirmatory surface water monitoring data to evaluate actual acute and chronic concentrations of disulfoton in the drinking water sources. This monitoring data is to be generated from a multi-year sampling program involving community water systems from surface water sources in multiple locations in different regions of the country to represent different use sites, crops, soil types, and rainfall regimes. Water samples are to be analyzed to determine the concentrations of parent disulfoton and each of the environmental degradates of toxicological concern. Also, prior to initiating this sampling program, the registrant is required to submit a study protocol to the Agency to ensure that the sampling locations and procedures are adequate to address the drinking water risk concerns.

***Drinking Water - Ground***

The DWEC to assess drinking water risks from disulfoton concentrations in ground water sources is 1.2 ppb. A Tier I screening-level model (SCI-GROW) was employed to estimate the maximum ground water concentrations from the application of a pesticide to crops. The model is based on the fate properties of the pesticide and the annual application rate. For disulfoton, fate data were not available for the degradates of concern; thus, estimates of fate properties were factored into the model estimates, which comprise a significant contribution to the predicted total concentration of disulfoton. Furthermore, the model assumes the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to the contamination than the use areas used to derive the model estimates. As such, the DWECs from this model should be considered a high-end to bounding estimate that is generally more appropriate for acute rather than chronic exposure.

In addition, the available monitoring data do not indicate that there is a concern of disulfoton concentrations in drinking water from ground water sources. For these reasons, the Agency believes that actual concentrations of disulfoton in ground water sources of drinking water are not of risk concern, and that no further mitigation nor monitoring is necessary.

### b. Homeowner Risk Mitigation

***Handler Risk***

Disulfoton is currently registered for residential use on small flower gardens, ornamental flowers and shrubs, including rose bushes and small trees, and outdoor potted plants. Most application methods for residential uses are not of risk concern to the Agency with MOEs > 100; however, some uses result in MOEs < 100 and are of risk concern. As indicated in Table 8, MOEs for residential uses of disulfoton range from 1.1 to 1900. Residential risks are not of risk concern (MOEs > 100) for the following use scenarios and application rates:

- ***Loading/applying granulars using a push-type spreader:***
  -use on flower gardens at an application rate of 0.3 lb ai/1000 $ft^2$
  -use on ornamental shrubs and small trees at an application rate of 0.01 lb ai/4 ft shrub
  -use on rose bushes at an application rate of 0.00126 lb ai/bush

- ***Loading/applying granulars using a spoon, measuring scoop, shaker can or by hand:***
  -use on potted plants at an application rate of 0.00034 lb ai/6 inch pot
  -use on rose bushes at an application rate of 0.00126 lb ai/bush

- ***Loading/applying granulars using a measuring cup/lid:***
  -use on flowerbeds at an application rate of 0.21 lb ai/1000 $ft^2$
  -use on shrubs at an application rate of 0.01 lb ai/4 ft shrub
  -use on rose bushes at an application rate of 0.0013 lb ai/bush

Residential risks are of risk concern (MOEs < 100) for the following use scenarios and application rates:

- ***Loading/applying granulars using a belly grinder:***
  -use on flower gardens at an application rate of 0.3 lb ai/1000 $ft^2$

- ***Loading/applying granulars using a spoon, measuring scoop, shaker can or by hand:***
  -use on flower gardens at an application rate of 0.3 lb ai/1000 $ft^2$
  -use on ornamental shrubs and small trees at an application rate of 0.01 lb ai/4 ft shrub

The following measures ***are necessary to*** mitigate residential risks that are of concern:

- Prohibit application of disulfoton with a belly grinder.

- Prohibit application to flower gardens and ornamental shrubs with a spoon, measuring scoop, shaker can, or by hand, *unless* the packaging and method of application of the end-use product conforms with the performance of a measuring cup/lid packaging currently manufactured for the Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granular product.

If the end-use registrant elects to change container packaging to conform with the subject Bayer product, the new packaging must be child resistant with a self-contained measuring device, which serves as the container lid and clearly measures the quantity to be applied. Although the Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granular product is the only such packaging of this type currently available at the time of this IRED, other similar packaging which meets or exceeds the safety specifications given above may also be used.

- Limit the maximum label rates for disulfoton to 0.3 lb ai/1000 $ft^2$ for use on flowerbeds; 0.01 lb ai/4 ft bush for use on shrubs; and 0.0013 lb ai/bush for use on rose bushes. Although the residential risk assessment for hand application with a self-contained measuring cup/lid was based on a rate of 0.21 lb ai/1000 $ft^2$ on flowerbeds (Table 8), the MOEs calculated for the rate of 0.3 lb ai/1000 $ft^2$ for use on flowerbeds would also be greater than 100 and not of risk concern. To be consistent with the maximum application rate to flowerbeds with a push type spreader, EPA is allowing the higher maximum application rate 0.3 lb ai/1000 $ft^2$ for use on flowerbeds for disulfoton packaged for hand application with a self-contained measuring cup/lid.

- As previously stated, all disulfoton products intended for hand application must be packaged with a self-contained measuring cup/lid that clearly measures the appropriate amount to be applied. These packaging must also meet EPA criteria for child-resistant packaging.

- Disulfoton products intended for application with a push-type spreader must limit the maximum application rates to 0.3 lb ai/1000 $ft^2$ for use on flowerbeds; 0.01 lb ai/4 ft bush for use on shrubs; and 0.0013 lb ai/bush for use on rose bushes, as specified above. Also, these products must be labeled "Do not apply by hand." and "Not for commercial use."

- All homeowner products must be soil incorporated or watered in.

- Delete the following uses from all product labels to comply with the technical label: all indoor uses, use in greenhouses, and use on home vegetable gardens, including use on spinach and tomatoes.

Only homeowner products containing 2% active ingredient or less are eligible for reregistration. (All products containing >2% active ingredient are classified as restricted use, based on the acute oral and dermal toxicity of disulfoton).

Residential risk from use of fertilizer spikes impregnated with disulfoton can not be determined at this time, because the Agency has no exposure monitoring data for this use scenario. Similarly, EPA can not determine the reregistration eligibility for this use without exposure monitoring data (i.e, OPPTS Guidelines 875.1100, 875.1600, and 875.1700). In some cases, the Agency would require these data as a condition of continued registration. However,

on March 28, 2002, the end-use registrant requested voluntary cancellation of all product registrations for fertilizer spikes impregnated with disulfoton (EPA Reg Nos 46260-2, 46260-12, 46260-35, and 46260-36); therefore, the Agency does not intend to include these data requirements in the DCI. Consistent with the existing stocks provision of this IRED, the end-use registrant will be allowed 26 months from the date of issuance of this document to distribute and sell products and 50 months for persons other than the registrant to distribute or sell products

***Post-Application Risk***

As mentioned previously in this document, the upper-bound residential post-application assessment of incidental soil ingestion (oral exposure) to toddlers results in MOEs > 100, which are not of risk concern to the Agency. Therefore, the Agency does not have a concern for post-application risk to toddlers from any activities, and no additional mitigation is necessary.

### c. Aggregate Risk Mitigation

The Agency's aggregate risk assessment for disulfoton is based on exposure estimates for food and residential uses, and uses a screening-level assessment of modeled estimates for drinking water contamination. Dietary (food) risk estimates are based on a refined assessment that incorporates percent crop treated data, monitoring data, and processing data.

***Acute Exposure***

The acute aggregate risk assessment for disulfoton combines exposure from food and drinking water sources only. Acute dietary (food) risk estimates are below 100% of the aPAD for the US population and all population subgroups. Children 1-6 years old is the most highly exposed population subgroup and result in an acute drinking water level of comparison (DWLOC) of 23 ppb. Based on screening-level model predictions of the remaining supported uses, the acute (peak) drinking water estimated concentration (DWECs) in surface water is 15.5 ppb for parent disulfoton and 39.0 ppb for total disulfoton (parent + degradates). The DWEC of parent disulfoton is less than the DWLOC and not of concern; however, the DWEC of total disulfoton (parent + degradates) is greater than the DWLOC and is of potential risk concern to the Agency as modeled. Also, the screening-level model predictions of acute DWECs in ground water is 1.2 ppb for total disulfoton, which is less than the DWLOC and not of risk concern to the Agency.

As stated previously, exceedances of the DWLOC by screening-level model estimates do not necessarily indicate a risk of concern, but generally indicate the need for better data, due to the uncertainties and limitations of the model predictions. The Agency believes that actual acute concentration of disulfoton in surface water is likely less than the DWLOC and is not of concern. To demonstrate this, confirmatory surface water monitoring data is to be generated to address this risk concern.

*Chronic Exposure*

The chronic aggregate risk assessment for disulfoton combines exposure from food and drinking water sources only. Chronic dietary (food) risk estimates are well below 100% of the cPAD for the US population and all population subgroups. Children 1-6 years old is the most highly exposed population subgroup with a chronic DWLOC of 1.3 ppb. Based on screening-level model predictions of the remaining supported uses, the average (chronic) DWECs in surface water is 1.6 ppb for parent disulfoton and 16.7 ppb for total disulfoton (parent + degradates). The DWEC of parent disulfoton is of the same magnitude as the chronic DWLOC and is not of concern. Although the DWEC for total disulfoton is greater than the DWLOC for children 1-6 and is of potential risk concern, the uncertainties and limitations of the model predictions lessen this concern. The Agency also believes that actual chronic concentrations of disulfoton in surface water are less than the DWLOC and are not of concern. To demonstrate this, confirmatory laboratory fate and surface water monitoring data are to be generated to address the risk concern.

The screening-level model predicts a chronic DWECs in ground water of 1.2 ppb, a value lower than the corresponding DWLOCs. Therefore, the Agency believes that concentrations of disulfoton in ground water sources of drinking water are not of risk concern, and that no further mitigation or monitoring is necessary.

*Short-Term Exposure*

The short-term aggregate risk assessment for disulfoton combines exposure from food uses, residential uses, and drinking water sources. Residential use is assessed for dermal exposure to adult handlers and oral exposure to children through incidental soil ingestion. Inhalation exposure is not part of the short-term aggregate assessment as data indicate negligible exposure. Short-term DWLOC estimates are calculated for disulfoton based on chronic dietary (food) exposure and dermal exposure values from residential exposure scenarios that have MOEs > 100. Residential exposure scenarios with MOEs < 100 were not included in the short-term aggregate assessment (see Table 8).

The short-term DWLOC is 14 ppb for children 1-6 years old, the most highly exposed population. As indicated above, the average (chronic) DWECs in surface water is 1.6 ppb for parent disulfoton and 16.7 ppb for total disulfoton (parent + degradates). The DWEC of parent disulfoton is less than the short-term DWLOC and not of concern. Although the DWEC for total disulfoton is slightly greater than the DWLOC, th Agency believes this exceedance does not necessarily indicate a risk of concern due to the uncertainties associated with model estimates. Confirmatory laboratory fate and surface water monitoring data are to be generated to address the potential risk concern.

**d. Occupational Risk Mitigation**

As described in PR Notice 2000-9, *Worker Risk Mitigation for OP Pesticides,* it is the

Agency's policy to mitigate occupational risks to the greatest extent necessary and feasible with personal protective equipment and engineering controls. In managing risk, EPA considers a wide range of factors are considered in making risk management decisions for worker risks. EPA must take into account the economic, societal, and environmental costs and benefits of the pesticide's use. In addition to the calculated MOEs, incident data, the nature and severity of adverse effects, uncertainties in the risk assessment, availability and relative risk of alternatives, importance of the chemical in integrated pest management (IPM) programs, and other similar factors.

***Worker Handler Risks***

As summarized in Table 10, occupational risks are of concern (i.e., MOEs < 100) for all scenarios, even when maximum PPE (i.e, double layer clothing, gloves, and a respirator) are utilized. These handler risks are also of concern for many scenarios with engineering controls, even at a level that provides protection from inhalation exposure (closed mixing/loading, enclosed cabs with air filtration). Engineering controls with inhalation protection are considered to be the maximum feasible mitigation. For workers wearing the maximum PPE described above, MOEs range from 1.5 (barley) to 61 for mixer/loaders and from <1 (ornamentals grown for field or nursery stock) to 69 for applicators. For workers using the engineering controls described above, MOEs range from 3.1 to 800 for mixer/loaders and from 1.8 to 160 for applicators. To remain eligible for reregistration, the following mitigation measures must be implemented for all occupational handler scenarios.

- Closed mixing/loading systems for all liquid formulations (see below);
- Closed transfer/loading systems for all granular formulations by June 2004;
- Enclosed cabs plus a dust-mist respirator for all ground equipment applicators (i.e., groundboom and tractor drawn spreader). The respirator requirement may be relaxed when using engineering controls that provide equivalent inhalation protection (such as air filtration), under the provisions of the Worker Protection Standard (WPS).
- Enclosed cockpits for aerial applicators;
- Mechanical flaggers for aerial application; or the use of global positioning system (GPS) equipment that negates the need for flaggers;
- When engineering controls are not feasible for applicators, handlers must wear maximum PPE (i.e., double layer clothing, chemical-resistant gloves and footwear, and a dust-mist respirator); and
- Application by open, handheld equipment, including belly grinders and bucket and spoon will be prohibited after June 2004. Where this is currently the application method of choice, growers will be allowed until June 2004 to transition to another method.

The closed mixing/loading system used for liquid disulfoton should contain a dry disconnect or dry coupler that allows no more than 2 mL drippage, such as the Secure-Link G® or other comparable system. Closed mixing/loading systems for all liquid formulations of disulfoton end-use products are currently in use and should be fully implemented by December 31, 2002.

***Post-Application Risk***

Post-application (re-entry) risks are of concern for workers performing tasks in areas that have received foliar applications of disulfoton. In lieu of satisfactory dislodgeable foliar residue (DFR) data, the Agency relied on assumptions for its re-entry assessment. Restricted-entry intervals (REIs) for these types of applications of disulfoton are stipulated in the crop specific regulatory rationale section below. The Agency acknowledges that additional DFR data (OPPTS Guideline 875.2100) could refine the post-application risk assessment and likely reduce the REI for certain crops. If the registrant wishes to generate such data to refine this assessment, the study needs to include residue data on both the parent and degradates.

For soil directed applications of the liquid and granular formulations, most of which are either in-furrow, shank injected, or other types of soil incorporation, the Worker Protection Standard designates the REI to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches. In addition, based on the use of the chemical and the timing of applications to these crops, the Agency does not expect significant soil contact from typical worker re-entry activities. Therefore, the Agency has no risk concerns for the post-application exposures to agricultural workers for these types of disulfoton applications, and no risk mitigation measures beyond the 48 or 72 hour REI are necessary for applications made to the soil.

***Uncertainty in and Refinements to the Occupational Risk Assessment***

There is some uncertainty associated with the toxicity of disulfoton. Numerous animal studies in several species show cholinesterase inhibition. The NOAEL used to assess short-term dermal exposure to workers is 0.5 mg/kg/day from a special 3-day dermal toxicity study in rats conducted on the 1% granular product. The LOAEL from this study is 1 mg/kg/day based on plasma and brain cholinesterase inhibition. The Agency believes that the NOAEL from this study is sufficient to assess dermal exposure of 1 to 7 days, which would cover most agricultural workers. However, the Agency is concerned that commercial handlers could be exposed for up to 14 days. To fully characterize the hazard associated with exposure ranging from 14 to 30 days, the Agency is requiring a confirmatory 21-day dermal study in the rat, the most sensitive species. In the interim, the Agency will base the short-term dermal risk assessment for commercial applicators on the 3-day dermal study. The Agency acknowledges that the occupational risk assessment based on the 3-day dermal toxicity study may underestimate risk to some commercial applicators.

There is also some uncertainty in the Agency's assessment of exposure to agricultural

workers. EPA used exposure monitoring data from PHED, which either lacks or contains limited exposure monitoring data for some application methods, including shank injection, in-furrow, and with a motorcycle mounted with a granular spreader. In these specific examples, the closest available exposure monitoring data scenario from PHED was used to assess potential exposure. The Agency made the following extrapolations based on PHED data:

- Data for mixers/loaders and applicators using a groundboom to apply liquid formulations were used to estimate exposure from at-plant, in-furrow application of liquid products.

- Data for loaders and applicators using a tractor drawn spreader to apply granular formulations were used to estimate exposure from in-furrow, at-plant application and exposure from broadcast of granulars using a motorcycle.

The Agency believes that in-furrow or shank injecting methods of applications result in less exposure to applicators than does the tractor drawn spreader or groundboom methods, from which the estimated risks were derived. Although the Agency does not have data at this time to corroborate this understanding, it is reasonable to expect the risk associated with applying disulfoton with soil incorporated methods are lower than currently estimated. Because of the uncertainties associated with the use of these surrogate scenarios, the Agency is requiring confirmatory exposure monitoring data (passive dosimetry) to better characterize exposure and risk for these scenarios. However, because of the uncertainties associated with the dermal endpoint, the registrant has the option to generate, and the Agency will accept biomonitoring data in lieu of the passive dosimetry to characterize exposure to applicators.

Last, the Agency typically uses default assumptions with regard to acreage treated per day for field crops depending upon the application method. However, crop-specific information shows that many minor crops grown in the Salinas Valley of California are planted in blocks, and that in many cases the actual acreage treated per day is lower than the Agency default assumptions. Because California's Department of Pesticide Regulation has stringent pesticide use reporting requirements, EPA verified acreage treated with disulfoton in that state, and concluded that for some crops that are grown in California, the actual acreage treated per day is lower than the assumptions used by the Agency to assess worker risks. Information on the acreage treated for specific crops grown in California, and its impact on corresponding worker MOEs are summarized with crop-specific mitigation in Section IV.D.3, *Crop Specific Mitigation* of this document.

### 2. Environmental Risk Mitigation

The Agency's ecological risk assessment for both the liquid and granular formulations shows RQ values which exceed the various levels of concern (LOCs) for acute risks to terrestrial birds and mammals and freshwater and estuarine invertebrates and chronic risks to birds and mammals, freshwater invertebrates, as well as marine and estuarine fish and invertebrates. The Agency also has risk concerns to endangered species, and potential concern to nontarget plants.

*Birds and Mammals*

The Agency has some acute risk concerns for birds and mammals potentially exposed to the liquid formulation. Acute RQs for birds range from 0.01 to 2.2, with the highest RQ associated with use on potatoes. EPA also has a risk concern for endangered avian species. Acute RQs for mammals range from <0.1 to 360, again with the highest RQ associated with potatoes. Note also that there is some uncertainty in the mammalian risk estimates, because they are based on rat toxicity studies, which were not designed to assess risk to wild mammals. In lieu of wild mammal acute toxicity data, EPA extrapolated an $LC_{50}$ value based on an $LD_{50}$ from an acute oral rat study to calculate acute RQs for mammals, which may account for the comparatively high RQs for mammals. In addition, EPA has some chronic risk concerns for birds and mammals potentially exposed to the liquid formulation. Chronic risk estimates for the liquid formulation range from 0.02 to 3.4 for birds and from 0.9 to 158 for mammals. The highest RQ is for use on potatoes in the Pacific Northwest. The Agency's phase out of disulfoton use on potatoes will address the highest avian and mammalian acute and chronic risks.

The Agency also has acute risk concerns for the granular formulation, with potential risk concerns at the lowest application rate of 1 lb ai/A. Acute avian RQs range from 0.1 to 75,200 and mammalian RQs range from 0.3 to 257,300. The highest RQs for both birds and mammals are associated with the Christmas tree use at the current Section 3 registration label rate of 78 lb ai/A. To mitigate this risk, the maximum application rate for disulfoton on Christmas trees is to be reduced to 4.5 lbs ai/A, the use is to be limited to fir species only, and disulfoton must be either soil incorporated, watered in, or applied to areas with permanent groundcover. At the lower application rate of 4.5 lbs ai/A for Christmas trees, peak RQs are significantly reduced to 4,350 for birds and 14,900 for mammals. Although the residual risks for the Christmas tree use are still high, Christmas tree growers in the region have submitted numerous testimonials emphasizing the ever increasing numbers and diversity of wildlife, including game animals. Although it is not clear whether there are population effects, the risk assessments suggests that there is acute risk to nontarget birds and mammals exposed to disulfoton. Excluding Christmas tree use, RQs for birds range from 0.1 to 346, and RQs for mammals range from 0.3 to 1184, with the highest RQs associated with use of disulfoton by nurseries on ornamental flowers.

Because of the toxicity of disulfoton, to help protect terrestrial birds and mammals, it is very important to minimize their potential exposure to disulfoton products that have been applied. Many of the mitigation measures previously described in this document to mitigate occupational and other risks of concern will also serve to minimize risk to birds and mammals, such as deleting certain uses (i.e., potatoes, barley, wheat, ornamentals), injecting or incorporating the chemical into the soil during application, reducing maximum application rates, and limiting the number of applications on asparagus, coffee, peanuts (North Carolina only), and potatoes.

*Aquatic Organisms*

Acute risks are of concern for some aquatic organisms. Acute RQs range from <0.01 to

0.33 for freshwater fish, and from <0.01 to 0.02 for estuarine fish, and are not of concern. However, acute RQs range from <0.01 to 2.1 for freshwater invertebrates, and from <0.01 to 0.55 for estuarine invertebrates. Some of the acute values for invertebrates are of concern.

Chronic risks are of concern for freshwater invertebrates, but not for freshwater fish. The Agency has a greater chronic risk concern for freshwater invertebrates than for estuarine invertebrates. Chronic RQs range from <0.01 to 149 for freshwater invertebrates, and from <0.01 to 2.3 for estuarine invertebrates. For freshwater fish, chronic RQs range from <0.01 to 0.8, and for estuarine fish, chronic RQs range from <0.01 to 3.0.

The highest RQs of concern to fish and invertebrates are associated with multiple aerial applications to potatoes, barley, and asparagus. The phase out of disulfoton use on potatoes and barley will mitigate some of these risks, and the RQs associated with use on asparagus may be an overestimate. Disulfoton use on asparagus is predominately in Washington and California, where there is little to no rainfall during the application period to cause runoff and potentially exposure aquatic organisms.

Many of the measures previously described in this document to mitigate occupational and terrestrial risks will also serve to mitigate aquatic risks of concern. For instance, deleting certain uses, injecting or incorporating the chemical into the soil, reducing maximum application rates, and limiting the number of applications will reduce potential runoff of disulfoton to nearby water bodies. To further mitigate aquatic risks, a 25 foot vegetative buffer between treated fields and all permanent water bodies will be necessary.

***Plants***

Because test data was not available to conduct a risk assessment for nontarget plants, and because of a phytotoxicity statement on the labels, the Agency has a potential phytotoxicity risk concern. Given that disulfoton is applied to growing crops it is unlikely to result in significant nontarget risks to plants. Confirmatory data are needed to determine the extent of any risk that may exist. Therefore, Tier I test data for terrestrial plants (OPPTS 850.4100 and 850.4150) are required.

***Insects***

The results of an acute contact study show that disulfoton is moderately toxic to bees and disulfoton sulfone and sulfoxide are very highly toxic to bees on an acute contact basis. A toxicity study of residue of the liquid EC (Di-Syston 8) on honey bees showed that disulfoton residues on foliage are not toxic to bees. The Agency believe that a precautionary label statement will be sufficient to address risk concerns. Specific label language is given in Table 16 of this document.

*Endangered Species*

As mentioned in Section III.B.3 of this document, the Agency included disulfoton in two formal consultations with the USFWS on endangered species. These consultations occurred in 1983 and 1989. As a result of these consultations, the USFWS issued jeopardy opinions identifying several endangered species, as well as reasonable and prudent alternatives and measures to address the risk concern. These opinions are reflected in the EPA's endangered species protection program county level interim bulletins. The disulfoton registration and use patterns have changed significantly since 1989, and many uses have been deleted, maximum application rates have been lowered, and the number of applications have been reduced. Therefore, the Agency conducted an additional endangered species assessment on the remaining registered disulfoton uses that would result in potential exposure to endangered species. From these remaining uses, potential impacts were identified for two bird species: the Puerto Rico Plain Pigeon and the Mountain Plover. The Agency does not believe that any measures are necessary to protect the Mountain Plover at this time. The Plover is found in western states where barley is grown, and this bird feeds on barley when the barley is young and less than three inches tall. Because disulfoton is used on barley late in the season, when the crop is quite tall, the Mountain Plover is not expected to be impacted by disulfoton use. Further, the use of disulfoton on barley is being phased out by June 2005. The Agency does not believe that any measures are necessary to protect the Puerto Rico plain pigeon. Potential exposure of this species was an issue associated with the use of disulfoton on coffee. However, technical assistance from the Puerto Rico office of the Fish and Wildlife Service revealed that this species does not utilize or otherwise occur in areas of Puerto Rico where coffee is produced. Therefore, because there will be no effect on this species, no mitigation measures are necessary.

### 3. Crop-Specific Decisions

The technical registrant, Bayer Corporation, has made a number of voluntary changes to their FIFRA Section 3 disulfoton labels to address risk concerns. These voluntary label changes include reducing maximum application rates or number of applications for some crops and deleting numerous uses. However, these voluntary measures were not sufficient to fully address the Agency's risk concerns. Therefore, EPA has identified additional measures necessary to mitigate risks on a crop-by-crop basis, after considering all potential risk mitigation options, the availability of alternatives and their effectiveness, and the benefits associated with each use (see Section III.C, *Alternatives and Benefits*). These measures included additional reductions in the rate and frequency of applications, where these are feasible. In the process of developing crop-specific mitigation measures, EPA considered current agricultural practices and the actual use of disulfoton in the field. In some cases, the current agricultural practices are protective of human health and the environment given the benefits of continued use. In such instances, pesticide product labels must be modified to reflect the current practice. In developing mitigation, EPA also considered personal protective equipment and engineering controls for workers and precautionary labeling.

As previously mentioned in the section describing measures necessary to mitigate worker

risks, growers will need to utilize engineering controls, which include the use of enclosed cabs. Growers with enclosed cabs that do not provide inhalation protection will also need to wear a dust-mist respirator; however, growers who have enclosed cabs with air filtration will not need any further inhalation protection. The Agency recognizes that there may be some growers of minor crops who may not own the necessary equipment and therefore may be economically impacted by adopting engineering controls. However, EPA believes that custom applicators who have equipment with the necessary engineering controls are available to growers who may not have the necessary equipment themselves.

Risk estimates are provided in the following section for both groundboom and tractor drawn spreader applicators that are in an enclosed cab and wearing a dust-mist respirator. Typical disulfoton labels specify maximum PPE (i.e., double layer clothing, and with or without a respirator). For groundboom applicators of the liquid formulation with maximum PPE and without a respirator, the corresponding MOEs increase by a factor of 3x for an applicator in an enclosed cab and wearing a dust-mist respirator (80% protection factor); and for groundboom applicators with maximum PPE and with a respirator, the MOEs increase by a factor of 1.9x. Similarly, for tractor drawn spreader applicators of the granular formulation with maximum PPE and without a respirator, the corresponding MOEs increase by a factor of 3.6x for an applicator in an enclosed cab and wearing a dust-mist respirator; and for tractor drawn spreader applicators with maximum PPE and with a respirator, the MOEs increase by a factor of 1.4x. The tabulated MOEs for applicator scenarios utilizing an enclosed cab with a dust-mist respirator are not included in Table 10 of this document, but the basis of these calculations are available in *Revised Occupational Exposure Assessment for the Reregistration Eligibility Decision Document for Disulfoton,* June 15, 2001, which can be found on the internet or the public docket.

Despite all of the mitigation measures previously described in this document, residual worker risks are still of concern for some crops and application methods. The Agency's decision considered the risks and benefits of continued disulfoton use as well as the availability of effective alternatives. EPA's risk-benefit findings, residual risks, and crop-specific decisions are summarized below.

***Asparagus***

The liquid formulation only is registered for use on asparagus through FIFRA Section 24(c) Special Local Need (SLN) registrations in Arizona, California, North Carolina, Oregon, and Washington. The granular formulation is not registered on asparagus. Most disulfoton use on asparagus is in California and Washington, which account for 96% of its use on this crop. In Washington, 50% of the asparagus crop is treated with disulfoton, and in California, 70% of the crop is treated. The liquid product is mostly aerially applied, but is sometimes applied by groundboom to the field edges to control the target pest, the European asparagus aphid. The current labels allow for up to three applications of disulfoton. The available alternatives to disulfoton are chlorpyrifos and dimethoate, but are not sufficiently efficacious in controlling the European asparagus aphid; therefore, the Agency believes that the critical need for the use of this chemical outweigh the risks.

Based on information from the USDA National Agricultural Statistics Service (NASS), the overall average asparagus farm size in California is 219 acres. Also, for asparagus farms in Washington, no farm is greater than 300 acres, and the average asparagus farm size is 62 acres. Other sources indicate that the maximum area that can be aerially treated in a day is about 75-150 acres in Washington, and about 150-200 acres in California. This information indicates an approximate 2 to 4-fold reduction in the default 350 acres treated per day used to assess occupational risks associated with aerial applications.

Applications of liquid disulfoton to asparagus are for foliar treatment; therefore, the REI for workers to re-enter treated fields is 26 days. However, because disulfoton is applied to asparagus post-harvest, during the fern stage when growers do not need to re-enter treated fields, this long REI is not expected to pose an undue hardship to growers. Also, the WPS allows REI exemptions to cover certain critical activities.

| Scenario | Worker MOE with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Aerial | 22 | 34 | 26 days |
| Groundboom | 46 | (66) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator
The aerial scenario is based on 175 acres treated/day

**Asparagus Decision.** Use of the liquid formulation only is eligible for reregistration, and only in states where disulfoton is registered as a 24(c) SLN for asparagus. The maximum number of allowable applications for asparagus must be reduced from three times per year to two times per year to help mitigate ecological risks. Also, the REI is to be extended to 26 days.

***Barley and Wheat***

Both liquid and granular formulations are registered for use on barley and wheat, but late-season aerial application of the liquid appears to be the predominant use. Use of disulfoton on these crops has been declining in recent years with <1% of either crop being treated nationally. Disulfoton is used to control late-season infestations of Russian wheat aphid in malting barley, which is used in beer production. Approximately 3% of all acres planted in barley experience localized pockets of aphid infestation. The limited acreage of malting barley crops that are affected by aphid damage are sometimes downgraded to lower value feed barley, depending upon the plumpness of the kernel.

The main alternative available to malting barley growers is lambda cyhalothrin (Warrior®), which is currently only available as a FIFRA Section 18 registration in certain states. Imidacloprid is also available to barley growers. Barley growers have been increasingly using lambda cyhalothrin to control aphids, which is contributing to the decline in disulfoton use. Although lambda cyhalothrin is more expensive than disulfoton, the cost differential does not appear to be a disincentive for growers, because it is clearly the preferred choice for treating

malting barley and is considered a safer alternative to disulfoton. However, growers have expressed some concern about the potential of aphids to develop resistance to the synthetic pyrethroid, lambda cyhalothrin. The Agency recognizes that resistence has been a problem with certain synthetic pyrethroids, but is unable to use this information to predict likely grower experience with lambda cyhalothrin in future years. A FIFRA Section 3 registration for lambda cyhalothrin on wheat, barley, and other cereal grains is pending and is expected to be granted in 2002.

As with its use on barley, only a small percentage of wheat fields are treated with disulfoton. When disulfoton is used on wheat, it is to control the Barley Yellow Dwarf Virus, which is transmitted by aphids. The highest reported use of disulfoton on wheat is in Kentucky, where a late-season application of the liquid is made by custom applicators. In addition to the pesticides that are available to barley growers, some of the key alternatives available to wheat growers are chlorpyrifos, malathion, methomyl and pyrethrins. The Agency considers the benefits associated with the use of disulfoton on barley, including the availability and effectiveness of alternatives, including lambda cyhalothrin, to be similar to its use on wheat.

Foliar applications of liquid disulfoton resulted in post-application risk concerns for up to 16 days after application to barley, and 13 days after application to wheat. Therefore, the REI for workers to re-enter treated fields is 16 days for barley and 13 days for wheat for this type of application. Because barley and wheat are mechanically harvested, this longer REI is not expected to pose an undue hardship to growers. Also, the WPS allows REI exemptions to cover critical activities, such as irrigation, agricultural emergencies, or short-term activities. MOEs and REIs are summarized below for barley and wheat use.

| **Scenario** | **Worker MOEs with Engineering Controls** | | **REI** |
|---|---|---|---|
| | **Mixer/Loader** | **Applicator** | |
| BARLEY | | | |
| Aerial (liquid) | 3.1 | 5.1 | 16 days for foliar applications with liquid formulation<br><br>48/72 hours for granular formulation |
| Aerial (granular) | 53 | 1.8 | |
| Groundboom | 18 | (27) | |
| Granular Tractor-Drawn Spreader | 320 | (37) | |
| WHEAT | | | |
| Aerial (liquid) | 4.1 | 6.8 | 13 days for foliar applications with liquid formulation<br><br>48/72 hours for granular formulation |
| Aerial (granular) | 53 | 1.8 | |
| Groundboom | 18 | (27) | |
| Granular Tractor-Drawn Spreader | 320 | (37) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Barley and Wheat Decision:** Use of both the liquid and granular formulation on barley and wheat are to be phased out by June 2005 to allow time for growers to transition to alternatives, including lambda cyhalothrin. In the interim, the REI for foliar application is to be extended to 16 days for barley and 13 days for wheat. For disulfoton applications that are soil directed, the REI remains at 48/72 hours. Also, the technical registrant had requested the liquid (Di-Syston 8EC) label for use on wheat be changed to reduce the number of foliar applications from two to one, for a seasonal maximum rate of 0.75 lb ai/A.

*Snap and Lima Beans*

Both the liquid and granular formulations are registered for use on beans, and growers use both formulations. Based on data from 1987 to 1998, approximately 12% of planted beans are treated with disulfoton. Disulfoton is applied at-plant and soil incorporated (i.e., in-furrow and injected as a side-dressing) to control thrips. Most of disulfoton use on lima beans is in Georgia, where 20-30% of the crop is treated. At present, foliar application of acephate is the only alternative pesticide to control thrips on lima beans. Disulfoton use on snap beans to control the potato leaf hopper is sporadic and appears to be declining. The target pest occurs intermittently and does not require control every year. Registered alternatives to disulfoton on snap beans include other organophosphates (acephate and dimethoate) or carbamates (carbaryl and methomyl).

The occupational risk estimates for this use are summarized below. As stated earlier, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as beans. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 23 | (33) | 48/72 hours |
| Tractor-Drawn Spreader | 800 | (91) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Bean Decision:** Use of both the liquid and granular formulation on snap and lima beans are eligible for reregistration. The technical registrant has reduced the maximum rate for the granular formulation from 2 lbs ai/A to 1 lb ai/A (which is reflected in the above table). Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

*Cabbage*

Both the liquid and granular formulations are registered for use on cabbage, and are used

mostly as a rescue remedy for cabbage aphid and green peach aphid infestations. The liquid formulation is shank injected and the granular formulation is applied as a soil incorporated band or side-dressing. Chemigation is an application method no longer being practiced by growers. According to USDA NASS data for the year 2000, approximately 3,400 lb ai of disulfoton was applied, with 3% of all cabbage grown nationally being treated with disulfoton. Most disulfoton use on cabbage is in California, where from 1997 to 1999, an average of 3100 lbs ai of disulfoton was applied to cabbage, primarily in Ventura County. Both the liquid and granular formulations of disulfoton are used in California. Imidacloprid is the main alternative, but it does not provide the same long residual control as disulfoton. Disulfoton provides the advantage of protecting cabbage plants from aphid infestation for the entire season, and if it were not available, may necessitate multiple applications imidacloprid.

The occupational risk estimates for this use are summarized below. As stated earlier, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as cabbage. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 23 | (33) | 48/72 hours |
| Tractor-Drawn Spreader | 530 | (62) | |
| Chemigation | 5.3 | | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Cabbage Decision:** Use of both the liquid and granular formulation on cabbage are eligible for reregistration, provided the chemigation application methods is deleted from labels. Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

***Cole Crops (Broccoli, Brussels Sprouts, Cauliflower)***

Both the liquid and granular formulations are registered for use on broccoli, Brussels sprouts, and cauliflower. The liquid is used exclusively in California's Salinas Valley, where it is applied by shank injection once per season as a rescue remedy to control cabbage and green peach aphids. Within the Salinas Valley, Monterey County appears to be where the liquid formulation is used predominantly. The importance of disulfoton use on cole crops in California is demonstrated by the usage data from 1997 to 1999 for Monterey County, California which indicate that as much as 60% of broccoli, 87% of Brussels sprouts, and 52% of cauliflower that was grown was treated with disulfoton. The granular formulation is mainly used on cole crops grown outside California.

Registered alternatives to disulfoton on cole crops include imidacloprid and the OP

pesticides oxydemeton-methyl, dimethoate, and chlorpyrifos. Currently, imidacloprid is applied at-plant, but it does not control the cabbage aphid throughout the entire growing season, due to its limited period of residual effectiveness. Also, imidacloprid is not effective as a foliar application. Chlorpyrifos is toxic to beneficial insects and also causes phytotoxicity at the high rates required to control the cabbage aphid.

Commercial applicators in California, who treat many farms and therefore receive the most exposure, generally treat no more than 40 acres per day. Private growers treat even less acreage. While commercial applicators may treat more than one farm during severe aphid outbreaks, they typically apply disulfoton no more than two or three times in one week. To assess risk based on typical current practices in California, the Agency adjusted worker MOEs in the table below to reflect the assumption that no more than 40 acres are treated per day for cole crops. Also, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as cole crops. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 92 | (132) | 48/72 hours |
| Tractor-Drawn Spreader | 800 | (91) | |
| Chemigation | 96 | | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator
MOEs for both groundboom and chemigation use are adjusted to reflect 40 acres treated/day

**Cole Crop Decision:** Based on the reduced acreage treated assumption for the groundboom and chemigation scenarios, the corresponding MOEs for mixers/loaders and applicators are near or above the target MOE of 100, and are therefore not of concern to the Agency. Hence, use of both the liquid and granular formulation on cole crops are eligible for reregistration. However, because the liquid formulation is used exclusively in California, the Section 3 label is to be modified to limit use to California only, which reflects current agricultural practice. Because disulfoton applications are soil directed, the REI remains at 48/72 hours. Also, to mitigate ecological risk, the technical registrant has reduced the number of soil applications for broccoli and cauliflower from two to one, for a seasonal total of 1 lb ai/A.

*Lettuce*

Only the liquid formulation of disulfoton is registered for use on lettuce. Disulfoton is applied pre-plant or at-plant by banding. Nearly all (>95%) iceberg lettuce and leaf lettuce grown in the United States is produced in California and Arizona. Based on 1987 to 1998 usage information, a weighted average of approximately 13,000 lbs ai of disulfoton was applied to lettuce nationally. However, most of disulfoton use on lettuce is in California, where from 1997

to 1999 an average of approximately 11,000 lbs ai of disulfoton was applied to lettuce. No use of disulfoton has been reported in other major lettuce producing states, including Florida and Arizona.

Disulfoton use on lettuce in California is mostly limited to the Salinas Valley, which includes Monterey County. Approximately 59% of the total amount of disulfoton that is used on head lettuce is used in Monterey County, and 57% of the total amount of disulfoton that is used on leaf lettuce is also used in Monterey County. The surrounding counties that encompass Salinas Valley consume much of the remaining amount of disulfoton used on lettuce. Disulfoton is used in this area primarily to control the lettuce root aphid, which is harbored in Lombardy poplars, a popular ornamental. Growers have indicated that root aphid infestation could result is as much as 20-30% of individual field loss. The main pesticide alternative available is imidacloprid, which has a short residual activity and therefore does not provide adequate control. As such, disulfoton is used as a rescue remedy, when other methods of pest control fail.

As mentioned previously, private growers and commercial applicators in the Salinas Valley generally treat fewer acres per day than was assumed in the occupational risk assessment. To assess risk based on typical current practices in California, the Agency adjusted worker MOEs in the table below to reflect the assumption that no more than 40 acres are treated per day for lettuce.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 46 | (66) | 48/72 hours |
| Chemigation | 46 | | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator
MOEs for both groundboom and chemigation use are adjusted to reflect 40 acres treated/day

**Lettuce Decision:** Use of the liquid formulation on lettuce is eligible for reregistration. However, because the liquid formulation is used exclusively in California, the Section 3 label is to be modified to limit use to California only, which reflects current agricultural practice. Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

***Cotton***

Both the liquid and granular formulations are registered for use on cotton. Approximately half of all disulfoton annually produced is used on cotton (420,000 lbs ai), with 5-8% of the crop being treated. Most use is in Louisiana, Missouri, Mississippi, and Texas, with some use in Alabama, Arkansas, Georgia, Florida, Tennessee, the Carolinas, and Virginia. Disulfoton is predominately used as a safener to protect cotton seedlings from the effects of the herbicide clomazone (Command®), which is the herbicide of choice to control velvet leaf, primrose, morning glory, and wild poinsettia. Disulfoton is applied in-furrow with the seed, while clomazone is applied as a band on top. Roughly equal amounts of both the liquid and

granular formulation are used by cotton growers, which is largely determined by the type of equipment available to the grower. If either formulation were no longer available, growers would incur substantial costs to convert their equipment to the other formulation. Also, because aerial applications are not being made by growers, this method of application is not being supported for reregistration and is being voluntarily cancelled.

Alternatives to disulfoton use on cotton include phorate and aldicarb. However, phorate, which is applied as a granular formulation, is not as efficacious against thrips; and aldicarb, which is very effective against thrips, does not act as a safener. Although use of disulfoton on cotton has been declining, due to the introduction of genetically modified glyphosate tolerant (RoundUp-Ready®) cotton, the percentage of acreage that can be planted with glyphosate tolerant cotton is limited. Therefore, disulfoton is still important in areas that use clomazone for weed control.

The occupational risk estimates for this use are summarized below. As stated earlier, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as cotton. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Aerial (SLN) (Voluntary Cancellation) | 15 | 25 | 48/72 hours |
| Groundboom | 18 | (27) | |
| Tractor-Drawn Spreader | 320 | (37) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Cotton Decision:** Use of both the liquid and granular formulation on cotton are eligible for reregistration. Also, labeling shall specify at-plant and in-furrow applications only, and for use as safener, which reflects current agricultural practice. Because disulfoton applications are to be limited to at-plant and in-furrow as a safener, the current REI of 48/72 hours is still protective and shall remain. Also, because aerial application to cotton is no longer being made by growers, it is not being supported for reregistration. Therefore, labels for disulfoton use on cotton use will need to be amended to prohibit aerial application, including the 24(c) SLN registration for aerial use in Texas. Moreover, to help mitigate ecological risk concerns, the technical registrant removed foliar application from the Section 3 disulfoton labels, and reduced the number of soil applications from three to one per year at a rate of 1 lb ai/A.

***Peanuts***

Only the granular formulation of disulfoton is registered for use on peanuts. Based on

1987 to 1998 usage data, a weighted average of 47,000 lb ai of disulfoton was applied annually to peanuts, which accounts for approximately 3% of the crop being treated. In the year 2000, disulfoton use on peanuts was reported in Alabama, Georgia, North Carolina, and Oklahoma. Disulfoton is applied in-furrow or as a soil incorporated side-dressing to control thrips and aphids. Since the time the occupational risk assessment was prepared, Bayer, the technical registrant, had reduced the maximum application rate for the Section 3 registration from 2 lbs ai/A to 1 lb ai/A. Moreover, North Carolina has also voluntarily agreed to reduce the maximum application rate to 1 lb ai/A for their 24(c) SLN registration. The occupational risk estimates based on the 1 lb ai/A rate are summarized below. Also, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as peanuts. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Loader | Applicator | |
| Tractor-Drawn Spreader | 800 | (91) | 48/72 hours |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Peanuts Decision:** With the reduction of the maximum application rate for disulfoton use on peanuts, the corresponding MOEs for loaders and applicators are near or above the target MOE of 100, and are therefore not of concern to the Agency. Hence, use of the granular formulation on peanuts is eligible for reregistration. Because disulfoton applications are soil directed, the REI remains at 48/72 hours. The technical registrant has reduced the maximum application rate on Section 3 labels from 2 lb ai/A to 1 lb ai/A. Similarly, North Carolina has also voluntarily agreed to reduce the maximum application rate to 1 lb ai/A for their 24(c) SLN registration; however, in accordance with the current 24(c) registration, two applications of disulfoton on peanuts is still permitted.

***Peppers***

Both the liquid and granular formulations are registered for use on a variety of peppers. The liquid registration is limited to a 24(c) SLN registration in California, where it is applied to the soil by shank injection. This is the application method of choice in California, because growers are not equipped to apply the granular formulation. Based on 1987 to 1998 usage data, a weighted average of 4,000 lb ai of disulfoton was applied annually to chili peppers, which accounts for approximately 25% of the crop being treated. Although a significant percentage of peppers grown in the US are harvested in New Mexico and California, peppers are also grown in other regions of the country. For instance, USDA NASS data for the year 2000 indicate that New Mexico harvested 57% of the chili peppers produced in the US, and California harvested 41% of the bell peppers produced in the US. These figures indicate that a considerable amount of peppers are grown outside these states as well. Most of the use of the liquid formulation is in the Salinas Valley of California where disulfoton is used as a rescue remedy to control the green

peach and cabbage aphid and the garden symphylan, a non insect pest. The green peach aphid vectors for several mosaic viruses lethal to pepper plants. The granular formulation, which is used outside California, is applied in a soil incorporated band.

Registered alternatives to disulfoton on peppers include imidacloprid, diazinon, dimethoate, malathion, chlorpyrifos, oxydemeton-methyl, and pyrethrins. Neither diazinon nor malathion is effective against the green peach aphid. Dimethoate is an inexpensive, frequently used alternative, but it is no longer effective for aphid control in some areas of California and New Mexico. Use of imidacloprid is increasing, but it does not provide effective control in some parts of California. Chlorpyrifos is toxic to beneficial insects and also causes phytotoxicity at the high rates required to control the cabbage aphid. Pyrethroids are not often used, because they are not compatible with integrated pest management (IPM) programs. Therefore, the Agency believes that there is a critical need for disulfoton use on peppers.

As mentioned previously, private growers and commercial applicators in the Salinas Valley generally treat fewer acres per day than was assumed in the occupational risk assessment. To assess risk based on typical current practices in California, the Agency adjusted worker MOEs in the table below for the groundboom scenario to reflect the assumption that no more than 40 acres are treated per day for peppers. MOEs for the granular tractor drawn spreader scenario were not adjusted because it is primarily used outside California. Also, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as peppers. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 46 | (66) | 48/72 hours |
| Tractor-Drawn Spreader | 400 | (45) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator
MOEs for the groundboom scenario are adjusted to reflect 40 acres treated/day

**Pepper Decision:** Use of both the liquid and granular formulations on peppers are eligible for reregistration. Because the liquid formulation is used exclusively in California, its use is limited to an existing FIFRA 24(c) SLN registration in California, which reflects current agricultural practice. Also, because disulfoton applications are soil directed, the REI remains at 48/72 hours.

***Potatoes***

Both the liquid and granular formulations of disulfoton are registered for use on potatoes to control aphids. The liquid is mainly used in the Pacific Northwest (PNW) (i.e., Oregon, Idaho, Washington, and Utah), where it is predominantly applied either aerially or by

chemigation (sprinkler irrigation) as an alternative to methamidophos (Monitor®), the pesticide of choice. The liquid formulation is generally applied as a foliar application for late-season aphid control in sensitive areas where growers cannot aerially apply methamidophos. The granular formulation appears to be used mostly outside the PNW, where it is applied to the soil and incorporated. Based on 1987-1998 usage data, an average of 4% of the nations potato acreage were treated with disulfoton. However, use of disulfoton on potatoes in recent years appears to be declining with only about 1% of the crop treated nationally in 1999. In Idaho, however, disulfoton use is slightly higher than the national average where 4% of the total potato acres grown were treated.

There are a number of alternative pesticides that are available that can be applied by chemigation to control aphids, which include pymetrozine, thiomethoxam (late-season), imidacloprid (early-season), and methamidophos. Methamidophos (Monitor®), the pesticide of choice for aerial applications is available to control aphids via chemigation. Imidacloprid can be applied at planting for control of early to mid-season aphid and Colorado potato beetle infestations. Both pymetrozine and thiomethoxam can be applied by chemigation, and are effective at late-season aphid control. Further, pymetrozine is less expensive than disulfoton; however, no cost data were available for thiomethoxam. Because pymetrozine and thiomethoxam are relatively new, they have yet to be widely used; however, efficacy field trials show promising results for aphid control. Moreover, the Agency believes that the economic loss resulting from substituting disulfoton with either methamidophos or the other alternatives mentioned would cause negligible economic impact to the overall potato industry. Because of the availability of these alternatives, which may be contributing to the decline in disulfoton use, and the negligible economic impact to the industry, the Agency believes that potato growers no longer have a critical need for disulfoton.

<table>
<tr><th rowspan="2">Scenario</th><th colspan="2">Worker MOEs with Engineering Controls</th><th rowspan="2">REI</th></tr>
<tr><th>Mixer/Loader</th><th>Applicator</th></tr>
<tr><td>Aerial (liquid)<br>(East of the Rockies)</td><td>21</td><td>35</td><td>20 days<br>(Foliar Application)</td></tr>
<tr><td>Groundboom</td><td>15</td><td>(22)</td><td rowspan="2">37 days<br>(Foliar Application)</td></tr>
<tr><td>Chemigation</td><td colspan="2">3.5</td></tr>
<tr><td>Aerial (granular)</td><td>61</td><td>2.1</td><td rowspan="2">48/72 hours<br>(Soil Directed<br>Application)</td></tr>
<tr><td>Tractor-Drawn Spreader</td><td>270</td><td>(31)</td></tr>
</table>

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Potato Decision:** Use of both the liquid and granular formulations are to be phased out by June 2005 to allow growers time to transition to the newer and safer alternatives. In the interim, the REI for foliar application to potatoes is to be extended to 37 days for overhead sprinkler irrigation and groundboom applications, and 20 days for aerial applications East of the Rockies. For disulfoton applications that are soil directed, the REI remains at 48/72 hours.

Also, to help further mitigate occupational and ecological risks, the technical registrant has reduced the total number of soil applications from two to one per year; has discontinued all foliar application West of the Rockies, except overhead sprinkler irrigation (chemigation); and reduced the maximum application rate from 3 to 0.5 lb ai/A for foliar applications East of the Rockies.

*Radish Grown for Seed*

Both the liquid and granular formulations are registered for use on radish grown for seed in Washington only through a 24(c) SLN registration. As part of this registration, disulfoton use is limited to the Columbia River Basin in Washington to control cabbage and turnip aphids, which are a pest not seen in other areas that can cause premature plant death and crop loss. Both formulations are applied to the soil and are either shank injected or soil incorporated. In the year 2000, only about 635 acres total of this crop was produced. Even though it is a minor crop, it is an economically important crop for growers in the Columbia River Basin, and disulfoton provides a niche use to this industry.

The only registered alternatives available to growers are pirimicarb, chlorpyrifos, and pymetrozine. Pirimicarb is used solely to control late-season aphid infestations; chlorpyrifos cannot be used during bloom when aphids can occur; and pymetrozine is more expensive than disulfoton and does not provide good lower canopy control. Another advantage of disulfoton is that it allows predatory and parasitic insects to develop in the seed radish fields.

The occupational risk estimates for this use are summarized below. As stated earlier, the Agency has some uncertainty regarding risk estimates for crops where disulfoton is either shank injected or applied in-furrow, such as radish. The Agency believes that these soil incorporated methods of application result in less exposure to the applicator than does the groundboom or tractor spreader methods, from which the estimated risks are derived.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Mixer/Loader | Applicator | |
| Groundboom | 23 | (33) | 48/72 hours |
| Tractor-Drawn Spreader | 400 | (45) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Radish Grown for Seed Decision:** Use of both the liquid and granular formulations on radish grown for seed are eligible for reregistration, through the existing FIFRA 24(c) SLN registration in Washington only. Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

*Clover Grown for Seed*

Only the granular formulation is registered for use on clover grown for seed in

Washington only through a 24(c) SLN registration. One soil directed application of disulfoton is made per crop season with a tractor drawn spreader to control aphids and mites. The occupational risk estimates for this use are summarized below. Because the occupational risks are low, information on the benefits associated with this use was not collected.

| Scenario | Worker MOEs with Engineering Controls | | REI |
|---|---|---|---|
| | Loader | Applicator | |
| Tractor-Drawn Spreader | 800 | (91) | 48/72 hours |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Clover Grown for Seed Decision**: The MOEs for loaders and applicators are near or above the target MOE of 100, and are therefore not of concern to the Agency. Hence, use of the granular formulation on clover grown for seed is eligible for reregistration, through the existing FIFRA 24(c) SLN registration in Washington only. Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

***Coffee Trees***

The granular formulation is registered for use in Puerto Rico only on coffee trees. Disulfoton is applied to the soil by custom applicators only using a bucket and spoon at a rate of 8.3 lbs ai/A. This rate is much a higher rate than that used for most other crops, but is validated by efficacy data. The benefits associated with the use of disulfoton on coffee trees in Puerto Rico are high, largely because of the need to control leafminers, which can cause up to a 40% reduction in yield. The only alternatives available to growers are aldicarb and azadirachtin; however, azadirachtin does not have the residual activity needed to control leafminers.

The occupational risk estimates for handling and applying disulfoton to coffee trees are summarized below. The Agency assessed risks using two application methods: hand application with a bucket and spoon with PPE, which is currently used by custom applicators in Puerto Rico; and a tractor drawn spreader with engineering controls, which serves as a surrogate for other potential application methods. The Agency believes that risks can be reduced by use of a closed loading/transfer system, with performance specifications similar to the device currently under development by Tuthill Sotera in cooperation with the North Carolina Cooperative Extension Service for use on Christmas trees. For comparison purposes, assuming this closed loading/transfer device being developed will provide at least the same level of protection as a closed system currently available for tractor drawn spreaders, the MOE for an individual loading the granulars with a closed transfer handheld device could be as high as 1500, based on the individual applying up to 5 acres in a day. The Agency acknowledges that this estimate does not include the exposure the same individual would received from also applying the chemical with this device, because data to complete this analysis is not yet available. However, the Agency expects that the protection provided by this type of device will be significantly better than the current bucket and spoon application practice.

| Scenario | Worker MOEs | | REI |
|---|---|---|---|
| | Loader | Applicator | |
| Bucket & Spoon | 0.2 - 0.4 [Minimum PPE] | | 48/72 hours |
| Tractor-Drawn Spreader | 96 [Eng. Controls] | (11) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Coffee Tree Decision:** Use of the granular formulation on coffee trees in Puerto Rico only is eligible for reregistration provided that a closed transfer system is implemented by June 2004 and the REI remains at 48/72 hours.

***Christmas Trees (Fraser firs)***

Only the granular is registered for use on conifers raised for the Christmas tree market. There is also a 24(c) SLN registration in North Carolina for use of disulfoton at a rate of 4.5 lbs ai/A to control balsam wooly algedid and spruce spider mite on Fraser firs. The Section 3 registration is for a rate of 3.75 to 7.5 grams per foot of tree height *or* 2.5 oz/inch of tree diameter at 4 feet above ground (diameter chest height), which extrapolates to 78 lb ai/A. According to the National Christmas tree association, disulfoton is used on firs grown for Christmas trees in 16 states. North Carolina represents the greatest use, with 60,000 lbs ai applied annually and 65% of the crop being treated. The target pests named above cause significant crop damage, resulting in downgrading of trees and reduced sale value. In cases of severe pest damage, trees must be held over for an additional year, at a cost to the grower, or infested trees must be destroyed.

Disulfoton is applied at bud break in early spring, followed by foliar applications of chlorpyrifos and esfenvalerate. Chlorpyrifos and esfenvalerate must be foliarly-applied by a commercial applicator by mist blower or high-powered hose sprayer. Foliar applications are problematic because they are usually uneven, which significantly affects efficacy. Further, the chlorpyrifos foliar spray is phytotoxic in some situations, and although esfenvalerate controls the balsam wooly adelgid to a limited extent, it allows the spider mite populations to increase. In comparison, disulfoton controls both the balsam twig aphid and spruce spider mite, while conserving beneficial insect predators. This information indicates that the need for disulfoton is critical, especially for use on Fraser firs in North Carolina, because firs are a high value perennial crop.

The occupational risk estimates for the predominant application methods used in North Carolina are summarized below, and represent the worse case for use on firs. The Agency believes that risks can be reduced by use of a closed loading/transfer system currently under development by Tuthill Sotera in cooperation with the North Carolina Cooperative Extension Service for use on Christmas trees.

| Scenario | Worker MOEs | | REI |
|---|---|---|---|
| | Loader | Applicator | |
| Bucket & Spoon | 0.4 - 0.7 [Minimum PPE] | | 48/72 hours |
| Tractor-Drawn Spreader (Motorbike) | 280 [Eng. Controls] | 23 [Maximum PPE] | |

**Christmas Tree Decision:** Use of the granular formulation on Christmas trees is eligible for reregistration, provided the Section 3 label maximum application rate is reduced to 4.5 lb ai/A, and use is limited to firs, and a closed transfer system is implemented by June 2002, and confirmatory exposure data for loader/applicators demonstrate that exposure and risk are comparable to other high benefit scenarios. Also, disulfoton must be soil incorporated, watered in, or applied to areas with permanent groundcover. Because disulfoton applications are soil directed, the REI remains at 48/72 hours.

***Commercially Grown Ornamentals***

Only the granular formulation is registered for use on numerous species of ornamental plants, including shrubs, trees, flowers and groundcover, and potted ornamental plants (field or nursery stock). The current label specifies application rates of 3.75 to 7.5 grams per foot of height for a tree or shrub; 2.5 oz per inch of trunk diameter measured 4 feet from the ground for trees; or 5 lb product (0.75 lb a.i.) per 1000 linear feet of row. For purposes of risk assessment, the Agency has converted these rates to 37 lb ai/A for trees, 109 lb ai/A for shrubs, and 29 lb ai/A for field grown ornamental flowers and groundcover. The Agency also assessed risks based on 13 lb ai/A, the lowest rate that the American Nursery & Landscape Association stated was necessary to ensure efficacy.

There is very little documented use of disulfoton on ornamentals and many alternative pesticides are available. Based on preliminary results of recent USDA NASS data for pesticide use in the nursery and floriculture industry, only 22 of 4,000 operations reported use of disulfoton. The California use reporting database also shows little use of the chemical for ornamental plants. Moreover, after conducting exhaustive outreach to major states which produce ornamentals, very little use was disclosed and many agricultural extension agents who work with ornamental plants do not recommend use of disulfoton. Also, there are significant uncertainties associated with potential post-application exposure from routine activities, such as transplanting. To adequately assess risks for these type of activities, post-application exposure monitoring, which include soil residue dissipation (OPPTS 875.2200) and dermal exposure (OPPTS 875.2400) data, would need to be provided to the Agency. These data might indicate the need for further REI restrictions.

Given the limited use and availability of cost-effective efficacious alternatives, the benefits of continued use are low, particularly when compared to the worker MOEs and uncertainty associated with post-application activities and risks. Worker risk estimates for the predominant use of disulfoton on field grown ornamental shrubs, trees, flowers, and groundcover

at an application rate of 13 lb ai/A are summarized below.

| Scenario | Worker MOEs | | REI |
|---|---|---|---|
| | Loader | Applicator | |
| Loading/Applying with Scoop & Bucket | 0.1 - 0.3 [Minimum PPE] | | 48/72 hours |
| Loading/Applying with Belly Grinder | 0.1 [Maximum PPE] | | |
| Tractor-Drawn Spreader | 120 [Eng. Controls] | (14) | |

( ) Indicates risk estimate for an applicator in an enclosed cab with a dust/mist respirator

**Ornamentals Decision:** Use of the granular formulation is to be phase out by June 2005, because of the limited existing need and use of the chemical, and the absence of information on the benefits of its continued use. For disulfoton applications that are soil directed, the REI remains at 48/72 hours.

### E. Labeling

In order to remain eligible for reregistration, other use and safety information needs to be placed on the labeling of all end-use products containing disulfoton. For the specific labeling statements, refer to Table 16 in Section V of this document.

#### 1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. Disulfoton has potential to result in effects to several aquatic species, in the absence of additional safeguards. EPA has adopted Reasonable and Prudent Measures (RPMs) provided by the U.S. Fish and Wildlife Service Biological Opinions and has or will implement these measures, as appropriate, through Endangered Species Interim Bulletins.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp.

#### 2. Spray Drift Management

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

by the Spray Drift Task Force and is developing policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, or ground hydraulic spray. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial application or other application methods associated with drift, where appropriate.

Based on these analyses, the Agency is in the process of developing more appropriate label statements for spray, and dust drift control to ensure that public health, and the environment are 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 (http://www.epa.gov/fedrgstr) announcing the availability of this draft guidance for a 90-day public comment period. After review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

In the interim, registrants may choose to use the proposed statements. Registrants should read and refer to the draft PR notice to obtain a full understanding of the proposed guidance and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

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

For products applied outdoors as liquids:

"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals."

"For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles."

"For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy."

For overhead chemigation:

"Apply only when wind speed is 10 mph or less."

On all product labels:

"The applicator also must use all other measures necessary to control drift."
"For ground rig applications, apply product no more than 4 feet above the ground or the crop canopy, and only when wind speed is 10 mph or less at the application site as measured by an anemometer."

"For aerial applications, use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. If application includes a no-spray zone, do not release dust at a height greater than 10 feet above the ground or the crop canopy."

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

For hand-applied products, including home and garden products, to be applied as sprays or dusts:

"Do not allow spray or dust to drift from the application site, and contact people, structures people occupy at any time, and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. Apply only when wind speed is not more than 10 mph. For sprays, apply largest size droplets possible."

Alternatively, registrants may elect to use the following language, which is the current Agency policy on drift labeling:

For products that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method, the following must be added to the labels:

"Do not allow this product to drift."

The Agency recognizes that the above option does not address other application types. Registrants may therefore wish to adapt some variation of the old, and proposed new language for their particular products, depending on their application methods.

### F. Disulfoton Risk Mitigation Summary

Based on the rationale for the interim decisions associated with the use of disulfoton, the following risk mitigation measures are also necessary to be incorporated in their entirety into labels for disulfoton-containing products in order for disulfoton to be eligible for reregistration.

Specific language of these revisions is set forth in the summary tables of Section V of this document. Likewise, the data required to be provided to the Agency to confirm these regulatory decisions are also listed in Section V.

***Dietary Risk***

- No label changes are necessary, however certain confirmatory data listed in Section V is required.

***Residential Risk***

Only end-use products containing 2% active ingredient or less are eligible for reregistration. The following measures are necessary to mitigate residential risk:

- Limit maximum label rates for disulfoton packaged for hand application with a self contained measuring cup/lid to 0.3 lb ai/1000 $ft^2$ for use on flowerbeds; 0.01 lb ai/4 ft bush for use on shrubs; and 0.0013 lb ai/bush for use on rose bushes.

- Limit the maximum label rate for disulfoton packaged for application with a push type spreader to 0.3 lb ai/1000 $ft^2$. Products to be applied by this method do not need to be in child resistant packaging, and commercial use of this product is prohibited.

- Prohibit application of disulfoton with a belly grinder.

- Prohibit application to flower gardens and ornamental shrubs with a spoon, measuring scoop, shaker can, or by hand, unless the packaging and method of application of the end-use product conforms with the performance of a measuring cup and lid packaging currently manufactured for the Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® Disulfoton 1% granular product.

- Package all products marketed and labeled for hand application in child resistant packaging with a self-contained measuring device, which serves as the container lid and clearly measures the quantity to be applied. Products marketed and labeled for application with a push type spreader do not need to be in child resistant packaging, but must be labeled "not for application by hand." Commercial use of the homeowner product is prohibited.

- Delete the following uses from all product labels: all indoor uses, use in greenhouses, and use on home vegetable gardens, including use on spinach and tomatoes.

***Occupational Risk***

<u>The following measures are necessary to mitigate handler risk</u>:

- Closed mixing/loading systems for liquid formulations by December 31, 2002;
- Closed loading systems for granular formulations by June 2004;
- Enclosed cabs plus a dust-mist respirator for all ground equipment applicators;
- Enclosed cockpits for all aerial applicators;
- Mechanical flaggers for aerial application; or the use of global positioning system (GPS) equipment that negates the need for flaggers;
- When engineering controls are not feasible, handlers must wear maximum PPE (i.e., double layer clothing, chemical-resistant gloves and footwear, and a dust-mist respirator);
- Use on cotton is limited to at plant, in furrow, and use as a herbicide safener only;
- Reduction of maximum application rate from 2 lb ai/A to 1 lb ai/A for beans and peanuts;
- For coffee and Christmas trees, application by open, handheld equipment, including belly grinders and bucket and spoon will be prohibited after June 2004. Where this is currently the application method of choice, growers will be allowed until June 2004 to transition to another method; and
- Use on barley, wheat, potatoes, and commercially grown ornamentals (field or nursery stock) is phased out by June 2005.

The following measures are necessary to mitigate risk to post-application workers:

- For soil directed application of the liquid formulation and for all granular formulations, the Worker Protection Standard designates the REI to be 48 hours, or 72 hours in regions where the annual rainfall is less than 25 inches. These are the current REIs on disulfoton product labels.
- For foliar application of the liquid formulation, a 26 day REI is necessary for asparagus. Longer REIs are also necessary for foliar application to barley (16 days), wheat (13 days), and potatoes (20 or 37 days depending upon method of application). As mentioned above, the uses on barley, wheat, potatoes, and ornamentals are to be phased out by June 2005.

***Ecological Risks***

The following measures are necessary to mitigate ecological risks. Disulfoton is eligible for reregistration provided that:

- A precautionary bee statement is added to all product labels for liquid formulations of disulfoton

- Use is prohibited within a level, well maintained 25 foot vegetative buffer between treated fields and all permanent water bodies. (Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for guidance.)

- No more than one application of disulfoton per calendar year for all crops, except for asparagus, barley, coffee, peanuts (North Carlina only), and potatoes (foliar application West of the Rockies only), for which no more than two applications of disulfoton per calendar year are permitted.

- Aerial application to cotton is prohibited;

- The maximum application rate for Christmas trees is reduced from 78 to 4.5 lbs ai/A nationally, the use is limited to fir species only, and disulfoton is soil incorporated, watered in, or applied to areas with vegetative groundcover.

- Uses on barley, wheat, potatoes, and ornamental plants, including trees, shrubs, and groundcovers (field or nursery stock), are phased out by June 2005. The phase out of these uses addresses ecological, as well as worker and drinking water risks of concern.

***Eligible Uses***

The following uses are eligible for reregistration, pending consideration of the cumulative assessment for the OPs:

- **Asparagus:** Liquid formulation only

- **Beans, lima and snap**: Both the liquid and granular formulations

- **Cabbage:** Both the liquid and granular formulations

- **Cole Crops (broccoli, Brussels sprouts, cauliflower)**: Both liquid (California only) and granular formulations

- **Lettuce:** Liquid formulation only; California only

- **Peppers:** Both the liquid and granular formulations

- **Peanuts:** Granular formulation only

- **Cotton:** Both the liquid and granular formulations

- **Radish Grown for Seed:** Both the liquid and granular formulations
- **Clover Grown for Seed:** Granular formulation only
- **Coffee Trees:** Granular formulation only
- **Christmas Trees:** Granular formulation only

***Uses to be Phased Out***

- **Barley and Wheat:** Both the liquid and granular formulations
- **Ornamentals:** Granular formulation only for field grown trees, shrubs, flowers and groundcover, and potted ornamentals (field or nursery stock)
- **Potatoes:** Both the liquid and granular formulations

## 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 submit the following:

### A. Data Call-In Responses

For disulfoton 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) any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:** (1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Christina Scheltema at (703) 308-2201 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed as follows:

By US mail:
Document Processing Desk (DCI/SRRD)
Christina Scheltema
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

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

**Within 90 days from the receipt of the product-specific data call-in (PDCI):** (1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and (2) any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:** (1) two copies of the confidential statement of formula (EPA Form 8570-4); (2) a completed original application for 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 16 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 Jane Mitchell at (703) 308-8061 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)
Jane Mitchell
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Jane Mitchell
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

## B. Manufacturing-Use Products

***Generic Data Requirements for Disulfoton***

The generic database supporting the reregistration of disulfoton for the above eligible uses has been reviewed and determined to be substantially complete, except for the following additional required confirmatory data:

1. Anaerobic Aquatic Metabolism (OPPTS 835.4400) (for parent, disulfoton sulfone, and disulfoton sulfoxide)

2. Aerobic Aquatic Metabolism (OPPTS 835.4300) (for parent, disulfoton sulfone, and disulfoton sulfoxide)

3. Mobility/Leaching and Absorption/Desorption (OPPTS 835.1240) (for parent, disulfoton sulfone, and disulfoton sulfoxide)

4. Terrestrial Plant Toxicity, Tier 1, Seedling Emergence (OPPTS 850.4100) and Vegetative Vigor (OPPTS 850.4150) for a typical liquid product, such as Di-Syston 8EC.

5. Certified Limits (OPPTS 830.1750)

6. UV/Visible Absorption of the PAI (OPPTS 830.7050)

7. Applicator Exposure Monitoring - Dermal Exposure, Outdoor (OPPTS 875.1100) and Applicator Exposure Monitoring, Inhalation Exposure, Outdoor (OPPTS 875.1300) for the following scenarios:
   - Liquid formulation, groundboom, enclosed cab + respirator
   - Granular formulation, tractor drawn spreader, enclosed cab + respirator

8. Mixer/Loader/Applicator Exposure Monitoring, Dermal and Inhalation Exposure, Outdoor (OPPTS 875.1100 and 1300) for the following scenarios:
   - Handheld closed loading, transfer, delivery system *(NC Applicator)*
   - Motorcycle mounted granular spreader with closed loading

9. Mixer/Loader Exposure Monitoring - Dermal Exposure, Outdoor (OPPTS 875.1100) and Mixer/Loader Exposure Monitoring - Inhalation Exposure, Outdoor (OPPTS 875.1300) for the following scenarios:
   - Liquid closed loading system, e.g., SecureLink
   - Granular, closed loading system, e.g., Smartbox, Lock 'N Load

10. 21-Day Dermal Toxicology in Rats (OPPTS 870.3200)

11. Crop Field Trials for Cotton Gin Byproducts (OPPTS 860.1500)

12. Crop Field Trials for Lettuce (OPPTS 860.1500)

13. Storage Stability for all Livestock Commodities (OPPTS 860.1380)

14. Drinking Water Monitoring for Surface Water Sources (OPPTS 835.7200)

Also, a Data Call-In Notice (DCI) was sent to registrants of OP pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies. The developmental neurotoxicity study is scheduled to be submitted in November 2004, and the registrant has satisfied the guideline requirements for the acute and subchronic neurotoxicity studies in rats.

***Labeling for Manufacturing Use Products***

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, and address PR Notices and applicable policies, as appropriate. The MUP labeling should bear the labeling contained in Table 16 at the end of this section.

## C. End-Use Products

***Additional Product-Specific Data Requirements***

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

instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, accompanies this IRED.

***Labeling for End-Use Products***

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 16 at the end of this section.

## D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this IRED document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this IRED document. 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 disulfoton products bearing old labels/labeling for 26 months from the date of issuance of this IRED document. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this IRED document. 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.

## E. Labeling Changes Summary Table

In order to be eligible for reregistration, all product labels are to be amended to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

**Table 16. Summary of RED Labeling for Disulfoton**

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| | **Manufacturing Use Products** | |
| Formulation Instructions required on all MUPs | "Only for formulation into an insecticide/miticide for the following use(s): (*fill in blank only with those uses that are being supported by the MUP registrant*)." | Directions for Use |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group. | "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."<br><br>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." | |
| Environmental Hazards Statements | "Environmental Hazards"<br>"This chemical is extremely toxic to birds, mammals, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA." | Precautionary Statements under Environmental Hazards.<br><br>Buffer zones also must appear in directions for use. |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| **End Use Products Intended for Occupational Users Only (Covered by the Worker Protection Standard)** | | |
| Restricted Use Pesticide (required for all products containing > 2% a.i.) | "RESTRICTED USE PESTICIDE"<br><br>Due to Acute Toxicity. "For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification." | Top of Front Panel |
| Handler PPE requirements (all formulations) | Note the following information when preparing labeling for all end use products:<br><br>For sole-active-ingredient end-use products that contain disulfoton, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.<br><br>For multiple-active-ingredient end-use products that contain disulfoton, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.<br><br>PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7. | Handler PPE Statements |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Handler PPE requirements for all liquid formulations.<br><br>*Only products marketed and packaged in containers that are closed system compatible will be eligible for reregistration.* | Personal Protective Equipment<br><br>"Some materials that are chemical resistant to this product are *(registrant inserts correct chemical resistant materials* following the instructions in Supplement 3 of PR Notice 93-7). If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart"<br><br>Handlers using engineering controls must wear:<br><br>Long-sleeved shirt and long pants<br>Shoes plus socks<br><br>In addition to the above, mixers and loaders must wear:<br>Chemical-resistant gloves<br>Chemical-resistant apron<br><br>See engineering controls for additional requirements.<br><br>Handlers engaged in those activities for which use of an engineering control is not possible must wear:<br><br>Coveralls over long-sleeved shirt and long pants,<br>Chemical-resistant gloves,<br>Chemical-resistant footwear plus socks,<br>Chemical-resistant apron (if exposed to the concentrate),<br>Chemical-resistant headgear (if overhead exposure), and<br>A NIOSH-approved dust mist filtering respirator with any N, R, P, or HE filter."<br><br>Note: *The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil."* | Precautionary Statements: Hazards to Humans and Domestic Animals |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Handler PPE requirements for all granular formulations.<br><br>*Only products marketed and packaged in closed systems will be eligible for reregistration.* | Personal Protective Equipment<br>"Some materials that are chemical resistant to this product are *(registrant inserts correct chemical resistant materials following the instructions in Supplement 3 of PR Notice 93-7)* If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart"<br><br>Handlers using engineering controls must wear:<br><br>Long-sleeved shirt and long pants,<br>Shoes plus socks<br><br>In addition to the above, loaders must wear:<br><br>Chemical-resistant gloves<br><br>Handlers engaged in those activities for which use of an engineering control is not possible must wear:<br><br>Coveralls over long-sleeved shirt and long pants,<br>Chemical-resistant gloves,<br>Chemical-resistant footwear plus socks,<br>Chemical-resistant headgear (if overhead exposure), and<br>A NIOSH-approved dust mist filtering respirator with any N, R, P, or HE filter ."<br><br>*Note: The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil."* | Precautionary Statements: Hazards to Humans and Domestic Animals |
| User Safety Requirements | "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."<br><br>"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." | Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Engineering Controls for Liquid Formulations | "Engineering Controls<br><br>Mixers and loaders must use a closed loading system providing dermal and inhalation protection and all loaders must use and maintain this system in a manner consistent with the Worker Protection Standard (WPS) for Agricultural Pesticides [40 CFR 170.240(d)(4). The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to no more than 2 mL per disconnect. In addition, mixers and loaders must:<br>Wear long-sleeved shirt and long pants, chemical-resistant gloves and apron, shoes, and socks;<br>Wear protective eyewear if the system operates under pressure; and<br>Be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the following PPE:<br>Coveralls, chemical-resistant footwear plus socks, chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist filtering respirator with any N R, P, or HE filter ."<br><br>"Applicators using motorized ground-equipment (except for motorcycles) must use and maintain an enclosed cab for dermal protection in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240 (d)(5) In addition, applicators using an enclosed cab must:<br>Wear long-sleeved shirt and long pants, shoes, and socks;<br>Wear a NIOSH-approved dust-mist filtering respirator with any N, R, P, or HE filter;<br>*or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified above; and<br>Be provided and have immediately available for use in case of an emergency when they must exit the cab, the following PPE:<br>Coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical-resistant footwear plus socks, Chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist filtering respirator with any N, R, P, or HE filter."<br><br>"Applicators re-entering the enclosed cab after spending time in the treated area must:<br>Take off any PPE that was worn in the treated area before reentering the cab, and<br>Store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."<br><br>For aerial application, ""Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]."""Human flagging is prohibited." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Engineering Controls for Granular Formulations<br><br>*Only products marketed and packaged in closed systems will be eligible for reregistration.* | "Engineering Controls<br><br>This product is packaged in a closed loading system (*registrant inserts the trade name of the closed system in which the product is marketed, such as Lock 'N Load or SmartBox*) and all loaders must use and maintain this system in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition, loaders must:<br>Wear long-sleeved shirt and long pants, chemical resistant gloves, shoes, and socks;<br>Be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown:<br>Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist filtering respirator with any N R, P, or HE filter."<br><br>"Applicators using motorized ground-equipment (except for motorcycles) must use and maintain an enclosed cab for dermal protection in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition, applicators using an enclosed cab must:<br>Wear long-sleeved shirt and long pants, shoes, and socks; and<br>*Either* wear a NIOSH-approved dust-mist filtering respirator with any N R, P, or HE filter *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling;<br>Be provided and have immediately available for use in case of an emergency when they must exit the cab, the following PPE:<br>Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist respirator with any N R, P, or HE filter."<br><br>"Applicators re-entering the enclosed cab after spending time in the treated area must:<br>Take off any PPE that was worn in the treated area before reentering the cab, and<br>Store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."<br><br>"Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]."<br><br>"Human flagging is prohibited." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| User Safety Recommendations | "User Safety Recommendations"<br><br>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."<br><br>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."<br><br>"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." | Precautionary Statements: Hazards to Humans and Domestic Animals<br><br>(Must be placed in a box immediately following Engineering Controls) |
| Environmental Hazards<br><br>Granular Formulations | "Environmental Hazards:<br><br>"This pesticide is extremely toxic to birds, mammals, fish and aquatic invertebrates. Collect any granules spilled during loading or application. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas."<br><br>"This product has a high potential for runoff for several months. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product."<br><br>"A level, well maintained 25 foot vegetative buffer strip between areas to which this product is applied and permanent surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for additional guidance. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."<br><br>"Disulfoton is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination." | Precautionary Statements under Environmental Hazards<br><br>Buffer zones should be repeated in Directions For Use. |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Environmental Hazards<br><br>Liquid Formulations | "Environmental Hazards:<br><br>"This pesticide is extremely toxic to birds, mammals, fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."<br><br>"This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product."<br><br>"A level, well maintained 25 foot vegetative buffer strip between areas to which this product is applied to permanent surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for additional guidance. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."<br><br>"Disulfoton is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."<br><br>"This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area." | Precautionary Statements under Environmental Hazards<br><br>Buffer zones should be repeated in Directions For Use. |
| Restricted-Entry Interval for Granular Formulations | "Do not enter or allow workers to enter into treated areas during the restricted entry interval (REI) of 48 hours." "The REI is 72 hours in areas where average rainfall is less than 25 inches a year." | Directions for Use, Agricultural Use Requirements Box |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Restricted-Entry Interval for Liquid Formulations | "Do not enter or allow workers to enter into treated areas during the restricted entry interval (REI). The REI for all crops except for those listed below is 48 hours. The REI for all crops except for those listed below is 72 hours in areas where average rainfall is less than 25 inches a year."<br><br>"The REI for foliar applications to asparagus is 26 days."<br>"The REI for foliar applications to potatoes with an overhead sprinkler or groundboom is 37 days."<br>"The REI for aerial applications to potatoes East of the Rockies is 20 days."<br>"The REI for foliar applications to wheat is 13 days."<br>"The REI for foliar applications to barley is 16 days."<br><br>"Exception: if the product is soil-injected or soil-incorporated, the WPS, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated." | Directions for Use, Agricultural Use Requirements Box |
| Early Re-entry Personal Protective Equipment established by the RED. | "The following PPE is required for early entry to treated areas that is permitted under the WPS and that involves contact with anything that has been treated, such as plants, soil, or water:<br>Coveralls worn over long-sleeve shirt and long pants,<br>Chemical-resistant gloves made of any waterproof material,<br>Chemical-resistant footwear plus socks, and<br>Chemical-resistant headgear (if overhead exposure)<br>Protective eyewear"<br><br>"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas" | |
| 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." | Directions for Use immediately preceding the Agricultural Use Requirements box. |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Other Application Restrictions (Risk Mitigation) | Application Restrictions (all crop sites)<br><br>"Application by hand-held equipment is prohibited for all sites except coffee trees and Christmas trees."<br><br>Crop-Specific Application Restrictions<br><br>Asparagus (Arizona, California, North Carolina, Oregon, and Washington 24(c) registrations): Di-Syston 8E label is to state "Do not apply more than twice per season."<br><br>Barley and Wheat: The Di-Syston 8E label must specify that for wheat, only one foliar application is allowed per year, at a maximum rate of 0.75 lb ai/A.<br><br>Beans: "Not for use on dry beans, peas, or lentils." The granular Di-Syston 15G label is to specify a maximum application rate of 1 lb ai/A.<br><br>Cabbage: The liquid Di-Syston 8 label is to specify, "Do not apply by chemigation."<br><br>Cole Crops (broccoli, Brussels sprouts, cauliflower): The liquid Di-Syston 8 label is to specify "For use in California only." "Apply by shank injection only." Both Di-Syston 8E and 15G labels are to state "Apply only once per year" for broccoli and cauliflower.<br><br>Lettuce: The liquid Di-Syston 8 label must state "For use in California only."<br><br>Cotton: Number of applications must be reduced from 3 to 1 per year, at a rate of 1 lb ai/A. All labels must state "Aerial applications are prohibited." "Apply at plant, in furrow only." "For use only as an herbicide safener."<br><br>Peanuts (North Carolina 24(c) Registration): "Maximum rate is 1 lb ai/A."'"Do not apply more than twice per season." The Section 3 label for Di-Syston 15G should specify "Apply only once per season at a maximum rate of 1 lb ai/A."<br><br>Potatoes: All labels must specify that the number of soil applications per year must be reduced from 3 to 1. All foliar application, except for overhead sprinkler irrigation, is prohibited west of the Rockies. East of the Rockies, the maximum foliar application rate must be reduced from 3 lbs ai/A to 0.5 lbs ai/A. | Directions for Use |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Other Application Restrictions, Continued (Risk Mitigation) | Crop-Specific Application Restrictions (Continued)<br><br>Christmas Trees: Maximum application rate on the Section 3 Di-Syston 15G label is 4.5 lb ai/A. Label must state: "For use on firs only." "Product must be either soil incorporated, watered in, or applied to areas with permanent groundcover."<br>Coffee Trees: "For use in Puerto Rico only." "Do not apply more than twice per season."<br><br>The following use sites must be deleted from all product labels: berries, Bermuda grass, corn, dry beans, fruit trees (nonbearing), lentils, oats, peas, pecans, poplars (grown for pulp), sorghum, soybeans, spinach, tobacco, tomatoes, triticale, and all indoor uses, including indoor potted plants and all greenhouse uses. | |
| **Products Intended for Residential Homeowner Users Only (Not Covered by Worker Protection Standard)** | | |
| Spray Drift Language and Buffer Zones | *For purposes of addressing requested deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.*<br><br>"A level, well maintained 25 foot vegetative buffer strip between areas to which this product is applied to permanent surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for additional guidance." | Directions for Use in General Precautions and Restrictions |
| Eligibility Restrictions | Only residential use products containing ≤ 2% a.i. are eligible for reregistration. | |

| DESCRIPTION | LABELING | PLACEMENT ON LABEL |
|---|---|---|
| Application Restrictions | Maximum application rate must not exceed 0.30 lb ai/A for flower beds, 0.01 lb ai/4 foot shrub, or 0.0013 lb ai per rosebush.<br><br>Product intended for hand application must be packaged in child resistant packaging with a self-contained measuring device which clearly measures the correct amount to be applied.<br><br>Product intended for application by a push-type spreader need not be in the packaging described above for hand application, but packaging must clearly state "Do not apply by hand." and "Not for commercial use."<br><br>"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Only persons applying this product may be in the area during application."<br><br>"Do not apply with a belly grinder"<br><br>"Product must be soil incorporated or watered in." | Directions for Use |
| Re-entry Statements | "Do not enter or allow people or pets to enter until after product is soil incorporated or watered in." | Directions for Use |
| Site Deletions | The following site must be removed from the label: spinach, tomatoes, home vegetable gardens, and all indoor uses, including indoor potted plants and greenhouses. | |

## VI. APPENDICES

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

All documents supporting the disulfoton IRED, in hard copy form, may be viewed in the OPP Public Regulatory Docket or downloaded or viewed via the Internet at the following site: www.epa.gov/pesticides/op. The OPP Public Docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m..

APPENDIX A: Use Patterns Eligible for Reregistration

APPENDIX B: Generic Data Requirements and Studies Used

APPENDIX C: EPA's Technical Support Documents for Disulfoton

APPENDIX D: Bibliography

APPENDIX E: Generic Data Call-In

APPENDIX F: Product-Specific Data Call-In

APPENDIX G: EPA's Batching of Disulfoton Products for Meeting Acute Toxicity Data Requirements for Reregistration

APPENDIX H: List of Registrants Sent the Data Call-In

APPENDIX I: List of Electronically Available Forms

# APPENDIX A

## Disulfoton (Case 102): Use Patterns Eligible for Reregistration

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **FOOD/FEED CROPS** | | | | | | |
| **Asparagus** | | | | | | |
| Postharvest (fern stage)<br>Foliar application<br>Ground or aerial | 8 lb/gal EC [AZ850007] [WA840036] | 1.0 lb a.i./A | 2 | 2 | 45 | Use limited to AZ, CA, NC, OR, and WA. REI is 26 days. No more than 2 applications per year. |
| | 8 lb/gal EC [CA840192] | 1.0 lb a.i./A | 2 | 2 | 30 | |
| | 8 lb/gal EC [NC860005] | 1.0 lb a.i./A | 2 | 2 | 120 | |
| | 8 lb/gal EC [OR840032] | 1.0 lb a.i./A | 2 | 2 | 180 | |
| **Beans, Succulent (including snap or green lima)** | | | | | | |
| At-planting<br>Soil injection<br>Ground | 8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | 60 | Not for use on dry beans, peas, or lentils. The feeding of treated vines or hay to livestock animals is prohibited. |
| At-planting<br>Banded soil<br>Ground | 15% G [3125-172] | 1.0 lb a.i./A | 1 | 1 | 60 | Not for use on dry beans, peas, or lentils. The feeding of treated vines or hay to livestock animals is prohibited. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **Broccoli** | | | | | | |
| Preplant incorporated or postemergence<br>Soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | NS | 8EC formulation is limited for use in California only. |
| At-planting or postemergence<br>Soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | 14 | 8EC formulation is limited for use in California only. |
| **Brussels Sprouts** | | | | | | |
| Preplant or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | NS | 8EC formulation is limited for use in California only. |
| At planting or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | 30 | 8EC formulation is limited for use in California only. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **Cabbage (including tight-heading varieties of Chinese cabbage)** | | | | | | |
| Preplant or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.5 lb a.i./A for 15G<br><br>2 lb a.i./A for 8EC | 1 | 1.5 for 15G<br><br>2 for 8EC | NS | Chemigation of EC is not permitted. |
| At-planting or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.5 lb a.i./A for 15G<br><br>2 lb a.i./A for 8EC | 1 | 1.5 for 15G<br><br>2 for 8EC | 42 | Chemigation of EC is not permitted. |
| **Cauliflower** | | | | | | |
| Preplant incorporated or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | NS | 8EC formulation is limited for use in California only. |
| At-planting or postemergence<br>Soil incorporated or soil injection<br>Ground | 15% G [3125-172]<br><br>8 lb/gal EC [3125-307] | 1.0 lb a.i./A | 1 | 1 | 40 | 8EC formulation is limited for use in California only. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **Coffee Beans** | | | | | | |
| Preharvest and postharvest<br>Soil (uniformly under tree canopy)<br>Ground | 15% G<br>[3125-172] | 0.3-0.6 g/ft of tree height not to exceed 8.3 lb a.i./A | 2 | 17 | 90 | Disulfoton use on coffee is limited to Puerto Rico only. No more than one preharvest and one postharvest application may be made during the year. Closed loading/transfer system must be implemented by June 2004. |
| **Cotton** | | | | | | |
| At-planting/replanting<br>Soil injection or in-furrow soil<br>Ground | 8 lb/gal EC<br>[3125-307] | 1.0 lb a.i./A | 1 | 1 | NS | Aerial applications are prohibited. Apply at-plant, in-furrow only. For use only as a herbicide safener. The feeding of treated forage to livestock is prohibited. |
| At-planting/replanting<br>Banded soil<br>Ground | 15% G<br>[3125-172] | 0.6-1.0 lb a.i./A | 1 | 1 | NS | |
| At planting<br>Soil injection or in-furrow soil<br>Ground | 6.5% G<br>[400-408]<br>[400-411]<br>[5481-415] | 1.0 lb a.i./A | 1 | 1 | NS | |
| At planting<br>Soil injection or in-furrow soil<br>Ground | 17.5% G<br>[400-475] | 1.0 lb a.i./A | 1 | 1 | NS | Aerial applications are prohibited. Apply at plant, in furrow only. For use only as a herbicide safener. The feeding of treated forage to livestock is prohibited. |
| **Lettuce** | | | | | | |
| Pre-plant or at-plant<br>Banded, soil injection, or chemigation<br>Ground | 8 lb/gal EC<br>[3125-307] | 1.0-2.0 lb a.i./A | 1 | 2 | 60 | 8EC formulation is limited for use in California only.<br>Application to transplanted lettuce is prohibited. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| At-planting<br>Banded soil or soil injection<br>Ground | 8 lb/gal EC [CA810044] | 2.0 lb a.i./A | 1 | 2 | 60 | 8EC formulation is limited for use in California only. |
| **Peanuts** | | | | | | |
| At-planting or postemergence<br>Banded soil or soil<br>Incorporated<br>Ground | 15% G [3125-172] | 1.0 lb a.i./A | 1 | 1 | NS | The feeding of treated vines or hay to livestock is prohibited. |
| At-planting or at-pegging<br>In-furrow or banded<br>Ground | 15% G [NC920011] | 1.0 lb a.i./A | 2 | 2 | 72 | The feeding of treated vines or hay to livestock is prohibited. |
| **Pepper** | | | | | | |
| At-planting/transplanting<br>Banded soil<br>Ground | 15% G [3125-172] | 1.0-2.0 lb a.i./A | 1 | 2 | 90 | |
| Postemergence<br>Soil incorporated<br>Ground | 8 lb/gal EC [CA770036] | 2.0 lb a.i./A | 1 | 2 | 60 | 8EC formulation is limited for use in California only. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **NON-FOOD/FEED USES** | | | | | | |
| **Radish Grown for Seed** | | | | | | |
| At first seed stalk bolting<br>Soil incorporated<br>Ground | 15% G [WA92002700] | 1.5 - 2.0 lb a.i./A | 1 | 2 | NS | Do not feed or graze radish forage or fodder. Do not cut radish tops for hay or forage. No portion of the treated filed, including seed, seed screeening, forage, or stubble may be used for human or animal consumption. |
| At first seed stalk bolting<br>Soil injection<br>Ground | 8 lb/gal EC [WA92002600] | 1.5 - 2.0 lb a.i./A | 1 | 2 | NS | |
| **Clover Grown for Seed** | | | | | | |
| Timing not specified<br>Soil incorporated<br>Ground | 15% G [WA980000400] | 1 lb a.i./A | 1 | 1 | NS | No portion of the clover plant may be used or distributed for food or feed. Treated seeds must be labeled or tagged, "Not for human or animal consumption." |
| **Christmas Trees (Fir Species)** | | | | | | |
| At first bud break<br>Broadcast<br>Ground | 15% G [NC88000100] | 3.0-4.5 lb a.i./A | 1 | 4.5 | NS | For use on firs only. Products must be soil incorporated, watered in, or applied to areas with permanent ground cover. Closed loading/transfer system must be implemented by June 2004 |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| At first bud break<br>Broadcast<br>Ground | 15% G<br>[3125-172] | 3.0-4.5 lb a.i./A | 1 | 4.5 | NS | |
| **Residential Use on Ornamental Flowers, Roses, Shrubs and Trees** | | | | | | |
| Timing not specified<br>Broadcast/soil incorporated or watered in<br>Ground | 1% G<br>[3125-517]<br>[16-171]<br>[239-2134]<br>etc. | 0.3 lb/1000 ft2 for flowerbeds<br>or<br>0.01 lb/4 ft shrub<br>or<br>0.0013 lb a.i./bush for roses | NS | NS | NS | For residential use only. Not for commercial use. Product must be soil incorporated or watered in. Do not apply with belly grinder. Product intended for hand application must be in child resistant packaging with a delf contained measuring cup/lid, which clearly measures correct amount to apply.<br><br>Not for use indoors or in greenhouses. Not for use on home vegetable gardens, including use on spinach and tomatoes. |
| Timing not specified<br>Broadcast/soil incorporated or watered in<br>Ground | 2% G<br>[7401-26]<br>[869-223]<br>[11474-70] etc. | | NS | NS | NS | |
| Timing not specified<br>Soil incorporated or watered in<br>Ground | 0.5%<br>[32802-32] | | NS | NS | NS | |
| Transplant/Potted plants<br>Soil incorporated or watered in<br>Ground | 0.37%<br>[8660-125] | | NS | NS | NS | |

## Disulfoton (Case 102): Use Patterns to be Phased Out by June 2005
## (Not Eligible for Reregistration)

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **FOOD/FEED CROPS TO BE PHASED OUT BY JUNE 2005** | | | | | | |
| **Barley** | | | | | | |
| At-planting<br>Drill or broadcast soil<br>or<br>Postemergence<br>Broadcast<br>Ground or Air | 15% G<br>[3125-172] | 1.0 lb a.i./A | 2 | 2 | 60<br>(grain)<br><br>30<br>(forage) | Applications may be repeated at a 21-day interval. A 30-day pregrazing interval (PGI) has been established. |
| At-planting<br>Soil injection<br>Ground | 8 lb/gal EC<br>[3125-307] | 0.25 oz/1,000 ft of row up to 1.0 lb a.i./A | 2 | 2 | 60<br>(grain)<br><br>30<br>(forage) | A 30-day PGI has been established. |
| Late season<br>Foliar application<br>Ground or aerial | 8 lb/gal EC<br>[3125-307] | 0.5-1.0 lb a.i./A | 1 | 1 | 30<br>(grain) | The grazing of treated fields is prohibited. |
| **Potato** | | | | | | |
| Preplant or postemergence<br>Soil incorporated in-furrow or banded<br>Ground | 15% G<br>[3125-172] | 15 - 23 oz per 1000 ft of row up to 3.0 lb a.i./A | 1 | 3 | 75 | |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| **Potato** *(continued)* | | | | | | |
| Pre-plant or at-plant<br>Banded, in furrow, or soil injection<br>or<br>Post-plant<br>Soil incorporated band or side dress<br>Ground | 8 lb/gal EC [3125-307] | 2.3-3.5 oz/1,000 ft of row up to 3.0 lb a.i./A | 1 | 3 | 75 | |
| Pre-plant, at-planting, or post-plant<br>Broadcast and soil incorporated or in furrow or soil injection<br>Ground | 8 lb/gal EC [3125-307] | 0.375-1.0 lb a.i./A | 2 | 2 | 30 | Application may be made following an at-planting application of either 8EC or 15G formulation provided that no more than a total of two applications of Disulfoton are made per year. |
| Post-plant, when Green peach aphid first appears<br>Foliar application<br>Aerial | 8 lb/gal EC [3125-307] | 0.5 lb ai/A | 2 | 1 | 30 | East of Rockies only. Do not tank mix with phosalone. |
| Post-plant<br>Foliar application<br>Sprinkler irrigation (chemigation) | 8 lb/gal EC [3125-307] | 3.0 lb a.i./A | 2 | 6 | 60 | Use limited to ID, OR, UT, and WA. Application may be made following an at-planting application of either 8EC or 15G formulation provided that no more than a total of two applications of Disulfoton are made per year. |
| **Wheat** | | | | | | |
| At-planting (Fall)<br>Drill or broadcast soil<br>Ground | 15% G [3125-172] | 0.25 oz/1,000 ft of row up to 1.0 lb a.i./A | 1 | 1 | 75 (forage) | A 75-day pre-grazing interval (PGI) has been established. |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation [EPA Reg. No.] | Single Application Rate | Maximum Number of Applications Per Season | Maximum Seasonal Rate, lbs ai/A | Preharvest Interval, Days | Use Limitations |
|---|---|---|---|---|---|---|
| At-planting (Fall)<br>Soil injection<br>Ground | 8 lb/gal EC<br>[3125-307] | 0.25 oz/1,000 ft of row up to 1.0 lb a.i./A | 1 | 1 | NS | The grazing of treated fields or cutting for forage after application is prohibited. |
| Spring or Fall<br>Foliar application<br>Ground or aerial | 8 lb/gal EC<br>[3125-307] | 0.25-0.75 lb a.i./A | 1 | 0.75 | 30 (grain) | Only one foliar application is permitted per season. The grazing of treated fields or cutting for forage after application is prohibited. |
| **NON-FOOD/FEED USES TO BE PHASED OUT BY JUNE 2005** | | | | | | |
| **Ornamentals (Commercial Use)** | | | | | | |
| Timing not specified<br>Soil incorporated<br>Ground | 15% G<br>[3125-172] | Shrubs<br>3.75 to 7.5 g a.i. per foot of height | NS | NS | NS | Apply every 4 to 6 weeks as needed. Distribute granules uniformly under shrub canopy. Incorporate into soil and water heavily. |
| Timing not specified<br>Soil implant<br>Ground | 15% G<br>[3125-172] | Trees<br>2.5 oz a.i. per inch of trunk diameter measured 4 feet above the ground | NS | NS | NS | Broadcast granules uniformly from trunk to drip line. Incorporate into soil and water heavily. For transplants, uniformly mix with backfill soil when planting |
| Timing not specified<br>Soil injection or In furrow<br>Ground | 15% G<br>[3125-172] | Flowers and Groundcover<br>0.75 lb a.i. per 1000 linear ft | NS | NS | NS | |

# APPENDIX B

## Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton

### GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0102 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply products within case 0102 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650. In cases where there is a data gap, or where additional confirmatory data are required in the RED, the new OPPTS guidelines are listed. These guidelines are also listed in the Generic DCI in the RED.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

| | |
|---|---|
| A | Terrestrial food |
| B | Terrestrial feed |
| C | Terrestrial non-food |
| D | Aquatic food |
| E | Aquatic non-food outdoor |
| F | Aquatic non-food industrial |
| G | Aquatic non-food residential |
| H | Greenhouse food |
| I | Greenhouse non-food |
| J | Forestry |
| K | Residential |
| L | Indoor food |
| M | Indoor non-food |
| N | Indoor medical |
| O | Indoor residential |

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| **PRODUCT CHEMISTRY** | | | | |
| 61-2A | | Start. Mat. & Mnfg. Process | ABCJK | 43058601, 43058603, 43058605 |
| 61-2B | | Formation of Impurities | ABCJK | 43058601 |
| 62-1 | | Preliminary Analysis | ABCJK | 43058602 |
| 62-2 | 830.1750 | Certification of limits | ABCJK | Data Gap |
| 63-2 | | Color | ABCJK | 00150088 |
| 63-3 | | Physical State | ABCJK | 00150088 |
| 63-4 | | Odor | ABCJK | 00150088 |
| 63-5 | | Melting Point | ABCJK | 00150088 |
| 63-6 | | Boiling Point | ABCJK | 00150088 |
| 63-7 | | Density | ABCJK | 00150088 |
| 63-8 | | Solubility | ABCJK | 00150088 |
| 63-9 | | Vapor Pressure | ABCJK | 00150088 |
| 63-10 | | Dissociation Constant | ABCJK | 43093601 |
| 63-11 | | Octanol/Water Partition | ABCJK | 00150088 |
| 63-12 | | pH | ABCJK | 00150088 |
| 63-13 | | Stability | ABCJK | 43093601 |
| | 830.7050 | UV/Visible Absorption of PAI | ABCJK | Data gap |
| **ECOLOGICAL EFFECTS** | | | | |
| 71-1A | | Acute Avian Oral - Quail/Duck | ABCJK | 0095655, 42585803 (parent), 42585102 (sulfoxide), 42585103 (sulfone) |
| 71-2A | | Avian Dietary - Quail | ABCJK | 0094233 (parent), 42585105 (sulfoxide), 42585106 (sulfone) |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| **71-2B** | | **Avian Dietary - Duck** | ABCJK | 0034769 (parent), 42585104 (sulfoxide), 42585101 (sulfone) |
| **71-3** | | **Wild Mammal Toxicity** | ABCJK | 00160000 (Mule deer) |
| **71-4A** | | **Avian Reproduction - Quail** | ABCJK | 43032501 (parent), waived for degradates |
| **71-4B** | | **Avian Reproduction - Duck** | ABCJK | 43032502 (parent), waived for degradates |
| **71-5A** | | **Simulated Field Study** | ABCJK | 00095657, 00095658 |
| **71-5B** | | **Actual Field Study** | ABCJK | Waived |
| **72-1A** | | **Fish Toxicity Bluegill** | ABCJK | 0068268 (parent), 42585107 (sulfoxide), 42585108 (sulfone) |
| **72-1C** | | **Fish Toxicity Rainbow Trout** | ABCJK | 0068268(parent), 42585110 (sulfoxide), 42585111 (sulfone) |
| **72-2A** | | **Invertebrate Toxicity** | ABCJK | 00153518, 00143401 (parent), 42585109 (sulfoxide), 42585112 (sulfone) |
| **72-3A** | | **Estuarine/Marine Toxicity - Fish** | ABCJK | 40071602 (parent), 44369901, 44369902 (sulfone), 44369902 (sulfoxide) |
| **72-3B** | | **Estuarine/Marine Toxicity - Mollusk** | ABCJK | 40071602, 40071603, 40098001 |
| **72-3C** | | **Estuarine/Marine Toxicity - Shrimp** | ABCJK | 40071603, requirement for degradates waived |
| **72-4A** | | **Early Life Stage Freshwater Fish** | ABCJK | 41935801, 42629001 |
| **72-4B** | | **Life Cycle Invertebrate** | ABCJK | 41935802, 43738001, 43738002, 43610901 |
| **72-4C-SS** | | **Marine Early Life Stage Fish** | ABCJK | 42629001, 43960501 |
| **72-4D-SS** | | **Marine Invertebrate Life Cycle** | ABCJK | 43610901 |
| **72-5** | | **Life Cycle Fish** | ABCJK | 43960501 (supplemental) |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| 72-6 | | Aquatic Organism Accumulation | ABCJK | 43042501 |
| 72-7A | | Simulated Field - Aquatic Organisms | ABCJK | Waived |
| 72-7B | | Actual Field - Aquatic Organisms | ABCJK | Reserved |
| 122-1 | 850.4100 | Terrestrial Plant Toxicity, Tier I, Seedling Emergence | ABCJK | Data gap |
| 122-1 | 850.4150 | Terrestrial Plant Toxicity, Tier I, Vegetative Vigor | ABCJK | Data gap |
| 141-1 | | Honey Bee Acute Contact | ABCJK | 42582902 (sulfone), 42582901 (sulfoxide) |
| 141-2 | | Honey Bee Residue on Foliage | ABCJK | 00163423 |
| 141-5 | | Field Test for Pollinators | ABCJK | Reserved |
| TOXICOLOGY | | | | |
| 81-1 | | Acute Oral Toxicity - Rat | ABCJK | 00139595 |
| 81-2 | | Acute Dermal Toxicity - Rabbit/Rat | ABCJK | 00139595 |
| 81-3 | | Acute Inhalation Toxicity - Rat | ABCJK | 00147754 |
| 81-4 | | Primary Eye Irritation - Rabbit | ABCJK | Waived |
| 81-5 | | Primary Dermal Irritation - Rabbit | ABCJK | Waived |
| 81-6 | | Dermal Sensitization - Guinea Pig | ABCJK | Waived |
| 81-7 | | Acute Delayed Neurotoxicity - Hen | ABCJK | 44996401 |
| 81-8-SS | | Acute Neurotoxicity - Rat | ABCJK | 42755801 |
| 81-9-SS 83-6 | 870.6300 | Developmental Neurotoxicity | ABCJK | Data gap under DCI 09/99 |
| 82-1A | | 90-Day Feeding - Rodent | ABCJK | 43058401 |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| 82-1B | | 90-Day Feeding - Non-rodent | ABCJK | Waived |
| 82-2 | | 21-Day Dermal - Rabbit | ABCJK | 00162338 |
| 82-2 | 870.3200 | 21-Day Dermal - Rat | ABCJK | Data gap for rat, partially satisfied by MRID 45239601 |
| 82-4 | | 90-Day Inhalation - Rat | ABCJK | 41224301 |
| 82-5A | | 90-Day Neurotoxicity - Hen | ABCJK | Reserved |
| 82-5B | | 90-Day Neurotoxicity - Mammal | ABCJK | 42977401 |
| 83-B-SS | | 6-month Chronic Feeding Study | ABCJK | 43058401 |
| 83-1A | | Chronic Feeding Toxicity - Rodent | ABCJK | 41850001 |
| 83-1B | | Chronic Feeding Toxicity - Non-Rodent | ABCJK | 44248002, 00073348 |
| 83-2A | | Oncogenicity - Rat | ABCJK | 41850001, 41850002 |
| 83-2B | | Oncogenicity - Mouse | ABCJK | 00129456 |
| 83-3A | | Developmental Toxicity - Rat | ABCJK | 00129458 |
| 83-3B | | Developmental Toxicity - Rabbit | ABCJK | 00147886 |
| 83-4 | | 2-Generation Reproduction - Rat | ABCJK | 44440801, 00157511 |
| 84-2A | | Gene Mutation (Ames Test) | ABCJK | 40638401 |
| 84-2B | | Structural Chromosomal Aberration | ABCJK | 43615701 |
| 84-4 | | Other Genotoxic Effects | ABCJK | 00139603, 00139609, 40495001 |
| 85-1 | | General Metabolism | ABCJK | 42808901, 42565101 |
| 85-2 | | Dermal Penetration | ABCJK | 43360201 |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| OCCUPATIONAL/RESIDENTIAL EXPOSURE | | | | |
| 132-1A | 875.2100 | Foliar Residue Dissipation | ABCJK | Data gap under DCI 10/95; MRID 44688001 provides supplemental information |
| 132-1B | 875.2200 | Soil Residue Dissipation | ABCJK | Data gap (ornamental use only, proposed for phase out, required only if use is retained) |
| 133-3* | 875.1100 | Dermal Passive Dosimetry Exposure* | ABCJK | Data gap for certain scenarios, 45333401, 44972201 |
| 133-4* | 875.1300 | Inhalation Passive Dosimetry Exposure* | ABCJK | Data gap for certain scenarios, 44972201 |
| 231* | 875.1100 | Estimation of Dermal Exposure at Outdoor Sites* | ABCJK | Data gap for certain scenarios, 42229401 |
| 232* | 875.1300 | Estimation of Inhalation Exposure at Outdoor Sites* | ABCJK | Data gap for certain scenarios, 42229401 |
| ENVIRONMENTAL FATE | | | | |
| 161-1 | | Hydrolysis | ABCJK | 00143405 |
| 161-2 | | Photodegradation - Water | ABCJK | 40471102 |
| 161-3 | | Photodegradation - Soil | ABCJK | 40471103 |
| 162-1 | | Aerobic Soil Metabolism | ABCJK | 43800101, 40042201, 41585101, 41585102 (parent) |
| 162-3 | 835.4400 | Anaerobic Aquatic Metabolism | ABCJK | Data gap, MRIDs 43042500 and 43042503 provide supplemental information |
| 162-4 | 835.4300 | Aerobic Aquatic Metabolism | ABCJK | Data gap; MRIDs 43042500 and 43042503 provide supplemental information |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| 163-1 | 835.1240 | Leaching/Adsorption/ Desorption | ABCJK | Data gap for parent and degradates; MRIDs 44373103, 00145469 provide supplemental information for parent |
| 163-2 | | Volatility - Lab | ABCJK | 42585802 |
| 163-3 | | Volatility - Field | ABCJK | 40471105 |
| 164-1 | | Terrestrial Field Dissipation | ABCJK | 43042502 |
| 164-2 | | Aquatic Field Dissipation | ABCJK | Waived |
| 164-3 | | Forest Field Dissipation | ABCJK | Waived |
| 164-5 | | Long Term Soil Dissipation | ABCJK | Waived |
| 165-1 | | Confined Rotational Crop | ABCJK | 43447701, 43447702 |
| 165-2 | | Field Rotational Crop | ABCJK | 43447703, 43447704 |
| 165-3 | | Accumulation - Irrigated Crop | ABCJK | Waived |
| 165-4 | | Bioaccumulation in Fish | ABCJK | 43042501, 43060101, 40471106, 40471107 |
| 165-5 | | Bioaccumulation - Aquatic NonTarget | ABCJK | Waived |
| | 835.7200 | Drinking Water Monitoring for Surface Water Sources | ABCJK | Data gap |
| RESIDUE CHEMISTRY | | | | |
| 171-4A | | Nature of Residue - Plants | ABCJK | 44342101, 43222404, 43222402, 44146501, 44146502, 43222403 |
| 171-4B | | Nature of Residue - Livestock | ABCJK | 40939002, 40939001 |
| 171-4D | | Residue Analytical Method - Animal | ABCJK | 00158270 |

| Data Supporting FIFRA Guideline Requirements for the Reregistration of Disulfoton | | | | |
|---|---|---|---|---|
| DATA REQUIREMENT | | | USE PATTERN | CITATION(S) |
| 171-4E | 860.1380 | **Storage Stability** | ABCJK | Data gap for livestock commodities under DCI 11/91; MRIDs 44248004, 43957301, and 43447705 satisfy guideline for other commodities |
| 171-4J | 860.1480 | **Magnitude of Residues - Meat/Milk/Poultry/Egg** | ABCJK | Reserved |
| 171-4K | 860.1500 | **Crop Field Trials** | ABCJK | Data gap under DCI 11/91 for lettuce and cotton gin byproducts; MRIDs 40204305, 40056701, 40204301, 40156605, 40156604, 40156602, 40156603, 40204302, 40204304, 00162859, 44248003, 40156601, 40204311, 40156610, 40156607, 44301901, 44146503, 42850201, 40204303, 40204309, 44248010, 44248005 satisfy guideline for all other commodities |
| 171-4L | | **Processed Food** | ABCJK | 44248006, 44248008, 40768901, 44248005, 44248010, 40561201 |
| 171-5 | | **Reduction of Residues** | ABCJK | Reserved |
| **SPRAY DRIFT** | | | | |
| 201-1 | | **Droplet Size Spectrum** | ABCJK | 40156612 |
| 202-1 | | **Drift Field Evaluation** | ABCJK | 40156612 |

* Reflects old OPP Guideline Number and Title. Study guideline numbers and titles were changed in the new harmonized OPPTS guidelines.

# APPENDIX C

EPA's TECHNICAL SUPPORT DOCUMENTS FOR DISULFOTON

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

The docket initially contained preliminary risk assessments and related documents as of January 8, 1999. Sixty days later the first public comment period closed. EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on March 10, 2000 for an additional public comment period. EPA revised the risk assessment again based on additional public comments and new information, including voluntary changes to the disulfoton labels and voluntary test data. EPA also reviewed benefits of disulfoton use and any available alternatives. These final revised risk assessments and benefits assessments form the basis of the regulatory decision described in the IRED.

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

www.epa.gov/pesticides/op

These documents include the following:

*Human Health Risk Assessment Documents*

1. Christina Jarvis (USEPA/OPPTS/OPP/HED). Risk Assessment and Reregistration Eligibility Decision (RED) Documents for Disulfoton (Revised Risk Assessment, Phase 4), February 10, 2000.

2. David Anderson (USEPA/OPPTS/OPP/HED). Disulfoton: Revised (3rd) Report of the Hazard Identification Assessment Review Committee, April 10, 2001.

3. Shanna Recore. (USEPA/OPPTS/OPP/HED). Review and Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds, June 6, 2001.

4. Christina Jarvis (USEPA/OPPTS/OPP/HED). Revised Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) Documents for Disulfoton, May 31, 2001 and addendum, August 9, 2002.
5. Richard Griffin (USEPA/OPPTS/OPP/HED). Revised Occupational Exposure Assessment for the Reregistration Eligibility Decision Document for Disulfoton, June 15, 2001.

6. David Anderson (USEPA/OPPTS/OPP/HED). Health Effects Division Toxicity Chapter for Reregistration Eligibility Decision (RED), June 25, 2001.

7. Christina Jarvis (USEPA/OPPTS/OPP/HED). Disulfoton: Aggregate Risk Assessment, March 6, 2002.

*Environmental Fate and Ecological Effects Documents*

8. Henry Craven and James Wolf (USEPA/OPPTS/OPP/EFED). Reregistration Eligibility Document for Disulfoton, September 5, 2000 and its addendum March 25, 2002.

9. James Wolf (USEPA/OPPTS/OPP/EFED). [Review of ] The Interagency Study of the Impact of Pesticide Use on Ground-Water in North Carolina, August 1, 2000.

10. James Wolf. (USEPA/OPPTS/OPP/EFED). Additional Information and Clarification for the Disulfoton RED [Review of California Surface Water Monitoring], October 20, 2000.

11. Henry Craven and Larry Turner (USEPA/OPPTS/OPP/EFED and FEAD). Endangered Species Addendum to EFED's Disulfoton Science Chapter, January 24, 2002

13. James Wolf (USEPA/OPPTS/OPP/EFED). Disulfoton: Summary of Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment, February 25, 2002.

14. Larry Turner (USEPA/OPPTS/OPP/FEAD). Puerto Rican Plain Pigeon and Disulfoton, April 24, 2002.

*Benefits and Alternatives Analysis*

15. Nikhil Mallampalli. (USEPA/OPPTS/OPP/BEAD). Asparagus Benefits Assessment for Disulfoton, September 11, 2001.

16. Colwell Cook. (USEPA/OPPTS/OPP/BEAD). Benefits of Disulfoton on Selected Vegetable Crops and Cotton, September 27, 2001.

17. Nikhil Mallampalli. (USEPA/OPPTS/OPP/BEAD). Benefits Assessment for Disulfoton Use on Potatoes and Radish Seed, September 28, 2001

18. Colwell Cook. (USEPA/OPPTS/OPP/BEAD). Use of Disulfoton on Bell and Pimento Peppers, November 3, 2001

19. Nikhil Mallampalli. (USEPA/OPPTS/OPP/BEAD). Cursory Assessment of Disulfoton Use in Coffee in Puerto Rico, November 26, 2001.

20. Colwell Cook. (USEPA/OPPTS/OPP/BEAD). Response to Questions Concerning Disulfoton Posed by Special Review and Reregistration Division [Regarding Ornamentals], December 17, 2001.

21. Colwell Cook. (USEPA/OPPTS/OPP/BEAD). Analysis of Disulfoton Use on Fraser Fir Trees in Western North Carolina. July 9, 2002. (Transmittal of OP Crop Use Matrices written in July 2000.)

# APPENDIX D

# MRID BIBLIOGRAPHY FOR DISULFOTON

## 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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# Appendix E

## GENERIC DATA CALL-IN

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

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

## DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 12/31/00

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

| 1. Company name and Address | 2. Case # and Name<br>0102 Disulfoton<br>Chemical # and Name 032501<br>Disulfoton | 3. Date and Type of DCI<br>GENERIC |
|---|---|---|

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

**DATA CALL-IN RESPONSE**

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

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

| 1. Company name and Address | 2. Case # and Name<br>0102 Disulfoton<br>Chemical # and Name 032501<br>Disulfoton | 3. Date and Type of DCI<br>GENERIC |
|---|---|---|

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

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

Date

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

# REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address

2. Case # and Name
0102 Disulfoton
Chemical # and Name 032501
Disulfoton

3. Date and Type of DCI
GENERIC

| 4. Guideline Requirement Number | 5. Study Title | PROTOCOL | Progress Reports 1 | 2 | 3 | 6. Use Pattern | 7. Test Substance | 8. Time Frame | 9. Registrant Response |
|---|---|---|---|---|---|---|---|---|---|
| 830.7050 | U/V Visible Absorption | | | | | ABCDJK | | 12 mos. | |
| 875.1100 * | Dermal Exposure | | | | | | | 12 mos. | |
| 875.1300 * | Inhalation Exposure | | | | | | | 12 mos. | |
| 830.1750 | Certified Limits | | | | | | | 12 mos. | |
| 835.1240 * | Soil Column Leaching | | Y | | | | | 24 mos. | |
| 835.4300 * | Aerobic Aquatic Metabolism | | Y | | | | | 24 mos. | |
| 835.4400 * | Anaerobic Aquatic Metabolism | | Y | | | | | 24 mos. | |
| 835.7200 * | Surface Drinking Water Monitoring Stu | | Y | Y | | ABCDJK | | 36 mos. | |
| | Protocol | Y | | | | | | 6 mos. | |
| 850.4100 | Ter Plant Tox,T1 (seedling emergence) | | | | | | | 12 mos. | |
| 850.4150 | Ter Plant Tox,T1 (vegetative vigor) | | | | | | | 12 mos. | |
| 860.1380 * | Storage Stability Data | | Y | | | | | 24 mos. | |
| 860.1500 * | Cropfield trials | | Y | | | ABDK | | 24 mos. | |
| 870.3200 * | 21/28-Day Dermal Toxicity | | Y | | | | | 24 mos. | |

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0102 Disulfoton
Chemical # and Name
032501 Disulfoton

| GUIDELINE | COMMENT |
|---|---|
| 875.1100 | Applicator Exposure Monitoring for the following scenarios:<br>* Liquid formulation, groundboom, enclosed cab + respirator<br>* Granular formulation, tractor-drawn spreader, enclosed cab + respirator<br><br>Mixer/Loader Exposure Monitoring for the following scenarios:<br><br>* Liquid, closed loading system (e.g., Secure Link G)<br>* Granular, closed loading system (e.g., Smartbox, LockN'Load)<br><br>Mixer/Loader/Applicator Exposure Monitoring for the following scenarios:<br><br>* Handheld closed loading, transfer and delivery system (e.g. North Carolina applicator)<br>* Motorcycle mounted granular spreader with closed loading |
| 875.1300 | Applicator Exposure Monitoring for the following scenarios:<br><br>* Liquid formulation, grondboom, enclosed cab + respirator * Granular formulation, tractor drawn spreader, enclosed cab + respirator<br><br>Mixer/Loader Exposure Monitoring for the following scenarios:<br><br>* Liquid closed loading system (e.g., Secure Link G)<br>* Granular closed loading system (e.g., Smartbox, Lock 'NLoad)<br><br>Mixer/Loader/Applicator Exposure Monitoring for the following scenarios:<br><br>* Handheld closed loading, transfer, and delivery system (NC applicator)<br>* Motorcycle mounted granular spreader with closed loading |

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

## * COMMENTS FOR GUIDELINE REQUIREMENTS

Case # and Name
0102 Disulfoton
Chemical # and Name
032501 Disulfoton

| GUIDELINE | COMMENT |
|---|---|
| 835.1240 | For disulfoton parent and sulfoxide and sulfone degradates |
| 835.4300 | For disulfoton parent and the sulfoxide and sulfone degradates |
| 835.4400 | For disulfoton parent and the sulfoxide and sulfone degradates |
| 835.7200 | For disulfoton parent and the sulfoxide and sulfone degradates |
| 860.1380 | For all livestock commodities |
| 860.1500 | For cotton gin byproducts and lettuce |
| 870.3200 | Study must be conducted in the rat, which is considered to be the most sensitive species. |

# 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 registrants under a separate cover.

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

**DATA CALL-IN RESPONSE**

Form Approved

OMB No. 2070-0107
2070-0057

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

| 1. Company name and Address | 2. Case # and Name | 3. Date and Type of DCI |
|---|---|---|
| SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 | 0102 Disulfoton | PRODUCT SPECIFIC |

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

Form Approved

OMB No. 2070-0107
2070-0057

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

| 1. Company name and Address | 2. Case # and Name | 3. Date and Type of DCI |
|---|---|---|
| SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 | 0102 Disulfoton<br><br>EPA Reg. No. NNNNNN-NNNNN | PRODUCT SPECIFIC<br>ID# NNNNNN-RD-NNNN |

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

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

# REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

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

| 1. Company name and Address | 2. Case # and Name | 3. Date and Type of DCI |
|---|---|---|
| SAMPLE COMPANY<br>NO STREET ADDRESS<br>NO CITY, XX 00000 | 0102 Disulfoton<br><br>EPA Reg. No. NNNNNN-NNNNN | PRODUCT SPECIFIC<br>ID# NNNNNN-RD-NNNN |

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

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

Date

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

# FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

## Case # and Name: 0102 Disulfoton

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

**Use Categories Key:**

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

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

**Prod Chem - Regular Chemical**

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

**Acute Toxic - Regular Chemical**

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

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

## FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

### Case # and Name: 0102 Disulfoton

**Footnotes (cont.):**

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

# APPENDIX G

## EPA'S BATCHING OF DISULFOTON PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing disulfoton 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 with in 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 in 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 IRED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select 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 ). 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.

Fifty eight products were found which contain disulfoton as the active ingredient. These products have been placed into four batches and a "No batch" in accordance with the active and inert ingredients and type of formulation.

**Batch 1**

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 3125-173 | 95.0 | Liquid |
| 3125-183 | 98.5 | Liquid |

**Batch 2**

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 70-236 | 15.0 | Solid |
| 3125-172 | 15.0 | Solid |
| 34704-586 | 15.0 | Solid |

**Batch 3**

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 192-74 | 2.0 | Solid |
| 192-119 | 2.0 | Solid |
| 11474-70 | 2.0 | Solid |

**Batch 3a***

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 4-153 | 2.0 | Solid |
| 869-223 | 2.0 | Solid |
| 3125-83 | 2.0 | Solid |
| 3125-116 | 2.0 | Solid |
| 7401-26 | 2.0 | Solid |
| 7401-323 | 2.0 | Solid |
| 28293-277 | 2.0 | Solid |
| 33955-490 | 2.0 | Solid |

*Batch 3a acute data may be cited to support Batch 3 products.

**Batch 4**

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 192-126 | 1.0 | Solid |
| 192-164 | 1.0 | Solid |
| 239-2134 | 1.0 | Solid |
| 572-346 | 1.0 | Solid |
| 769-908 | 1.0 | Solid |
| 802-426 | 1.0 | Solid |
| 869-76 | 1.0 | Solid |
| 3125-152 | 1.0 | Solid |
| 3125-517 | 1.0 | Solid |
| 5887-61 | 1.0 | Solid |
| 5887-171 | 1.0 | Solid |
| 8660-191 | 1.0 | Solid |
| 9688-94 | 1.0 | Solid |
| 33955-489 | 1.0 | Solid |
| 34704-785 | 1.0 | Solid |
| 42057-51 | 1.0 | Solid |
| 49585-28 | 1.0 | Solid |

Batch 4a†

| EPA Reg. No. | Percent active ingredient | Formulation Type |
|---|---|---|
| 4-253 | 1.0 | Solid |
| 4-420 | 1.0 | Solid |
| 16-171 | 1.0 | Solid |
| 769-850 | 1.0 | Solid |
| 7401-235 | 1.0 | Solid |
| 9404-3 | 1.0 | Solid |
| 46260-2 | 1.0 | Solid |
| 46260-12 | 1.0 | Solid |
| 46260-35 | 1.0 | Solid |
| 59144-23 | 1.0 | Solid |

†Batch 4a acute data may be cited to support for Batch 4 products.

**No Batch**

| EPA Reg. No. | Percent active ingredient(s) | Formulation Type |
|---|---|---|
| 264-459 | Ethoprop - 10.0<br>Disulfoton - 5.0 | Solid |
| 264-464 | Ethoprop - 46.0<br>Disulfoton - 23.0 | Solid |
| 400-408 | PCNB - 6.50<br>Terrazole - 1.63<br>Disulfoton - 6.50 | Solid |
| 400-411 | PCNB - 6.50<br>Disulfoton- 6.50 | Solid |
| 400-475 | PCNB - 17.5<br>Terrazole - 4.3<br>Disulfoton- 17.5 | Liquid |
| 2935-362 | PCNB - 6.5<br>Disulfoton - 6.5 | Solid |
| 5481-415 | PCNB - 6.5<br>Disulfoton - 6.5 | Solid |
| 8660-125 | Disulfoton - 0.37 | Solid |
| 7401-4 | Disulfoton - 0.99 | Solid |
| 3125-158 | Disulfoton - 68.0 | Liquid |
| 3125-307 | Disulfoton - 85.0 | Liquid |
| 32802-32 | Disulfoton - 0.5 | Solid |
| 34704- 287 | PCNB - 6.5<br>Disulfoton - 6.5 | Solid |
| 34704-475 | Disulfoton - 0.625 | Solid |
| 46260-36 | Disulfoton - 2.0 | Solid |

# APPENDIX H
# LIST OF REGISTRANTS SENT DCI

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

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

### Case # and Name: 0102 Disulfoton

| Co. Nr. | Company Name | Additional Name | Address | City & State | Zip |
|---|---|---|---|---|---|
| 000004 | BONIDE PRODUCTS, INC. | | 6301 SUTLIFF ROAD | ORISKANY NY | 13424 |
| 000016 | DRAGON CHEMICAL CORPORATION | | 7033 WALROND DRIVE, NW BOX 7311 | ROANOKE VA | 24019 |
| 000070 | VALUE GARDENS SUPPLY, LLC | | BOX 585 | ST. JOSEPH MO | 64502 |
| 000192 | VALUE GARDENS SUPPLY, LLC | | BOX 585 | ST. JOSEPH MO | 64502 |
| 000239 | THE SCOTTS COMPANY | D/B/A THE ORTHO GROUP | BOX 1749 | COLUMBUS OH | 43216 |
| 000400 | UNIROYAL CHEMICAL CO INC | A SUBSIDIARY OF CROMPTON CORPORATI | 74 AMITY RD | BETHANY CT | 06524 |
| 000769 | VALUE GARDENS SUPPLY, LLC | | BOX 585 | ST. JOSEPH MO | 64502 |
| 000802 | LILLY MILLER BRANDS | AGENT FOR: CENTRAL GARDEN & PET | 16201 SE 98TH | CLACKAMAS OR | 97015 |
| 000869 | GREEN LIGHT COMPANY | | P.O. BOX 17985 | SAN ANTONIO TX | 78217 |
| 003125 | BAYER CORP | AGRICULTURE DIVISION | 8400 HAWTHORN RD BOX 4913 | KANSAS CITY MO | 64120 |
| 005481 | AMVAC CHEMICAL CORP | ATTN: JON C. WOOD | 4695 MACARTHUR COURT, SUITE 1250 | NEWPORT BEACH CA | 92660 |
| 005887 | VALUE GARDENS SUPPLY, LLC | | BOX 585 | ST. JOSEPH MO | 64502 |
| 007401 | BRAZOS ASSOCIATES, INC. | AGENT FOR: VOLUNTARY PURCHASING GR | 2001 DIAMOND RIDGE DRIVE | CARROLLTON TX | 75010 |
| 008660 | EARTH CARE | DIVISION OF UNITED INDUSTRIES CORP | BOX 142642 | ST. LOUIS MO | 63114 |
| 009404 | SUNNILAND CORP | | BOX 8001 | SANFORD FL | 32772 |
| 011474 | SUNGRO CHEMICALS, INC. | | P. O. BOX 24632 | LOS ANGELES CA | 90024 |
| 032802 | HOWARD JOHNSON'S ENTERPRISES INC | | 700 W. VIRGINIA ST STE 222 | MILWAUKEE WI | 53204 |
| 034704 | JANE COGSWELL | AGENT FOR: PLATTE CHEMICAL CO INC | BOX 667 | GREELEY CO | 80632 |
| 042057 | MORGRO CHEMICAL CO | | 145 WEST CENTRAL AVE | SALT LAKE CITY UT | 84107 |
| 046260 | ADAMS TECHNOLOGY SYSTEMS | AGENT FOR: EASY GARDENER, INC. | 5145 FOREST RUN TRACE - SUITE B | ALPHARETTA GA | 30022 |
| 059144 | REGWEST COMPANY | AGENT FOR: GRO TEC INC | 30856 ROCKY ROAD | GREELEY CO | 80631 |
| 066158 | COLUMBIA BASIN VEGETABLE SEED ASSN | | BOX 53 | QUINCY WA | 98848 |

# Appendix I

## LIST OF 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@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 (PR Notice 98-5) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf |
| 8570-35 | Data Matrix (PR Notice 98-5) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf |
| 8570-36 | Summary of the Physical/Chemical Properties (PR Notice 98-1) | http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf |
| 8570-37 | Self-Certification Statement for the Physical/Chemical Properties (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' website.

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.

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 website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: http://npic.orst.edu..

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; and
- 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 chemical abstract system (CAS) number if one has been assigned.