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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

# MEMORANDUM

**DATE:** July 31, 2006

**SUBJECT:** Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

**FROM:** Debra Edwards, Director
Special Review and Reregistration Division
Office of Pesticide Programs

**TO:** Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.[1] These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

[1] Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

**Attachment A:**

Organophosphates included in the OP Cumulative Assessment

| Chemical | Decision Document | Status |
|---|---|---|
| Acephate | IRED | IRED completed 9/2001 |
| Azinphos-methyl (AZM) | IRED | IRED completed 10/2001 |
| Bensulide | IRED | IRED completed 9/2000 |
| Cadusafos | TRED | TRED completed 9/2000 |
| Chlorethoxyphos | TRED | TRED completed 9/2000 |
| Chlorpyrifos | IRED | IRED completed 9/2001 |
| Coumaphos | TRED | TRED completed 2/2000 |
| DDVP (Dichlorvos) | IRED | IRED completed 6/2006 |
| Diazinon | IRED | IRED completed 7/2002 |
| Dicrotophos | IRED | IRED completed 4/2002 |
| Dimethoate | IRED | IRED completed 6/2006 |
| Disulfoton | IRED | IRED completed 3/2002 |
| Ethoprop | IRED | IRED completed 9/2001<br>IRED addendum completed 2/2006 |
| Fenitrothion | TRED | TRED completed 10/2000 |
| Malathion | RED | RED completed 8/2006 |
| Methamidophos | IRED | IRED completed 4/2002 |
| Methidathion | IRED | IRED completed 4/2002 |
| Methyl Parathion | IRED | IRED completed 5/2003 |
| Naled | IRED | IRED completed 1/2002 |
| Oxydemeton-methyl | IRED | IRED completed 8/2002 |
| Phorate | IRED | IRED completed 3/2001 |
| Phosalone | TRED | TRED completed 1/2001 |
| Phosmet | IRED | IRED completed 10/2001 |
| Phostebupirim | TRED | TRED completed 12/2000 |
| Pirimiphos-methyl | IRED | IRED completed 6/2001 |
| Profenofos | IRED | IRED completed 9/2000 |
| Propetamphos | IRED | IRED completed 12/2000 |
| Terbufos | IRED | IRED completed 9/2001 |
| Tetrachlorvinphos | TRED | TRED completed 12/2002 |
| Tribufos | IRED | IRED completed 12/2000 |
| Trichlorfon | TRED | TRED completed 9/2001 |


# Interim Reregistration Eligibility Decision for Dimethoate

**June 12, 2006**

# Interim Reregistration Eligibility Decision

# for

# Dimethoate

**List [B]**

**Case No. 0088**

# Interim Reregistration Eligibility Decision (IRED) Document for Dimethoate

Approved by: _____

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

Date: _____

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## Glossary of Terms and Abbreviations

| | |
|---|---|
| AGDCI | Agricultural Data Call-In |
| ai | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| AR | Anticipated Residue |
| BCF | Bioconcentration Factor |
| CFR | Code of Federal Regulations |
| cPAD | Chronic Population Adjusted Dose |
| CSF | Confidential Statement of Formula |
| CSFII | USDA Continuing Surveys for Food Intake by Individuals |
| DCI | Data Call-In |
| DEEM | Dietary Exposure Evaluation Model |
| EC | Emulsifiable Concentrate Formulation |
| EDWC | Estimated Drinking Water Concentration |
| EEC | Estimated Environmental Concentration |
| EPA | Environmental Protection Agency |
| EUP | End-Use Product |
| FCID | Food Commodity Intake Database |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| G | Granular Formulation |
| GENEEC | Tier I Surface Water Computer Model |
| GLN | Guideline Number |
| HAFT | Highest Average Field Trial |
| IR | Index Reservoir |
| $LC_{50}$ | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. |
| $LD_{50}$ | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOAEL | Lowest Observed Adverse Effect Level |
| MATC | Maximum Acceptable Toxicant Concentration |
| Φg/g | Micrograms Per Gram |
| Φg/L | Micrograms Per Liter |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |

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

## 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 (hereafter 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 risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted by August 2006. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process. FQPA also amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors that include an assessment of cumulative effects of chemicals with a common mechanism of toxicity. The reason for consideration of other substances is that the possibility exists that low-level exposures to multiple chemicals that cause a common toxic effect lead to the same adverse health effect as would a high level of exposure to any one of the other substances individually.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Dimethoate is a member of the organophosphate (OP) class of pesticides. The OPs, as a group, have been determined to share a common mechanism of toxicity. The Agency has completed a revised cumulative risk assessment for OPs (USEPA, 2002), which can be found on the Agency's website http://www.epa.gov/pesticides/cumulative/rra-op/. The Agency intends to issue the final tolerance reassessment reregistration decisions for dimethoate and the OPs in August 2006. The Agency may need to pursue further risk mitigation for dimethoate to address any risks identified in the cumulative assessment for the OPs.

This document presents EPA's revised human health and ecological risk assessments and its progress toward tolerance reassessment, and the interim reregistration eligibility decision for dimethoate. The 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 based on data, public comments, and other information received in response to the preliminary risk assessments, section IV presents the Agency's reregistration eligibility, tolerance

reassessment, and risk management decisions; section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and section VI provides information on how to access related documents. Finally, the Appendices list related and supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides, and in the Public Docket under docket number EPA-HQ-OPP-2005-0084.

## II. Chemical Overview

### A. Regulatory History

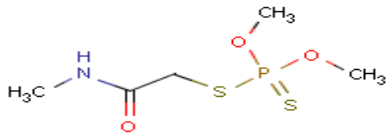
Dimethoate is a systemic organophosphate insecticide used on a large variety of field grown agricultural crops, tree crops, and ornamentals. It was first registered in the United States in 1962. All non-agricultural uses, including residential uses, were cancelled in 2000. In addition, seven crops that were identified as significant dietary risk contributors (apples, broccoli raab, cabbage, collards, grapes, head lettuce, and spinach), along with four crops for which there were no field trial data to support tolerances (fennel, lespedeza, tomatillo, and trefoil) were cancelled in 2005 (Federal Register Notice/Vol. 70, No. 138/Wednesday, July 20, 2005/Notices/41714). None of these crops were considered in the current risk assessments. Dimethoate is classified as a general use pesticide, and is applied using ground and aerial equipment. About 1.8 million pounds of active ingredient are used annually, with the largest use occurring on alfalfa. Use on four major crops - alfalfa, wheat, cotton, and corn - account for more than 64% of total dimethoate use.

There are currently 40 products containing dimethoate registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). There are also 39 active Special Local Need registrations registered under Section 24(c) of FIFRA. This Interim Reregistration Eligibility Decision document evaluates risks from all currently registered uses.

EPA released the revised human health and ecological risk assessments for a third round of public comments on September 6, 2005. Prior to this, the last public comment period had occurred in 1999, at which time the registrant submitted a developmental neurotoxicity study. The results of that study necessitated major revisions to the risk assessments.

## B. Chemical Identification

**Chemical Structure:**



| | |
|---|---|
| **Common Name:** | Dimethoate |
| **Chemical Name:** | *O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate |
| **Chemical Family:** | Organophosphate |
| **Empirical Formula:** | $C_5H_{12}NO_3PS_2$ |
| **CAS Registry Number:** | 60-51-5 |
| **Case Number:** | 0088 |
| **OPP Chemical Code:** | 035001 |
| **Molecular weight:** | 229.3 |
| **Trade Names:** | Digon, Duragon, Rebelate, Dimate |
| **Basic Manufacturers:** | Cheminova, BASF Corporation, Drexel Chemical Co. |

Dimethoate is a white crystalline solid with a mercaptan odor and a melting point of 45-48$^{o}$ C. It is soluble in water at 25 g/L at 21$^{o}$ C, is highly soluble in chloroform, methylene chloride, benzene, toluene, alcohols, esters, and ketones, and is only slightly soluble in xylenes, carbon tetrachloride, and aliphatic hydrocarbons. Dimethoate is also stable in aqueous solutions at pH 2-7, but hydrolyzes in alkaline media.

The major toxic degradate of dimethoate is omethoate (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate). Omethoate is registered as an active ingredient internationally, but not in the United States.

## C. Use Profile

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

**Type of Pesticide:** General use systemic insecticide/acaricide

**Summary of Use:** Used for control of a variety of insect pests on a number of fruit, vegetable, grain, and field crops, as well as ornamentals and non-cropland adjacent to agricultural fields

Food uses: Registered for use on the following crops/sites:

Alfalfa, asparagus, beans (excluding cowpeas), broccoli, Brussels sprouts, cauliflower, celery, cherries, Chinese cabbage, cotton, endive, field corn, grapefruit, leaf lettuce, lemons, lentils, kale, melons, mustard greens, oranges, pears, peas, pecans, peppers, popcorn, potatoes, safflower, sorghum, soybeans, Swiss chard, tangerines, tangelos, tomatoes, turnips, watermelons, wheat

Non-food uses:

Alfalfa for seed, forestry applications, grass for seed, non-crop land adjacent to vineyards, nursery stock (including conifer seed farm uses), ornamentals (various)

Uses not supported for reregistration:

*Food crops:* kohlrabi, lupine, sainfoin, triticale
*Non-agricultural uses* – cottonwoods grown for pulp, outdoor household domestic dwelling (ornamentals and shrubs), recreational areas, outdoor commercial/institutional/industrial premises, outdoor refuse/solid waste, phragmites reed beds, and sewage treatment systems

**Target Pests:** Aphids, citrus thrips, grasshoppers, leafminers, mites, whiteflies, beetles, weevils, midges, scale, fruitworms, moths, leafrollers, rootworms, mealybugs, leafhoppers, lygus bugs, and maggots

**Formulation Types:** Emulsifiable concentrate and wettable powder end-use products

**Method and Rates of Application:**

Application Methods: Applied primarily as a foliar spray, although soil and bark drench uses are registered

Application Equipment: Aircraft, groundboom, airblast, chemigation, backpack sprayer, low pressure handwand, and soil drench equipment, sprinkler can and paint brush

| | |
|---|---|
| Application Rates: | Currently labeled use rates vary from a minimum of 0.16 lbs a.i./acre to a maximum of 33.2 lbs. a.i./acre per application. Many labels do not specify numbers of applications, but typically 1 to 6 applications per year are made. For most crops, the maximum application rate is 0.5 lbs a.i./acre with typically 3 applications made per year. Note that Douglas fir seed orchards in Oregon and Washington, pinyon pine, and cottonwood application rates range from 8.0 lbs a.i./acre to 33.2 lb a.i./acre with one application per year. |
| Application Timing: | Bearing, early spring, foliar, non-bearing nurserystock, nurserystock, petal fall, petal fall through foliar, postharvest, postplant, preharvest, seed, seed crop, when needed |
| **Use Classification:** | General |

### D. Estimated Usage of Pesticide

The estimate for total domestic use (annual average) of dimethoate is approximately 1.8 million pounds of active ingredient, with the majority of use occurring on the following crops: wheat, alfalfa, cotton, and corn.

## III. Summary of Dimethoate Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessments form the basis of interim regulatory decisions for dimethoate. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2005-0084 and may be accessed on the internet at http://www.regulations.gov.

EPA released the revised risk assessments for dimethoate for a third public comment phase on September 6, 2005. In response to comments received, the risk assessments were further updated and refined.

### A. Human Health Risk Assessment

The Agency prepared a revised human health risk assessment, "Dimethoate: The Post-SAP HED Chapter of the Reregistration Eligibility Decision Document (RED)" written by Diana Locke, et al (January 31, 2006), which addresses toxicology data and comments submitted during the most recent public comment period for dimethoate. In

addition, the drinking water assessment was revised to include all the uses that are supported by the technical registrant with fully defined use patterns.

### 1. Toxicity of Dimethoate

(For a complete discussion, see section 3.0 of the human health risk assessment.)

Table 1. Acute Toxicity of Dimethoate

| Guideline No. | Study Type | MRID No. | Results | Toxicity Category |
|---|---|---|---|---|
| 870.1100 | Acute Oral - Rat | 00164219 | $LD_{50}$ = 358 mg/kg males), 414 mg/kg (females) | II |
| 870.1200 | Acute Dermal - Rabbit | 00164220 | $LD_{50}$ = > 2.0 g/kg | III |
| 870.2500 | Acute Dermal Irritation - Rabbit | 00164221 | Not a dermal irritant | IV |
| 870.2600 | Skin Sensitization - Guinea Pig | 254924 | Not a skin sensitizer | N/A |
| 870.6100 | Acute Delayed Neurotoxicity - Hen | 42884401 | No clinical signs of acute delayed neurotoxicity and no compound-related histological changes in nerve tissue. | N/A |

* Acceptable acute and primary eye irritation studies have not been submitted, and are therefore considered data gaps at this time.

As with other organophosphate (OP) pesticides, the critical effect of dimethoate for various exposure durations is inhibition of cholinesterase (ChE) in the brain or blood compartment. ChE inhibition is the most sensitive endpoint in numerous studies with adult and juvenile animals following oral, dermal, or inhalation exposures of dimethoate or omethoate (the primary metabolite). ChE inhibition was the most sensitive endpoint in an inhalation study with omethoate.

Oral studies evaluating the subchronic, chronic, developmental, and reproductive toxicity in laboratory animals are available for both dimethoate and omethoate. Developmental neurotoxicity (DNT), comparative cholinesterase, and special cross fostering studies are available for dimethoate. These studies show that brain ChE inhibition occurs at doses similar to or lower than those causing ChE inhibition in blood. Furthermore, these studies show that brain ChE inhibition occurs at doses similar to those associated with increases in pup mortality observed in the DNT study. The FIFRA Scientific Advisory Panel met on November 30 and December 1, 2004 to deliberate on the interpretation of the data from these studies and concluded that brain ChE inhibition is an appropriate endpoint to use for risk assessment.

The risk assessment for dimethoate is based on benchmark dose values, rather than No Observed Adverse Effect Level (NOAEL) and Lowest Observed Adverse Effect Level (LOAEL) values. The Agency used this method because NOAELs and LOAELs do not necessarily reflect the relationship between dose and response for a given chemical, but instead are reflective of dose selection. In order to evaluate the appropriate

point of departure (PoD) for ChE inhibition and pup mortality, EPA performed a benchmark dose (BMD) analysis. ChE inhibition data from the following dimethoate studies in rats were analyzed: the comparative ChE study, the reproductive toxicity studies, and the 28-day subchronic toxicity study.

The dose at which 10% ChE inhibition would be expected to occur ($BMD_{10}$) and the lower 95% confidence intervals ($BMDL_{10}$) were estimated by fitting the ChE data to an exponential dose-response model, using generalized nonlinear least squares. The $BMD_{10}$ was selected because it is generally at or near the limit of sensitivity for discerning a statistically significant decrease in ChE activity across the blood and brain compartments and is a response level close to the background ChE level.

The dose and endpoint for establishing the acute reference dose (aRfD) for all population subgroups is the $BMDL_{10}$ = 1.3 mg/kg for postnatal day 11 (PND 11) in female pups. The endpoint of concern (ChE inhibition) was seen after a single oral dose, and thus is appropriate for the general population and duration of concern. An uncertainty factor (UF) of 100 was applied to account for inter-species extrapolation (10X) and intra-species variability (10X), resulting in an aRfD of 0.013 mg/kg. The dose and endpoint (ChE inhibition) for establishing the chronic reference dose (cRfD) for all population subgroups is the $BMDL_{10}$ of 0.22 mg/kg/day from a chronic feeding study on rats, which is the endpoint that was used in the dietary risk assessment for the OP cumulative assessment. Again, an UF of 100 was applied, resulting in a cRfD of 0.0022 mg/kg/day. The $BMDL_{10}$ and other toxicity endpoints are outlined in Table 2 below.

*FQPA Safety Factor*

The FQPA Safety Factor (as mandated by the Food Quality Protection Act of 1996) is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to pesticide residues in food and drinking water or from residential exposures, or to compensate for an incomplete database. In the case of dimethoate, the Agency has concluded that the FQPA Safety Factor should be removed based on the lack of pre- and/or postnatal susceptibility resulting following exposure to dimethoate/omethoate, the lack of residual uncertainties for pre- and/or postnatal toxicity, and the fact that the dimethoate food and drinking water assessments are not expected to underestimate exposure.

*Cancer Classification*

The Agency's Cancer Peer Review Committee (CARC) classified dimethoate as a Group C carcinogen (possible human carcinogen; final document dated 8/29/91) based on equivocal hemolymphoreticular tumors in male B6C3F1 mice, the compound-related (no dose response) weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors in male Wistar rats, and positive mutagenic activity associated with dimethoate. For the purposes of risk assessment and characterization for dimethoate, the PAD approach, and not a $Q_1$* approach, was considered more appropriate for quantification of potential human risk for

the following reasons: as stated above, the mouse carcinogenicity study showed equivocal hemolymphoreticular tumors, and the rat carcinogenicity study showed a compound-related, weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors, but there was no dose response. In addition, the chronic Reference Dose (RfD) is considered protective enough of any potential cancer risk since the NOAEL from which it is derived (0.05 mg/kg/d) is at least an order of magnitude lower than the NOAELs or LOAELs derived from the systemic effects seen in the rat and mouse carcinogenicity studies. On June 25, 1992, the FIFRA Scientific Advisory Panel (SAP) concurred with the Agency's classification of dimethoate as Group C carcinogen.

Table 2. Toxicity Endpoints for Human Health Risk Assessment for Dimethoate

| Exposure Scenario | Dose, Uncertainty Factor, and Safety Factor | Effect | Study |
|---|---|---|---|
| Acute Dietary (all populations) | $BMDL_{10}$ = 1.3 mg/kg<br><br>UF = 100<br>FQPA SF = 1 | Brain ChE inhibition in PND11 females ($BMD_{10}$ = 1.5 mg/kg) | Comparative ChEI study in rats. MRID 45529702 |
| | **Acute RfD = Acute PAD = 0.013 mg/kg** | | |
| Chronic Dietary (all populations) | $BMDL_{10}$ = 0.22 mg/kg/d<br><br>UF = 100<br>FQPA SF = 1 | Brain ChE inhibition in females ($BMD_{10}$ = 0.25 mg/kg/d). | 2-Year chronic feeding study in rats.<br>MRID 00164177 |
| | **Chronic RfD = Chronic PAD = 0.0022 mg/kg/d** | | |
| Short- (1-30 days) and Intermediate-term (1-6 months) Occupational Dermal | $BMDL_{10}$ = 18.67 mg/kg/d<br><br>UF = 100 | Brain ChE inhibition in males at 28 days ($BMD_{10}$ = 28.70 mg/kg/d). | 28-Day repeated dose dermal toxicity in rats.<br>MRID 44999101 |
| | **Short- and Intermediate-term Occupational Dermal LOC = 100** | | |
| Short- (1-30 days) and Intermediate-term (1-6 months) Occupational Inhalation | $BMCL_{10}$ = 0.38 mg/m$^3$ (approx 0.10 mg/kg/d)<br><br>UF = 100 | Brain ChE inhibition in males at 15 days ($BMC_{10}$ = 0.51 mg/m$^3$ ). | Omethoate 21-day repeated dose inhalation study in rats. MRID 46358601.<br>(See discussion of relative toxicity of omethoate in Sect. III.A.2 below.) |
| | **Short- and Intermediate-term Occupational Inhalation LOC = 100** | | |
| Cancer | Classification: Group C or Possible Human Carcinogen | | |

UF = Uncertainty Factor (10X for inter-species extrapolation and 10X for intra-species variation)
FQPA SF = Food Quality Protection Act Safety Factor
RfD = Reference Dose
PAD = Population Adjusted Dose (RfD ÷ FQPA SF)
LOC = Level of Concern

## 2. Dietary Exposure and Risk from Food and Water

Acute and chronic probabilistic dietary risk assessments were conducted using DEEM-FCID™, Version 2.02, which incorporates consumption data from USDA's CSFII, 1994-1996 and 1998, as well as monitoring data from PDP and the FDA Surveillance Monitoring Program, estimated percent crop treated information, and processing/cooking factors, where applicable. Since the tolerance expression includes both dimethoate and omethoate, the residues of parent and its metabolite were summed for use in the dietary risk assessment. Furthermore, since it was determined that omethoate is twelve times more toxic than dimethoate in acute dietary exposure and three times more toxic in chronic dietary exposure, residues of omethoate [including limit of detection (LOD) values] in/on the same sample were multiplied by a toxicity adjustment factor (TAF) of 12 in the acute and by a factor of 3 in the chronic dietary risk assessment before addition to dimethoate residues. Exposure estimates are reported in milligrams per kilogram of body weight per day, and risk is expressed as a percent of the aPAD or cPAD. Exposure estimates that are less than 100% of the PAD are below the EPA's level of concern. For a more detailed discussion on the relative toxicity of omethoate, see Section 4.3.8 of the human health risk assessment.

The estimated drinking water concentrations (EDWCs) were calculated for multiple crops, including those that are the major use sites for dimethoate, and other representative sites. If appropriate, regional percent cropped area factors (PCA) were considered. EPA assumed that dimethoate would convert completely (100%) to omethoate during drinking water treatment, and therefore the TAFs were applied to the acute and chronic exposure assessments, respectively. Please see "A Re-assessment of the Drinking Water Exposure Due to Dimethoate Residues in Drinking Water, Considering New Recommended Maximum Label Patterns from the Technical Registrant" (Jones, R., 12/21/05) for detailed information. Table 3 shows the highest EDWCs, resulting from use on broccoli in California (which is also representative of cauliflower and celery) and the lowest EDWCs, resulting from use on pecans in Georgia.

Table 3. EDWCs for Dimethoate on Selected Agricultural Crops.

| Source | Acute EDWC | Chronic EDWC |
|---|---|---|
| | ---------- µg $L^{-1}$ dimethoate equivalents ---------- | |
| **Surface Water** | | |
| Broccoli/Cauliflower/Celery | 558 | 23.5 |
| Pecans | 19.6 | 0.28 |
| **Ground Water** | | |
| SCI-GROW | 0.044 | 0.044 |

Surface water monitoring data are available from a number of sources; however, they are limited in scope, are not nationally representative, and did not include analysis of omethoate. The California Department of Pesticide Regulation (CDPR) conducted a monitoring study in which sampling was done over several years. The highest concentration of dimethoate found was 2.4 µg/L, in the San Joaquin River basin. Given the sampling pattern and frequency within the study, it is uncertain whether higher concentrations would be observed at other times. The CDPR study did not monitor for omethoate.

Ready to drink, treated drinking water data are not available for dimethoate. Dimethoate converts to omethoate to some extent as a result of oxidation that occurs when drinking water is treated via chlorination. One study has been conducted to test conversion to omethoate during chlorination; however, the resulting data are limited in scope. Due to the serious limitations of these data, 100% conversion of dimethoate to omethoate during drinking water treatment of surface waters has been assumed as a protective measure for this assessment. For more details on the conversion of dimethoate to omethoate during drinking water treatment, see "A Re-assessment of the Drinking Water Exposure Due to Dimethoate Residues in Drinking Water, Considering New Recommended Maximum Label Patterns from the Technical Registrant" (Jones, R., 12/21/05).

The ground water EDWCs were estimated using the SCI-GROW model, version 2.3. Since modeled EDWCs for ground water were much lower than surface water concentrations, only surface water EDWCs were used in the dietary risk assessment.

*Acute Dietary Risk Assessment for Food + Water*

Estimated residues in drinking water were incorporated directly into the acute dietary assessment. A refined, Tier 3 assessment was conducted using the full distribution of estimated residues in surface water, generated by the PRZM-EXAMS model for dimethoate use on California broccoli, the crop scenario resulting in the highest estimated peak surface water concentration, and for Georgia pecans, the crop scenario resulting in the lowest estimated peak surface water concentration.

Dietary risk from food alone occupies 32% of the aPAD. When food and water are considered together, the resulting acute dietary exposure and risk estimates for the California broccoli scenario exceed EPA's level of concern for all population subgroups. Risk from aggregate dietary exposure on an acute basis occupies 460% of the aPAD for the most highly exposed subgroup, infants less than one year of age.

Table 4. Summary of Acute Dietary Exposure and Risk for Dimethoate at 99.9th Percentile

| Population Subgroup | Food Only | | Food + Drinking Water (CA Broccoli) | | Food + Drinking Water (GA Pecans) | |
|---|---|---|---|---|---|---|
| | Dietary Exposure (mg/kg/day) | % aPAD | Dietary Exposure (mg/kg/day) | % aPAD | Dietary Exposure (mg/kg/day) | % aPAD |
| General US Population | 0.002134 | 16 | 0.017872 | 140 | 0.002160 | 17 |
| Infants < 1 year | 0.001958 | 15 | 0.060155 | 460 | 0.002419 | 19 |
| Children 1-2 years old | 0.004160 | 32 | 0.026520 | 200 | 0.004373 | 34 |

*Chronic Dietary Risk Assessment for Food + Water*

A refined, Tier 3 chronic dietary exposure assessment was also conducted for the supported food uses of dimethoate and for drinking water. Anticipated residues were derived using field trial data, percent crop treated data, and, where available, processing factors.

For the chronic assessment, a single point estimate (23.5 ppb) of dimethoate residues in surface water was used to assess exposure from drinking water. The estimated surface water concentration represents the 90th percentile annual mean concentration generated by the PRZM-EXAMS model for California broccoli, the crop scenario resulting in the highest estimated annual mean concentration.

Chronic dietary risks based on this analysis are below the Agency's level of concern for all population subgroups. Risk from aggregate dietary exposure on a chronic basis occupies 33% of the cPAD for the most highly exposed subgroup, infants less than one year of age.

Table 5. Summary of Chronic Dietary Exposure and Risk for Dimethoate at 99.9th Percentile

| Population Subgroup | Food Only | | Food + Drinking Water (CA Broccoli) | | Food + Drinking Water (GA Pecans) | |
|---|---|---|---|---|---|---|
| | Dietary Exposure (mg/kg/day) | % cPAD | Dietary Exposure (mg/kg/day) | % cPAD | Dietary Exposure (mg/kg/day) | % cPAD |
| General US Population | 0.000028 | 1.3 | 0.000233 | 11 | 0.000031 | 1.4 |
| Infants <1 year | 0.000042 | 1.9 | 0.000715 | 33 | 0.000051 | 2.3 |
| Children 1-2 years old | 0.000111 | 5.1 | 0.000416 | 19 | 0.000115 | 5.2 |

*Dietary Risk Characterization*

For regulatory purposes, the Agency has assumed that 100% of the modeled water concentrations of dimethoate will convert to omethoate during drinking water treatment.

Therefore, the 12X toxicity factor for acute assessments and the 3X toxicity factor for the chronic assessments were applied directly to the distribution of water residue values. Data exist which indicate that in some instances, conversion could be as low as 20%, but these data have serious limitations. The Agency is requiring the registrant to investigate the rate and amount of dimethoate conversion to omethoate during water chlorination under various water quality regimes.

In light of the conservative assumptions regarding conversion to omethoate, the Agency considered surface water modeling results from several crop and regional scenarios. The resulting aggregated food plus drinking water values for dimethoate are above 100% of the aPAD for some uses. Food alone represents 32% of the aPAD for the most highly exposed population subgroup, and the addition of modeled water residues results in estimates below the Agency's level of concern for several uses. Preliminary DEEM modeling showed that a peak water residue estimate of 140 ppb is equivalent to 106% of the aPAD for food and water for the most exposed population. Of the 25 modeled scenarios, 17 resulted in peaks less than 140 ppb which is below the Agency's level of concern prior to mitigation and 8 scenarios resulted in peak residues at 140 ppb or greater. The mitigation the Agency is requiring is expected to reduce drinking water estimates for all sites except broccoli, celery and cauliflower grown in coastal California.

For broccoli, celery and cauliflower, modeling was done for applications in the winter season (November and December), and the predicted water concentrations were high as a result of runoff from the high amount of rain received in coastal California in the winter. Sensitivity analyses were conducted to explore different mitigation options, and showed that reducing the number of applications or prohibiting aerial applications did not result in drinking water risk estimates below 100% of the aPAD (when added to food risks). USDA provided refined usage information indicating that while several applications a year are needed for these vegetables, dimethoate is not used in November and December in coastal areas of California. EPA then considered the effects of changing the application timing to the fall or spring, or modeling applications in other areas of the country, and these considerations did result in much lower values. The Agency believes that when these facts are taken into account along with the conservative assumption of 100% conversion to omethoate during drinking water treatment, the drinking water residues resulting from dimethoate applications to these vegetables do not pose dietary risks of concern.

### 3. Residential and Other Non-occupational Risk

All residential and other non-occupational uses of dimethoate were voluntarily cancelled in 2002 (Federal Register Notice/Vol. 67, No. 84/Wednesday, May 1, 2002/Notices/21669). Therefore, EPA did not conduct a residential exposure and risk assessment for dimethoate.

### 4. Aggregate Exposure and Risk

(For a complete discussion, see Section 7 of the human health risk assessment.)

The Food Quality Protection Act (FQPA) amendments to the Federal Food, Drug and Cosmetic Act (FFDCA, Section 408(b)(2)(A) (iii) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures for which there is reliable information." Aggregate exposure will typically include dietary exposures (food plus drinking water), residential uses of a pesticide, and other non-occupational sources of exposure.

There are no residential or other non-occupational uses of dimethoate. Therefore, when addressing aggregate exposures, only the aggregate dietary pathways of food and drinking water were considered. Since drinking water was incorporated directly into the acute and chronic dietary assessments, the dietary risk estimates discussed above reflect total estimated acute and chronic aggregate risks from dimethoate.

Acute aggregate risk estimates for food and drinking water exceed EPA's level of concern for all population subgroups when estimated residues in drinking water from the California broccoli scenario are assessed. When mitigation (i.e., reduced maximum application rates, reduced numbers of applications per year, and increased retreatment intervals) is considered, food and drinking water residues from all other uses do not exceed the Agency's level of concern. Chronic aggregate risk estimates for food and drinking water are below the Agency's level of concern for all population subgroups, including the most highly exposed subgroup, infants less than one year of age.

### 5. Occupational Exposure and Risk

(For a complete discussion, see section 9 of the human health risk assessment.)

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk is measured by a Margin of Exposure (MOE), which describes how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). The target MOE for dimethoate is 100, which includes the default uncertainty factors for interspecies extrapolation and intraspecies variation. MOEs that fall below 100 indicate a possible need for mitigation.

Occupational handler scenarios were assessed using the short- and intermediate-term endpoint for dermal and inhalation exposures. The short- and intermediate-term dermal endpoint is a $BMDL_{10}$ of 18.67 mg/kg/day, based on a 28-day repeated dose dermal toxicity study on rats. The short- and intermediate-term inhalation endpoint is 0.1 mg/kg/day, derived from an inhalation concentration level of 0.38 $mg/m^3$ ($BMDL_{10}$) from a 28-day repeated dose inhalation study of omethoate using rats. Dermal and inhalation exposures were combined to assess handler risk.

Occupational handler risk estimates have been assessed for short- and intermediate-term exposures. Most occupational exposures are expected to occur in a

short-term pattern (up to 30 days), but some intermediate-term (one to six month) exposures are anticipated in some handler exposure scenarios, particularly those involving applications by commercial applicators to large-acreage crops (e.g., field corn, wheat, alfalfa, cotton). Long-term exposures are those that would result from use of a pesticide for more than several months in a single year, and are not expected for dimethoate.

No chemical-specific data for assessing worker exposures during pesticide handling activities were submitted, so short- and intermediate-term dermal and inhalation exposures for handlers were developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1.

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle dimethoate during the usual use patterns associated with the pesticide. Several major occupational exposure scenarios were identified based on the type of equipment that potentially can be used to make dimethoate applications.

The calculations of short- and intermediate-term total risks to handlers indicate that most occupational handler risks are below the Agency's level of concern (i.e., MOEs are greater than 100) at some level of risk mitigation. Table 6 below shows only those handler scenarios for which MOEs are less than 100.

Table 6. Summary of Handler Scenarios with MOEs Less Than 100 When Assessed with Maximum Feasible Mitigation

| Exposure Scenario | Crop | Maximum Application Rate (lbs a.i./A) | Daily Treated Area (Acres) | MOE w/ Maximum Feasible Mitigation Controls |
|---|---|---|---|---|
| Mixing/loading liquids for aerial and chemigation applications | Citrus | 2.0 | 350 | 77[b] |
| | Woody ornamentals, Christmas tree plantations, and conifer seed orchards (other than Douglas firs in OR and WA) | 2.0 | 350 | 77[b] |
| | Cottonwood grown for pulp | 4.0 | 350 | 39[b] |
| Mixing/loading liquids for aerial applications | Wheat | 0.67 | 1,200 | 67[b] |
| | Alfalfa, alfalfa grown for seed, cotton, field corn, pop corn, grass grown for seed, safflower, sorghum, and soybeans | 0.5 | 1,200 | 90[b] |
| Mixing/loading wettable | Pears | 1.0 | 350 | 68[b] |

| Exposure Scenario | Crop | Maximum Application Rate (lbs a.i./A) | Daily Treated Area (Acres) | MOE w/ Maximum Feasible Mitigation Controls |
|---|---|---|---|---|
| powders for aerial and chemigation applications | | 0.75 | 350 | 91[b] |
| Mixing/loading/applying liquids with high pressure handwand sprayers | Woody ornamentals, Christmas tree plantations, and conifer seed orchards (other than Douglas firs in OR and WA) | 0.01[c] | 1,000 gallons | 34[a] |
| Aerial spray applications of liquids | Wheat | 0.67 | 1,200 | 92[b] |
| | Cottonwood grown for pulp | 4.0 | 350 | 53[b] |
| Applying liquids with airblast/mistblower sprayers | Douglas fir seed orchards in OR and WA | 8.3 | 20 | 76[b] |

[a]Maximum feasible mitigation measure denotes additional PPE (double layer clothing plus gloves and a half-face or full-face respirator).
[b]Maximum feasible mitigation measure denotes engineering controls (i.e., closed systems for mixers and loaders or closed cabs for applicators).
[c]Expressed in lbs a.i./gal

*Post-Application Occupational Risk*

For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely reenter (i.e., MOEs ≥ 100). The postapplication occupational risk assessment considered exposure to dimethoate from entering treated fields and orchards. Given the nature of activities in these locations, and the fact that dimethoate is applied at various times during plant growth, contact with treated surfaces is likely. Potential exposure scenarios include key tasks, such as harvesting, thinning, and pruning, as well as secondary tasks, such as scouting, irrigating, and hand weeding. Other tasks of concern were also identified for corn (detassling) and herbaceous ornamentals (tasks related to cutting carnations and roses).

Postapplication exposures are influenced by geographic location and environmental conditions near the time of application and the type of plant to which the application is directed. For most crops, data show that following applications in arid areas (i.e., outdoor areas where average annual rainfall is less than 25 inches), residues persist longer than in non-arid areas. As a result, estimated REIs tend to be longer in arid areas.

Table 7. Summary of Postapplication Risk Assessment for Dimethoate

| Crop Group | Max Single App. Rate (lbs a.i./A) | Key Tasks | | | Secondary Tasks | | |
|---|---|---|---|---|---|---|---|
| | | Transfer Coefficient | REI (days) | | Secondary Transfer Coefficient | REI (days) | |
| | | | Non-Arid | Arid | | Non-Arid | Arid |
| Endive, escarole, kale, leaf lettuce, mustard greens, Swiss chard, turnips | 0.25 | 2,500 harvest, thin | 12 hrs | 1 | 1,500 scout & irrigate | 12 hrs | 12 hrs |
| Peas | 0.16 | 2,500 harvest | 12 hrs | 12 hrs | 1,500 scout & irrigate | 12 hrs | 12 hrs |
| Brussels sprouts | 1 | 5,000 harvest, irrigate, prune, thin & tie | 3 | 9 | NA | | |
| Wheat | 0.67 | 1,000 scout, irrigate | 1 | 12 hrs | NA | | |
| Beans, lentils, celery | 0.5 | 2,500 harvest | 1 | 2 | 1,500 scout & irrigate | 1 | 12 hrs |
| Melons, watermelons | 0.5 | 2,5000 harvest, prune & thin | 1 | 2 | 1,500 scout, irrigate & hand weed | 1 | 12 hrs |
| Tomatoes | 0.5 | 1,000 harvest, prune, stake, thin, tie & train | 12 hrs | 12 hrs | 700 scout & irrigate | 12 hrs | 12 hrs |
| Asparagus | 0.5 | 500 scout &irrigate | 12 hrs | 12 hrs | NA | | |
| Broccoli, cauliflower | 0.5 | 5,000 harvest, irrigate, prune, thin & tie | 2 | 5 | NA | | |
| Alfalfa, alfalfa grown for seed, soybeans, safflower, cotton, potatoes | 0.5 | 1,500 scout & irrigate | 1 | 12 hrs | NA | | |
| Field corn, popcorn | 0.5 | 1,000 scout, irrigate & hand weed | 12 hrs | 12 hrs | NA | | |
| Grain sorghum | 0.5 | 1,000 scout, | 12 hrs | 12 hrs | NA | | |

| Crop Group | Max Single App. Rate (lbs a.i./A) | Key Tasks | | | Secondary Tasks | | |
|---|---|---|---|---|---|---|---|
| | | Transfer Coefficient | REI (days) | | Secondary Transfer Coefficient | REI (days) | |
| | | | Non-Arid | Arid | | Non-Arid | Arid |
| | | irrigate | | | | | |
| Herbaceous ornamentals | 0.5 | 500 tasks related to cut flowers & foliage, except roses & carnations | 12 hrs | 12 hrs | 400 tasks related to nursery crops, except cut flowers or foliage | 12 hrs | 12 hrs |
| Peppers | 0.33 | 1,000 harvest, stake & tie | 12 hrs | 12 hrs | 700 scout & irrigate | 12 hrs | 12 hrs |
| Douglas Fir Seed Orchards in OR and WA | 8.3 | 1,000 scout, irrigate & weed | 22 | 39 | NA | | |
| Cottonwoods grown for pulp | 4 | 1,000 scout, irrigate & weed | 14 | 24 | NA | | |
| Conifer seed orchards (except Douglas fir seed orchards in OR and WA) | 2 | 1,000 scout, irrigate & weed | 7 | 11 | NA | | |
| Woody ornamentals and Christmas tree plantations | 2 | 3,000 prune & thin | 19 | 36 | 1,500 harvest | 13 | 14 |
| Pecans | 0.33 | 500 prune & scout | 12 hrs | 12 hrs | NA | | |
| Pears | 1 | 3,000 harvest, prune, train & tie | 10 | 14 | 1,000 scout, irrigate & hand weed | 2 | 4 |
| | 0.75 | | 8 | 12 | | 2 | 2 |
| | 0.5 | | 5 | 7 | | 12 hrs | 12 hrs |
| Citrus | 2 | 3,000 prune | 24 | 36 | 1,000 scout, irrigate & hand weed | 7 | 9 |
| | 1 | | 13 | 14 | | 2 | 4 |
| | 0.5 | | 6 | 7 | | 12 hrs | 12 hrs |
| Cherries | 1 | 3,000 harvest & prune | 10 | 14 | 1,000 scout, irrigate & hand weed | 2 | 4 |
| | 0.33 | | 2 | 4 | | 12 hrs | 12 hrs |

The risk assessment indicates that REIs of 12 hours are long enough for MOEs to reach 100 for many crops; however, acute toxicity of omethoate was not taken into consideration. If an active ingredient is categorized as a toxicity category I due to dermal

toxicity, skin irritation, or eye irritation, the Agency requires a minimum of a 48-hour REI. Data were not available on the acute toxicity of omethoate, but omethoate is known to form on plants after application; therefore, EPA believes a minimum REI of 48-hours is appropriate for dimethoate. This is consistent with current labels.

EPA will not be setting separate REIs for detassling corn, for which proposed REIs are 4 and 15 days for non-arid and arid conditions, respectively, due to the fact that this task is relevant only for seed corn, and dimethoate is not registered for use on seed corn.

#### 6. Human Incident Data

For a review of the pesticide poisoning incident data for dimethoate, EPA consulted the following data bases: (1) OPP Incident Data System; (2) Poison Control Centers; (3) California Department of Pesticide Regulation; and (4) National Pesticide Telecommunications Network.

A review of the published incident data indicates that for outdoor agricultural uses, the primary sources of occupational exposures associated with poisoning are postapplication field residues and spray drift. Risks from agricultural uses appear to be somewhat lower than with other insecticides. Dimethoate has the highest reported incidence of poisonings (none life-threatening) among OPs used in residential settings, but all residential uses for dimethoate were cancelled in 2002 (Federal Register Notice/Vol. 67, No. 84/Wednesday, May 1, 2002/Notices/21669).

### B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for dimethoate is presented below. The complete risk assessment is available in the public docket at http://www.regulations.gov (docket # EPA-HQ-OPP-2005-0084).

#### 1. Environmental Exposure

##### a. Environmental Fate and Transport

Dimethoate is a highly mobile, relatively non-persistent organophosphate insecticide. The primary route of dissipation is microbially-mediated hydrolytic and oxidative degradation in aerobic soil, particularly under moist conditions, with a half-life of 2.2 days. Dimethoate does not photodegrade. It hydrolyzes very slowly in sterile buffered solutions at pHs 5 and 7 (156 and 68 days, respectively), but hydrolyzes rapidly to desmethyl dimethoate and dimethylthiophosphoric acid with a half-life of 4.4 days at pH 9. The anaerobic half-life was found to be approximately 22 days, with the major non-volatile degradate being desmethyl dimethoate.

In a soil column leaching study, 72-100% of the applied radioactivity was eluted from the columns (loam, silt loam, sandy loam, and sand). A study measuring the

volatility of dimethoate from the soil surface showed that volatility is not a significant route of dissipation.

The primary toxic degradate, omethoate, was found under field conditions, though it was not detected in the laboratory studies. The presence of omethoate has been established through field studies in insects, plants, and mammals. Omethoate was the only degradate analyzed in the dimethoate field dissipation study. The other degradates identified in the laboratory studies were not included in the analysis because it is believed that: 1) based on the aerobic soil metabolism study, they would not persist in the field; and, 2) they are not toxicologically significant.

### b. Aquatic Organism Exposure

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in groundwater. Surface water models are used to estimate exposure to freshwater aquatic animals, since monitoring data are generally not from studies targeted on small water bodies and primary streams, where many aquatic animals are found. The modeling results used in risk calculations for dimethoate are detailed in "A Supplement to the Environmental Fate and Ecological Risk Assessment for the Re-registration of Dimethoate," dated January 13, 2006.

The Estimated Environmental Concentration (EEC) values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources. Unlike the human drinking water assessment, the assessment of aquatic environmental concentrations accounts for exposure to parent dimethoate only. Omethoate is not expected to be a major degradate in water except as a result of chlorination (i.e., drinking water treatment). Also, foliar dissipation data were used in the modeling.

Several crop scenarios were assessed in the ecological risk assessment. The California broccoli scenario represents the agricultural use with the maximum EEC, and so was chosen for regulatory purposes. The highest and lowest EEC values used to assess exposure to aquatic animals can be found in Table 8 below. For a complete listing of EECs please refer to the ecological risk assessment.

Table 8. Estimated Environmental Concentrations (µg ai/L) of Dimethoate in Surface Water for Selected Use Patterns

| Crop | Maximum µg/L | 4-Day µg/L | 21-Day µg/L | 60-Day µg/L | 90-Day µg/L |
|---|---|---|---|---|---|
| Broccoli, CA | 33.4 | 32.0 | 28.2 | 21.6 | 17.7 |
| Peas | 1.28 | 1.20 | 0.96 | 0.60 | 0.44 |

### c. Terrestrial Organism Exposure

The Agency assessed exposure to terrestrial organisms by first predicting the amount of dimethoate residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items is based on the Fletcher nomogram and the current maximum application rates and minimum application intervals proposed by the technical registrant for dimethoate. The Fletcher nomogram is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994). For non-food uses, the Agency used a conservative estimate of 25 applications with a 3-day re-application interval, since no maximum numbers of applications or minimum retreatment intervals appear on current product labels or were proposed by the registrant.

Terrestrial exposure estimates for avian and mammalian risk assessments were derived using the TREX model (Version 1.1), which calculates the decay of a chemical applied to surfaces of food items as single or multiple applications. A complete list of the EEC values used to assess exposure to terrestrial animals can be found in the ecological risk assessment.

## 2. Environmental Effects (Hazard)

### a. Toxicity to Aquatic Organisms

Freshwater and Estuarine/Marine Fish

Dimethoate is practically non-toxic to estuarine/marine fish and moderately toxic to freshwater fish on an acute basis. Chronic toxicity testing with aquatic animals revealed reduced growth for freshwater fish (NOAEC = 0.43 mg/L). No data were available on the chronic effects of dimethoate on estuarine/marine fish. Table 9 summarizes the data that support the toxicity endpoints used in assessing the risks to fish.

Table 9. Summary of Acute and Chronic Toxicity Estimates for Fish Using Technical Grade Dimethoate

| Species | Acute Toxicity | | Chronic Toxicity | |
|---|---|---|---|---|
| | 96-hr LC50 (mg/L) | Acute Toxicity (MRID) | NOAEC/LOAEC (mg/L) | Affected Endpoints (MRID) |
| Rainbow Trout *Oncorhynchus mykiss* | 6.2 | Moderately toxic (400940-02) | 0.43/0.84 | Reduced growth (431063-03) |

Freshwater and Estuarine/Marine Invertebrates

Dimethoate is considered to be slightly toxic to estuarine/marine invertebrates and very highly toxic to freshwater invertebrates on an acute basis. Chronic toxicity testing with aquatic animals revealed reduced growth, survival, and reproductive effects (NOAEC = 0.04 mg/L) for freshwater invertebrates. No studies are available on the chronic toxicity of dimethoate to estuarine/marine invertebrates. Table 10 provides a

summary of the data that support the toxicity endpoints used in assessing the risks to aquatic invertebrates.

Table 10. Summary of Acute and Chronic Toxicity Estimates for Aquatic Invertebrates Using Technical Grade Dimethoate

| Species | Acute Toxicity | | Chronic Toxicity | |
|---|---|---|---|---|
| | 96-hr LC50 (mg/L) | Acute Toxicity (MRID) | NOAEC/LOAEC (mg/L) | 96-hr LC50 (mg/L) |
| Stonefly *Pteronarcys californica* | 0.043 (48-hr) | Very highly toxic (00003503) | ND* | ND |
| Water flea *Daphnia magna* | 3.32 | ND | 0.04/0.1 | Reproductive, survival, growth (428647-01) |
| Mysid shrimp *Mysidopsis bahia* | 15 | Slightly toxic (427600-03) | ND | ND |

*ND = Not determined

Aquatic Plants

No toxicity data have been submitted to the Agency for either terrestrial or aquatic plants; however, information from the open literature indicates that dimethoate is highly toxic to blue-green algae.

### b. Toxicity to Terrestrial Organisms

Birds

Dimethoate is considered very highly toxic to birds on an acute basis. Chronic toxicity testing resulted in reproductive effects (reduced egg production and number of viable embryos), growth effects (reduced 14-day survivor weight), and survival effects (reduced number of 14-day survivors) in birds. The chronic NOAEC was 4 mg/kg diet.

Table 11. Summary of Avian Toxicity Data

| Species | $LD_{50}$ (mg/kg) | Acute Oral Toxicity (MRID) | 5-day $LC_{50}$ (ppm) | Subacute Dietary Toxicity (MRID) |
|---|---|---|---|---|
| Red-winged blackbird *Agelaius phoeniceus* | 5.4 | Very highly toxic (00020560) | ND* | ND |
| Ring-necked pheasant *Phasianus colchicus* | ND | ND | 332 | Highly toxic (00022923) |

*ND = Not determined

Table 12. Summary of Avian Chronic Toxicity Data

| Species | NOAEC/ LOAEC (ppm) (MRID) | Affected Endpoints |
|---|---|---|
| Northern bobwhite quail *Colinus virginianus* | 4.0/10.1 (440490-01) | Reduced egg production, viable embryos, 3-week old embryos, normal hatchlings, 14-day old survivors, 14-day old survivor weight, adult male and female body weight, and egg shell thickness |

No registrant-submitted data are available with which to evaluate the toxicity of omethoate to birds and no data on avian species are available through ECOTOX. Although the open literature suggests that birds can be particularly sensitive to the O-analog (oxon) of phosphorodithioate insecticides, there are no data currently available to determine whether this is true for omethoate. Thus, the sensitivity of birds to omethoate is an uncertainty in the Agency's risk assessment.

Mammals

Dimethoate is moderately toxic to mammals on an acute exposure basis. Data from a developmental neurotoxicity study (NOAEC=0.1 mg/kg bw) were used to assess the risk of chronic toxicity of dimethoate to mammals. This endpoint is considerably more sensitive than that used in the previous (1999) risk assessment for dimethoate. The NOAEL from the developmental neurotoxicity study of rats is based on reproductive impairment as measured by decreased pup survival and increased percentage of rat litters lost. After treating maternal rats during gestation and nursing, there was a dose-dependent increase in pup death and litter loss.

Table 13. Summary of Acute and Chronic Toxicity Data for Mammals Exposed to Dimethoate

| Species | Acute Toxicity | | | | Chronic Toxicity | |
|---|---|---|---|---|---|---|
| | $LD_{50}$ (mg/kg) | Acute Oral Toxicity (MRID) | 5-day $LC_{50}$ (ppm) | Subacute Dietary Toxicity (MRID) | NOAEC/ LOAEC (ppm) (MRID) | Affected Endpoints |
| Laboratory mouse *Mus musculus* | 120 | Moderately toxic (00055371) | ND | ND | ND | ND |
| Laboratory rat *Rattus norvegicus* | 420 | Moderately toxic (247669) | ND | ND | 32/400 mg/kg/day (00051675) | CHeI and decreased weight |
| | | | | | 0.1/1.0 mg/kg/day (455297-03) | Pup mortality |

Non-target Insects

Dimethoate is characterized as highly toxic to bees on an acute exposure basis, based on a honey bee acute contact study ($LD_{50}$ = 0.05 µg/bee). Contact toxicity data on parasitic wasps (*Bathyplectus curculionus*) indicate that some beneficial insects may be

considerably more sensitive than honeybees ($LD_{50}$=0.00043 µg/wasp) on an acute contact basis.

### 3. Ecological Risk Estimation

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 non-target organisms from the use of dimethoate products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive 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), given in Table 14, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects on non-target organisms. When the RQ exceeds the LOC for a particular category, (e.g., endangered species), the Agency presumes a risk of concern to that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the relative degree of uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 14. EPA's Levels of Concern and Associated Risk Presumptions

| **Risk Presumption** | **LOC terrestrial animals** | **LOC aquatic animals** |
|---|---|---|
| **Acute Risk** - there is potential for acute risk | 0.5 | 0.5 |
| **Acute Endangered Species** - endangered species may be adversely affected | 0.1 | 0.05 |
| **Chronic Risk** - there is potential for chronic risk | 1 | 1 |

For a more detailed explanation of the ecological risks posed by the use of dimethoate, refer to "A Supplement to the Environmental Fate and Ecological Risk Assessment for the Re-registration of Dimethoate," dated January 13, 2006.

#### a. Risk to Aquatic Organisms

Freshwater Fish and Invertebrates

No acute RQs exceed the acute risk LOC for freshwater fish or invertebrates (RQs range from <0.01 to 0.03).

No chronic RQs exceed the chronic risk LOC for freshwater fish (RQs range from <0.01 to 0.14). For freshwater invertebrates, the only exceedance of the LOC is associated with use on Christmas trees (RQ = 1.96). Risks to aquatic animals from use of dimethoate on Christmas trees was estimated assuming 25 applications at the maximum labeled rate, with 3 day application intervals. This number of applications is likely

greater than the actual value, but was assessed because current labels do not specify limits. As a result of this reregistration decision, labels will be revised to limit the number of applications per season. For all other use scenarios, chronic RQs were below the LOC.

Estuarine/Marine Fish and Invertebrates

RQs were not calculated for estuarine/marine animals; however, since the acute toxicity endpoints for estuarine/marine fish and invertebrates are considerably higher than for their freshwater counterparts ($LC_{50}$ > 111,000 µg/L for sheepshead minnow, and $LC_{50}$ = 15,000 µg/L for mysid shrimp), the Agency believes that none of the acute RQs would exceed the acute risk LOC. No chronic toxicity data are currently available for estuarine/marine fish or invertebrates, and therefore chronic risks could not be assessed.

### b. Risk to Non-target Terrestrial Organisms

Birds

Avian RQs were calculated based on maximum residues of dimethoate on forage items following a single application and an $LC_{50}$ of 332 ppm from a subacute dietary toxicity study on ring-necked pheasants. At rates of 1 lbs a.i./A or less, the highest acute RQ is for birds feeding on short grass (RQ = 0.72). At rates greater than or equal to 0.75 lbs a.i./A, the acute risk and endangered species LOCs are exceeded for birds foraging on short grass. The acute endangered species LOC is not exceeded for birds feeding on tall grass and broadleaf plants/insects. In order to reduce RQs to below the endangered species LOC for the most vulnerable avian species, rates would have to be reduced to a single application of 0.13 lbs a.i./A. This low rate would not be efficacious.

Following multiple applications of dimethoate, the acute risk LOC is exceeded for all applications equal to or greater than 1 lbs a.i./A (RQ = 0.72). Multiple applications at rates greater than 0.16 lbs a.i./A exceed the endangered species LOC for herbivores across all uses (Table 15). Mean avian acute RQs were not calculated for multiple applications, but would be expected to result in no acute risk exceedances, except with application rates greater than 1 lbs a.i./A, but endangered species exceedances would still occur.

Table 15. Summary of Estimated Acute Avian RQs from Multiple Application of Dimethoate at Maximum Foliar Residues

| **Use Site**<br><br>**Application Rate (#/year / interval)** | **Food Items** | **Maximum RQ** |
|---|---|---|
| Citrus<br><br>1.0 lb a.i./A (2/31) | Short grass | 0.72 |
| | Tall grass | 0.33 |
| | Broadleaf plants/small insects | 0.41 |
| | Fruits, pods, seeds, and large insects | 0.05 |
| Broccoli, Cauliflower, Celery | Short grass | 0.44 |

| Use Site<br><br>Application Rate (#/year / interval) | Food Items | Maximum RQ |
|---|---|---|
| 0.5 lb a.i./A<br>(6/7) | Tall grass | 0.20 |
| | Broadleaf plants/small insects | 0.25 |
| | Fruits, pods, seeds, and large insects | 0.03 |
| Cotton, Safflower<br><br>0.5 lb a.i./A<br>(2/14) | Short grass | 0.37 |
| | Tall grass | 0.17 |
| | Broadleaf plants/small insects | 0.21 |
| | Fruits, pods, seeds, and large insects | 0.02 |
| Alfalfa<br><br>0.5 lb a.i./A<br>(1/na) | Short grass | 0.36 |
| | Tall grass | 0.17 |
| | Broadleaf plants/small insects | 0.20 |
| | Fruits, pods, seeds, and large insects | 0.02 |

LOC = 0.5 for acute risk and 0.01 for endangered species

Chronic avian RQs exceed the LOC (RQ≥1.0) by factors of one to 178 for nearly all use scenarios at maximum residues. At mean residue levels, RQs decrease by roughly 60%. Chronic RQ values based on mean residues range from 0.28 to 63. At application rates below 0.5 lbs a.i./A, the chronic risk LOC is not exceeded for birds feeding on fruits, pods, seeds and large insects, however, if the retreatment interval is reduced to 7 days, the LOC is exceeded. In order to reach maximum residues that do not result in RQs exceeding the chronic risk LOC, the maximum single application rate would have to be reduced to 0.016 lbs a.i./A, a rate that is not efficacious.

Table 16. Summary of Estimated Chronic Avian RQs from Use of Dimethoate at Mean Foliar Residues

| Use<br><br>Application Rate (#/year / interval) | Food Items | Mean RQ |
|---|---|---|
| Citrus<br><br>1.0 lbs a.i./A<br>(2/3) | Short grass | 63[a] |
| | Tall grass | 27[a] |
| | Broadleaf plants/small insects | 33[a] |
| | Fruits, pods, and large insects | 5.2[a] |
| Broccoli, Cauliflower, Celery<br><br>0.5 lbs a.i./A<br>(6/7) | Short grass | 13[a] |
| | Tall grass | 5.5[a] |
| | Broadleaf plants/small insects | 6.9[a] |
| | Fruits, pods, and large insects | 1.1[a] |
| Cotton, Safflower | Short grass | 11[a] |
| | Tall grass | 4.7[a] |

| Use<br><br>Application Rate (#/year / interval) | Food Items | Mean RQ |
|---|---|---|
| 0.5 lbs a.i./A (2/14) | Broadleaf plants/small insects | 5.8[a] |
| | Fruits, pods, and large insects | 0.91 |
| Alfalfa | Short grass | 11[a] |
| | Tall grass | 4.5[a] |
| | Broadleaf plants/small insects | 5.6[a] |
| | Fruits, pods, and large insects | 0.88 |

[a]Exceeds chronic risk level of concern (RQ≥1.0)

Mammals

The acute mammalian risk assessment is based on a mouse acute oral $LD_{50}$ of 120 mg/kg and RQ values are expressed as dose-based values. The dose-based RQs are calculated using a body weight-adjusted and consumption-weight equivalent dose. By expressing the Kenaga nomogram estimated residues in terms of daily equivalent dose, estimated environmental concentrations can then be compared to the dose-based $LD_{50}$. After a single application rate of 1 lb a.i./A, the acute risk LOC is exceeded for mammals weighing less than 35 grams and feeding on short grass, tall grass, and broadleaf plants/insects, with RQs up to 3.5.

Following multiple applications of dimethoate at rates greater than 0.25 lbs a.i./A, the acute risk LOC is exceeded for small and intermediate-sized mammals feeding on short grass (RQs range from 0.76 to 5.3). The acute endangered species LOC is exceeded across small and intermediate-sized herbivorous mammals at application rates greater than 0.16 lbs a.i./A.

Table 17. Summary of Estimated Acute Mammalian RQs from Multiple Applications of Dimethoate at Maximum Foliar Residues

| Use Application Rate (#/year / interval) | Body Weight (g) | Mammalian Acute Risk Quotients | | | |
|---|---|---|---|---|---|
| | | Short Grass | Tall Grass | Broadleaf Plants/Small Insects | Fruits/Pods/ Large Insects |
| Citrus | 15 | 1.8 | 0.81 | 1.0 | 0.11 |
| | 35 | 1.5 | 0.7 | 0.85 | 0.09 |
| 1.0 lbs a.i./A (2/31) | 1,000 | 0.81 | 0.37 | 0.46 | 0.05 |
| Broccoli, | 15 | 1.10 | 0.50 | 0.61 | 0.06 |
| Cauliflower, | 35 | 0.93 | 0.43 | 0.52 | 0.07 |
| Celery<br><br>.5 lbs a.i./A (6/7) | 1,000 | 0.50 | 0.23 | 0.28 | 0.03 |
| Cotton, | 15 | 0.92 | 0.42 | 0.52 | 0.06 |
| Safflower | 35 | 0.78 | 0.36 | 0.44 | 0.05 |

| Use Application Rate (#/year / interval) | Body Weight (g) | Mammalian Acute Risk Quotients | | | |
|---|---|---|---|---|---|
| | | Short Grass | Tall Grass | Broadleaf Plants/Small Insects | Fruits/Pods/ Large Insects |
| .5 lbs a.i./A (2/14) | 1,000 | 0.42 | 0.19 | 0.24 | 0.03 |
| Alfalfa | 15 | 0.89 | 0.41 | 0.50 | 0.06 |
| | 35 | 0.76 | 0.35 | 0.43 | 0.05 |
| 0.5 lb a.i./A (1 app per year) | 1,000 | 0.41 | 0.19 | 0.23 | 0.03 |

As seen in Table 18 below, all uses of dimethoate result in RQs which exceed the chronic mammalian level of concern based on a NOAEL of 0.1 mg/kg/day. For a complete listing of mammalian RQs for both maximum and mean foliar residues, please see Tables 28 and 29 of the environmental risk assessment. For further information on the chronic risks to mammals, please see Section 5 "Risk Characterization" below.

Table 18. Summary Estimated Chronic Mammalian RQs from Multiple Applications of Dimethoate Based on Mean Foliar Residues

| Use Application Rate | Body Weight (g) | Mammalian Risk Quotients | | | | |
|---|---|---|---|---|---|---|
| | | Short Grass | Tall Grass | Broadleaf Plants/Small Insects | Fruits/Pods/ Large Insects | Seeds |
| Citrus | 15 | 1,042 | 477 | 586 | 65 | 14 |
| | 35 | 890 | 408 | 501 | 56 | 12 |
| 2.0 lbs a.i./A (2/31) | 1,000 | 477 | 219 | 268 | 30 | 6.6 |
| Broccoli, | 15 | 639 | 293 | 359 | 40 | 8.5 |
| Cauliflower, | 35 | 546 | 250 | 307 | 34 | 7.6 |
| Celery<br>0.5 lbs a.i./A (6/7) | 1,000 | 293 | 134 | 135 | 18 | 4.1 |
| Cotton, Safflower | 15 | 538 | 247 | 303 | 34 | 7.5 |
| | 35 | 460 | 211 | 259 | 29 | 6.4 |
| 0.5 lbs a.i./A (2/14) | 1,000 | 247 | 113 | 139 | 15 | 3.4 |
| Alfalfa | 15 | 521 | 239 | 293 | 33 | 7.2 |
| | 35 | 445 | 204 | 250 | 28 | 6.2 |
| 0.5 lb a.i./A (1 app per year) | 1,000 | 238 | 109 | 134 | 15 | 3.3 |

LOC = 1.0

Non-target Plants

There are no available plant toxicity data on dimethoate, so EPA has not calculated risks to non-target plants.

## 4. Ecological Incidents

There are a total of 22 field incidents reported between 1972 and 2000. Most of the reported incidents are not recent. Relative to other organophosphate pesticides, dimethoate was ranked 13th out of 32 organophosphate pesticides evaluated in terms of the number of incidents reported in the Ecological Incident Information System.

The majority (73%) of reported incidents involved terrestrial animals and were split equally between birds (8) and bee-related (8) incidents. Canada geese and cedar waxwings were the most frequently affected birds. The number of geese killed ranged from 25 to "hundreds" while the number of waxwings killed ranged from 60 to 80. All of the incidents involving Canada geese (4) were associated with the use of dimethoate on alfalfa; of these, two were from the registered use of the pesticide (one of which was for treated seed) and two were a result of accidental misuse. The three incidents involving cedar waxwings were from the registered use of dimethoate in the garden or on woody ornamentals. Of the eight incidents involving bees, seven occurred in Washington State and were primarily associated with the use of dimethoate on beans and orchard crops.

Of the five reported incidents that involved aquatic animals, one resulted from the registered aerial use of dimethoate, and that was on soybeans. In this incident, 9,237 fish were reported killed with the majority of affected fish being minnows (89%), sunfish (6%), and shad (2%). Five turkeys were also reported killed in this same incident. There are insufficient details reported for the incident to determine whether there were unusual circumstances (*e.g.* a rain event) which may have resulted in increased aquatic exposure. The remaining four incidents affecting aquatic animals were from intentional or accidental misuse; two were associated with loading areas, one from use on tobacco and one from use on a lake.

The one incident reported to have involved damage to grass resulted from the misuse of dimethoate on spray applications to lentils in Washington; the extent of damage to the grass is not reported. There have been no other reported incidents of phytoxicity resulting from dimethoate use.

Consistent with risk estimates for birds, reports of non-target species mortality have involved birds. Although risk quotients estimated for fish do not suggest that fish will be subject to acute mortality, incident reports show that freshwater fish have been affected.

## 5. Risk Characterization

Although RQs do not exceed levels of concern for aquatic species, dimethoate has been shown to be moderately toxic to fish and highly toxic to aquatic invertebrates. This is evidenced by reported fish kills associated with the use of dimethoate, signifying the possibility of aquatic effects.

Dimethoate was shown to be very highly toxic to some species of birds by the acute oral route. There are acute LOC exceedances at the application rate of 1.0 lb ai/A for small birds eating short grass, with a maximum RQ of 0.7. Organophosphorus compounds are known to be toxic to birds by dermal and inhalation routes. There have been several incidents involving birds including large birds such as Canadian geese, which may be the result of exposures by these non-dietary routes.

For chronic risks to birds, the avian assessment shows LOC exceedances with the maximum RQs of 63 for two applications at 1 lbs ai/A, based on mean foliar residues.

There are exceedances for acute risk LOC for small mammals with the maximum RQ of 2.6 for small mammals eating short grass treated with two applications of 1.0 lb ai/A. There are no reported mammalian incidents resulting from acute toxicity exposures to dimethoate.

The highest estimated ecological risks from use of dimethoate are chronic risks to mammals, with RQs calculated using mean foliar residues ranging from <1 to 1,092. The high values are from two applications of 1.0 lb ai/A with a 3 day re-application interval. Most applications are at a maximum of 0.5 lb ai/A which results in RQs around 220.

The endpoint used for risk assessment comes from a developmental neurotoxicity study, which was conducted for the human health risk assessment. The endpoint used for the ecological risk assessment is rat pup mortality, observed at very low levels of exposure (NOAEL of 0.1 mg/kg/day). A different endpoint (cholinesterase inhibition) from the same study was used for the human health risk assessment because: 1) ChE inhibition occurred at lower doses, and was therefore considered to be more protective for human health risks; and 2) the mechanism of the pup mortality is not well understood. The Science Advisory Panel noted that the pup mortality observed in the DNT study is dose-related, and the Agency believes that although pup mortality is not a standard endpoint, it is an appropriate endpoint to use for chronic mammalian risk assessment.

The previous ecological chronic mammalian risk assessment, dated January 23, 1998, was based on the standard two generation reproduction study. The endpoint for this study was a NOAEL of 32 mg/kg/day based on maternal effects and decreased reproduction. RQ calculated from this endpoint ranged from <1-10.

While there are differences in the magnitude of the RQs from both assessments, both sets of RQs indicate that potential for chronic, reproductive risk to small mammals is very high. Applications of dimethoate are made to large acreage crops such as alfalfa, corn and cotton. It is expected that mammals whose forage range is small, will be affected if they live in or near treated areas.

To reduce the chronic mammalian risk quotient below the Agency's level of concern, the application rate would have to be lowered to 0.02 lb ai/A, which would be far below the efficacious level for pest control. The Agency is requiring lowered

application rates and lowered numbers of applications to reduce exposure for non-target mammals, and thereby provide some protection against population loss.

### 6. Endangered Species Considerations

The Agency's preliminary risk assessment for endangered species indicates that RQs exceed the endangered species LOC for birds and mammals. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of dimethoate, can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

## IV. Interim Risk Management, Reregistration, and Tolerance Reassessment Decision

### A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical or manufacturing-use grade) data required to support reregistration of products containing dimethoate as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the dietary, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient dimethoate. Based on these data, the Agency has sufficient information on the human health and ecological effects of dimethoate to make its interim decisions as part of the tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA, pending completion of the cumulative assessment of the organophosphate class of pesticides, of which dimethoate is a member. Additional mitigation may be necessary after this cumulative assessment is completed. The Agency has determined that products containing dimethoate will be eligible for reregistration provided that (i) required product-specific data are submitted; (ii) the risk mitigation measures outlined in this document are adopted; (iii) label amendments are made to reflect these measures; and (iv) any additional measures needed to reduce cumulative risks are adopted. Needed label changes and language are listed in Section V. Appendix A is a detailed table listing all dimethoate uses that are eligible for reregistration, or uses which require tolerances or tolerance consideration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the interim reregistration eligibility of dimethoate, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data, or additional data necessary to confirm the decision presented here.

Based on its evaluation of dimethoate, the Agency has determined that dimethoate products, unless labeled and used as specified in Sections IV and V this document, would present risks inconsistent with FIFRA and FFDCA. 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 the use of dimethoate. If all changes outlined in this document are incorporated into the product labels, then all current risks for dimethoate will be adequately mitigated for the purposes of this interim determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary, as explained in Section IV.D.3 of this document.

## B. Public Comments and Responses

Through the Agency=s public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for dimethoate. During the most recent public comment period on the risk assessments, which closed on November 7, 2005, the Agency received comments from five sources: Cheminova, the Natural Resource Defense Council, The Rachel Carson Council, and two private citizens. The comments included some urging the Agency to be more stringent in its regulation of dimethoate, as well as some requesting that the Agency retain certain uses. These comments, in their entirety, are available in the public docket (docket # OPP-2005-0084) at http://www.regulations.gov. EPA has prepared responses to these comments and they are posted in the docket, along with this IRED.

In addition, EPA worked with USDA to solicit input from the grower community on the importance of dimethoate use for those crops with < 1% of cropped area treated with dimethoate. EPA received many comments from growers through this process. EPA has considered these comments, and will be responding to them through a formal response to comments memo, which will be placed in the public docket, along with this document.

The IRED and technical supporting documents for dimethoate are also available to the public through EPA=s electronic public docket and comment system, the Federal Docket Management System (FDMS), under [legacy] docket identification (ID) number EPA-HQ-OPP-2005-0084. In addition, the dimethoate IRED may be downloaded or viewed through the Agency=s website at http://www.epa.gov/pesticides/reregistration/status.htm.

## C. Regulatory Position

### 1. Food Quality Protection Act Findings

#### a. ARisk Cup@ Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment is 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 has completed a revised cumulative risk assessment for OPs (USEPA, 2002), which can be found on the Agency's website http://www.epa.gov/pesticides/cumulative/rra-op/. The Agency intends to issue the final tolerance reassessment reregistration decisions for dimethoate and the OPs in August 2006. The Agency may need to pursue further risk mitigation for dimethoate to address any risks identified in the cumulative assessment for the OPs.

EPA has determined that risk from food (dietary sources only) exposure to dimethoate is within its own "risk cup." An aggregate assessment was conducted, and considered exposures through food and drinking water. No residential uses or non-occupational exposure scenarios exist. This assessment showed that risks from food alone are below the EPA's level of concern, but that risks from food and drinking water together are above the Agency's level of concern on an acute basis for all population subgroups when surface water modeling for some of the vegetables is considered. Exceedances of the level of concern result from estimated residues of dimethoate and omethoate in drinking water, which were estimated using a conservative assumption that 100% percent of dimethoate converts to omethoate during drinking water treatment via chlorination. Please refer to the dietary risk characterization section of this document for more information on the conservative assumptions made in the drinking water assessment.

The Agency is requiring mitigation that is expected to reduce the amount of dimethoate that reaches surface water bodies, including reducing application rates and the maximum numbers of applications per year, as well as increasing the number of days between applications. For citrus, aerial application will be prohibited. All applications to citrus will also be prohibited in Florida, since this use contributed to drinking water concerns in previous assessments. In addition, the registrant will be required to conduct studies evaluating the conversion of dimethoate to omethoate during drinking water chlorination under a variety of conditions. Given these requirements, the Agency has determined that the human health risks from these combined exposures will be within acceptable levels. In other words, EPA has made an interim decision (pending cumulative) that tolerances for dimethoate meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water.

### b. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and

Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

### c. Cumulative Risks

Dietary risks summarized in this document are those that result only from the use of dimethoate. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Dimethoate and omethoate (not registered in the U.S.) are members of the organophosphate (OP) class of pesticides. The Agency has completed a revised cumulative risk assessment for OPs, (*USEPA, 2002*) which can be found on the Agency's web site http://www.epa.gov/pesticides/cumulative/rra-op/. It assesses the cumulative effects of exposure to multiple OPs, including dimethoate. The Agency intends to issue final tolerance reassessment reregistration decisions for dimethoate and the OPs in August 2006 and may need to pursue further risk mitigation for dimethoate to address any risks identified in the cumulative assessment for the OPs.

## 2. Interim Tolerance Summary

Tolerances for residues of dimethoate in/on plant commodities [40 CFR §180.241] are presently expressed in terms of the combined residues of dimethoate and its principal metabolite, omethoate. Following evaluation of plant metabolism studies, the Agency has determined that the appropriate dimethoate residues are those which are currently regulated.

Additional residue data are needed to confirm the appropriateness of existing tolerance levels. At such time as the additional field trial data are received and deemed adequate, these certain tolerances may be revised; however, based on existing data, dietary risks are below EPA's level of concern and EPA considers the tolerances to be reassessed at their current levels.

The Codex Alimentarius Commission has established separate maximum residue limits (MRLs) for dimethoate *per se* and omethoate *per se* in/on various commodities (see *Guide to Codex Maximum Limits for Pesticide Residues, Part 2, FAO CX/PR, 4/93*) resulting from application of the insecticides dimethoate, formothion, and omethoate.

Formothion and omethoate are presently not registered for use in the U.S. The Codex and U.S. tolerances are not harmonized with respect to MRL/tolerance expression since the U.S. tolerance expression is in terms of the combined residues of dimethoate and omethoate, as a metabolite.

An interim summary of dimethoate tolerance reassessment and recommended modifications in commodity definitions is presented in Table 19, below.

Table 19. Interim Tolerance Summary for Dimethoate

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| **Tolerances Listed Under 40 CFR §180.204(a):** | | | |
| Alfalfa | 2 | 2 | Separate tolerances should be established for *Alfalfa, forage* and *Alfalfa, hay*, each at 2 ppm |
| Apples | 2 | Revoke | Use cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |
| Pears | 2 | 2 | Change to *Pear*. |
| Beans, dry | 2 | 2 | [*Bean, dried and Bean, succulent*] |
| Beans, lima | 2 | 2 | |
| Beans, snap | 2 | 2 | |
| Blueberries | 1 | 1 | Change to *Blueberry*. |
| Broccoli | 2 | 2 | |
| Cabbage | 2 | Revoke | Use cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |
| Cauliflower | 2 | 2 | |
| Collards | 2 | Revoke | Use cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |
| Kale | 2 | 2 | |
| Mustard greens | 2 | 2 | |
| Cattle, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. *Change cattle, mbyp* to *Cattle, meat byproducts* |
| Cattle, mbyp | 0.02(N) | 0.02 | |
| Cattle, meat | 0.02(N) | 0.02 | |
| Celery | 2 | 2 | |
| Endive (escarole) | 2 | 2 | Change to *Endive*. |
| Lettuce | 2 | Revoke | Change to *Leaf lettuce*. Use on head lettuce cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Spinach | 2 | Revoke | Use cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |
| Swiss chard | 2 | 2 | |
| Corn, fodder | 1 | 1 | Separate tolerances should be established for *Corn, field, stover (fodder)* and *Corn, pop, stover (fodder)*, each at 1 ppm. Change to Corn, field, stover and Corn, pop, stover |
| Corn, forage | 1 | 1 | *[Corn, field, forage] and Corn, sweet, forage* |
| Corn, grain | 0.1(N) | 0.1 | Separate tolerances should be established for *Corn, field, grain* and *Corn, pop, grain*, each at 0.1 ppm. Negligible residue designation is inappropriate. |
| Cottonseed | 0.1 | 0.1 | *[Cotton, undelinted seed]* |
| Eggs | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. |
| Goats, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. Change to *Goat, fat Goat, meat byproducts, Goat, meat* |
| Goats, mbyp | 0.02(N) | 0.02 | |
| Goats, meat | 0.02(N) | 0.02 | |
| Grapefruit | 2 | 2 | |
| Lemons | 2 | 2 | Change to *Lemon.* |
| Oranges | 2 | 2 | Change to *Orange.* |
| Tangerines | 2 | 2 | Change to *Tangerine.* |
| Grapes | 1 | Revoke | Use cancelled 7/20/05. Existing stocks may be sold until 7/20/06, and use may continue until stocks are depleted. |
| Hogs, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. Change to *Hog, fat; Hog, meat byproducts; Hog, meat* |
| Hogs, mbyp | 0.02(N) | 0.02 | |
| Hogs, meat | 0.02(N) | 0.02 | |
| Horses, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. Change to *Horse, fat; Horse, meat byproducts; Horse, meat.* |
| Horses, mbyp | 0.02(N) | 0.02 | |
| Horses, meat | 0.02(N) | 0.02 | |
| Lentils | 2.0 | Revoke | The established tolerance for peas applies to lentils. |
| Melons | 1 | 1 | Change to *Melon.* |

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Milk | 0.002(N) | TBD | Once outstanding metabolism data are submitted, the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required. Negligible residue designation is inappropriate. |
| Peas | 2 | 2 | [*Peas, dried and succulent*] Change to Pea, dried and Pea, succulent. |
| Pecans | 0.1 | 0.1 | Change to Pecan. |
| Peppers | 2 | 2 | Change to Pepper. |
| Tomatoes | 2 | 2 | Change to Tomato. |
| Potatoes | 0.2 | 0.2 | Change to Potato. |
| Poultry, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate. Poultry, mbyp should be Poultry, meat byproducts. |
| Poultry, mbyp | 0.02(N) | 0.02 | |
| Poultry, meat | 0.02(N) | 0.02 | |
| Safflower seed | 0.1 | 0.1 | *[Safflower, seed]* |
| Sheep, fat | 0.02(N) | 0.02 | Negligible residue designation is inappropriate.inappropriate. Sheep, mbyp should be Sheep, meat byproducts. |
| Sheep, mbyp | 0.02(N) | 0.02 | |
| Sheep, meat | 0.02(N) | 0.02 | |
| Sorghum, forage | 0.2 | 0.1 | Based on available field trial data, HED recommends a lower tolerance. |
| Sorghum, grain | 0.1 | 0.1 | Change to Sorghum, grain, grain. |
| Soybeans | 0.05(N) | 0.05 | Negligible residue designation is inappropriate. Change to Soybean, seed. |
| Soybeans, forage | 2 | 2 | Change to Soybean, forage. |
| Soybeans, hay | 2 | 2 | Change to Soybean, hay. |
| Turnips, roots | 2 | 0.2 | Based on available field trial data, HED recommends a lower tolerance for dimethoate residues of concern in/on turnip roots. Should be Turnip, roots. |
| Turnips, tops | 2 | 2 | Should be Turnip, tops. |
| Wheat, grain | 0.04(N) | 0.04 | Negligible residue designation is inappropriate. |
| Wheat, green fodder | 2 | 2 | *[Wheat, forage]* |
| Wheat, straw | 2 | 2 | |
| **Tolerances That Need To Be Proposed/Established Under 40 CFR §180.204(a):** | | | |
| Cowpeas, forage | None | TBD | Tolerances for these commodities will be required if the registrant wishes to support use of dimethoate on cowpeas grown for livestock feeding. |

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ *[Correct Commodity Definition]* |
|---|---|---|---|
| Cowpeas, hay | None | TBD | |
| Cotton, gin byproducts | None | TBD | Residue data are required. |
| Peas, field, vines | None | TBD | Tolerances for these commodities will be required if the registrant wishes to support use of dimethoate on field peas. Change to Pea, field, vines and Pea, field, hay |
| Peas, field, hay | None | TBD | |
| Sorghum, stover (fodder) | None | 0.1 | Change to Sorghum, grain, stover. |
| Wheat hay | None | 2 ppm | CBRS does not expect residues in/on wheat hay to be higher than the tolerance level established for wheat straw. Therefore, a level of 2 ppm may be proposed for wheat hay. |
| **Tolerances Listed Under 40 CFR §180.204(b)** | | | |
| Asparagus | 0.15 | 0.15 | |
| Brussels sprouts | 5 | 5 | CBRS recommends that this tolerance be listed under 40 CFR §180.204(a). |
| Cherries | 2 | 2 | Change to Cherry. |
| **Tolerances Listed Under 40 CFR §186.2100** | | | |
| Dried citrus pulp | 5 | Revoke | Revoked concomitant with the establishment of tolerance for *[Citrus, pulp, dried]* - to be listed under 40 CFR §180.204(a). |

## D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of dimethoate. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. In general, the application rates and maximum numbers of applications have been reduced, and retreatment intervals have been increased, to reduce dietary, worker, and ecological risks. These actions will result in reduced exposure to dimethoate. Table 20 lists all the use sites for which application rates and label requirements have been revised.

In order to reduce drinking water risks of concern, application rates and the number of applications are being lowered for a number of crops. Aerial applications are prohibited for citrus and use is not allowed on citrus grown in Florida which contributed to drinking water concerns in previous risk assessments. In addition, best management practices (BMPs) will be added to labels, with the purpose of reducing the amount of dimethoate that enters surface water bodies through spray drift. These BMPs include requiring medium or coarser sprays for aerial applications and prohibiting aerial sprays in winds greater than 10 miles per hour. To further reduce the amount of dimethoate entering surface water bodies as runoff, the Agency recommends use of Vegetative Filter Strips, if practical.

In order to reduce occupational risks of concern, in addition to reduced application rates and a reduction in numbers of applications permitted, handlers will be required to use additional protective equipment, such as additional PPE or engineering controls, depending on the handler scenario. All human flaggers supporting aerial applications will be required to be in closed cabs. Also, high pressure handwand applications will be prohibited for applications to woody ornamentals. Use on cottonwoods grown for pulp will be cancelled. See Table 20 below for detailed mitigation which is required in order for dimethoate to be eligible for reregistration. EPA expects that these mitigation measures will result in MOEs of 100 or greater for most handler scenarios.

Postapplication risks will be reduced by extending REIs for some crops, in particular, orchard fruits and woody ornamentals. The occupational risk assessment for dimethoate indicates that REIs of 12 hours are adequate to reach MOEs of 100 for a number of scenarios. However, when the acute toxicity of omethoate is taken into consideration, the Agency believes a 48 hour REI is more appropriate. Therefore, no crop scenario has an REI shorter than 48 hours. This is consistent with current labels. Regarding cole crops (broccoli, cauliflower, Brussels sprouts, and celery), the human health risk assessment indicates that a five day REI is needed to reach an MOE of 100 for applications in arid areas. Growers of these crops indicated an REI of greater than 3 days is not feasible for them; EPA assessed the impacts of this longer REI, and concurred. Therefore, EPA is allowing an REI of 3 days for applications made to cole crops in arid areas which results in an MOE of 89.

Risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment for dimethoate are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Rather, this assessment serves as a screen to determine the need for any species specific assessments that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency’s specific assessments result in the need to modify use of the pesticide in specific geogrpahic areas, those changes to the pesticide’s registration will take through the process described in the Agency’s Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

The primary ecological risks of concern are to birds and mammals on a chronic basis. The Agency is attempting to reduce those risks by reducing application rates and numbers of applications, and increasing application intervals.

**Table 20. Revised Use Site Parameters and Requirements for Dimethoate**

| Crop | App method | Max rate per app (lbs a.i./A) | # apps/ interval | REI (days) | | Other |
|---|---|---|---|---|---|---|
| | | | | Non-arid | Arid | |
| Cherries | Aerial | 1 (SLN) | 1 | 10 | 14 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Airblast:** M/L must wear gloves and apron, Applicators must wear gloves and a respirator. |
| | Aerial, chemigation, and airblast | 0.33 | | 2 | 4 | |
| Asparagus | Aerial, chemigation, groundboom | 0.5 | 2/14 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Citrus | Chemigation, and airblast | 1 | 1 | 10 | 14 | Prohibit aerial applications. Prohibit all applications in Florida. **Chemigation:** M/L must wear gloves, apron, and respirator. **Airblast:** M/L must wear gloves and apron, Applicators must wear gloves and a respirator. |
| Pears | Aerial, chemigation, airblast (liquid and WP) | 1 | 1 | 10 | 14 | *For WPs:* water-soluble packaging plus gloves and apron for M/L *For liquids:* **Aerial/Chemigation***:* gloves, apron, respirator for M/L; **Airblast:** M/L must wear gloves and apron, *For both:* Pilots in enclosed cockpits, gloves and respirator for airblast applicators |
| Alfalfa (seed and hay) | Aerial, chemigation, groundboom | 0.5 | 1 (per cutting) | 2 | 2 | **Aerial** and Chemigation**:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators |
| Succulent peas | Aerial, chemigation, groundboom | 0.16 | 1 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Beans – fresh, snap, lima, dry | Aerial, chemigation, groundboom | 0.5 | 2/14 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Broccoli | Aerial, chemigation, | 0.5 | 3/7 | 2 | 3 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed |

| Crop | App method | Max rate per app (lbs a.i./A) | # apps/ interval | REI (days) | | Other |
|---|---|---|---|---|---|---|
| | | | | Non-arid | Arid | |
| | groundboom | | | | | cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators<br>**Also:** BMPs, vegetative filter strips |
| Cauliflower | Aerial, chemigation, groundboom | 0.5 | 3/7 | 2 | 3 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for appl.<br>**Also:** BMPs, vegetative filter strips |
| Celery | Aerial, chemigation, groundboom | 0.5 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators<br>**Also:** BMPs, vegetative filter strips |
| Cotton | Aerial | 0.5 | 2/14 | 2 | 2 | **Aerial/ Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Lentils | Aerial, chemigation, groundboom | 0.5 | 2/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators<br>**Also:** BMPs for aerial |
| Melon | Aerial, chemigation, groundboom | 0.5 | 2/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators<br>**Also:** BMPs |
| Potatoes | Aerial, chemigation, groundboom (liquid and WP) | 0.5 | 2/7 | 2 | 2 | *For WPs:* water-soluble packaging plus gloves and apron for M/L; Pilots in enclosed cockpits; gloves for groundboom apps<br>*For liquids:*<br>**Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits.<br>**Groundboom:** M/L must wear gloves and apron, gloves for applicators<br>**Also:** BMPs |

| Crop | App method | Max rate per app (lbs a.i./A) | # apps/ interval | REI (days) | | Other |
|---|---|---|---|---|---|---|
| | | | | Non-arid | Arid | |
| Soybeans | Aerial, chemigation, groundboom | 0.5 | 2/7 | 2 | 2 | **Aerial/Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Tomatoes | Aerial, chemigation, groundboom | 0.5 | 2/6 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators. |
| Field corn; popcorn | Aerial, chemigation, groundboom | 0.5 | 1 | 2 | 2 | **Aerial/Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators |
| Safflower | Aerial, chemigation, groundboom | 0.5 | 1 | 2 | 2 | **Aerial/Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators. |
| Sorghum | Aerial, chemigation, groundboom | 0.5 | 2/7 | 2 | 2 | **Aerial/Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators. |
| Wheat | Aerial, chemigation, groundboom | 0.5 | 1 | 2 | 2 | **Aerial/Chemigation:** closed systems plus gloves and apron for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators. |
| Pecans | Aerial, chemigation, airblast | 0.33 | 1 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, and respirator for M/L; Pilots in enclosed cockpits. **Airblast:** gloves and apron for M/L; gloves and respirator for apps. |
| Peppers | Aerial, chemigation, groundboom | 0.33 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, gloves for applicators. |
| Grass for seed | Aerial, chemigation, | 0.5 | 2/90 | 2 | 2 | **Aerial/Chemigation:** M/L must wear gloves, apron, and respirators. |

| Crop | App method | Max rate per app (lbs a.i./A) | # apps/ interval | REI (days) | | Other |
|---|---|---|---|---|---|---|
| | | | | Non-arid | Arid | |
| | groundboom | | | | | Pilots in enclosed cockpits. **Groundboom:** gloves and apron for M/L; gloves for applicators. |
| Leaf lettuce | Aerial, chemigation, groundboom | 0.25 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators |
| Swiss chard | Aerial, chemigation, groundboom | 0.25 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. |
| Endive (escarole) | Aerial, chemigation, groundboom | 0.25 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. |
| Kale | Aerial, chemigation, groundboom | 0.25 | 2/15 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. |
| Turnips | Aerial, chemigation, groundboom | 0.25 | 3/7 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. |
| Mustard greens | Aerial, chemigation, groundboom | 0.25 | 2/9 | 2 | 2 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. |
| Brussels sprouts | Aerial, chemigation, groundboom | 0.5 | 3/7 | 2 | 3 | **Aerial/Chemigation:** gloves, apron, respirator for M/L; Pilots in enclosed cockpits. **Groundboom:** : M/L must wear gloves and apron, gloves for applicators. **Also:** BMPs, vegetative filter strips |
| Herbaceous ornamentals | Groundboom, low pressure handwand | 0.25 | 1 | 2 | 2 | **Groundboom and Low Pressure handwand:** M/L must wear gloves and apron, Gloves for applicators. **High Pressure Handwand:** M/L |

| Crop | App method | Max rate per app (lbs a.i./A) | # apps/ interval | REI (days) | | Other |
|---|---|---|---|---|---|---|
| | | | | Non-arid | Arid | |
| | | | | | | must wear gloves and apron, Gloves and respirator for applicators. |
| Douglas fir seed orchards in WA and OR | Airblast- | 4.15 | 1 | 16 | 25 | **Airblast:** M/L must wear gloves and apron, Applicators must wear gloves and a respirator. |
| Conifer seed orchards | Aerial, Groundboom | 1 | 1 | 2 | 4 | **Aerial:** M/L must wear gloves, apron, and respirator. Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, Gloves for applicators. |
| Woody ornamentals and Christmas tree nurseries | Aerial, Groundboom | 1 | 3/14 | 10 | 14 | **Aerial:** M/L must wear gloves, apron, and respirator. Pilots in enclosed cockpits. **Groundboom:** M/L must wear gloves and apron, Gloves for applicators. |
| Cottonwood grown for pulp | Canceling use | | | | | |

* Enclosed cockpits are required for all aerial applications.

### 1. Significance of Use

Dimethoate is a systemic insecticide which is widely used to control pests on vegetable and row crops. It has a relatively short pre-harvest interval (PHI) and some residual efficacy which often makes it a compound of choice for fresh market vegetable production.

During the three public comment periods on the dimethoate risk assessments, the Agency received many grower comments in support of retaining dimethoate use for various crops.

EPA divided uses into two groups based on percent crop treated. If a low percentage of a crop is treated, the Agency makes the preliminary assumption that the significance of use on that crop is also low. For these crops, the Agency consulted with the USDA Office of Pest Management Policy (OPMP) to determine whether there were niche uses which should be considered in any mitigation plan. The twelve use sites in this category are: alfalfa, cherries, citrus, cotton, corn (field and pop), grass grown for seed, pears, pecans, peppers, safflower, and succulent peas. OPMP received comments from their Regional offices on dimethoate use. While growers in some regions do not apply any dimethoate on these crops, all twelve sites had some limited usage, primarily for control of flare-ups of spider mites, thrips, aphids, or fleahoppers. There was also some occasional use for grasshopper control which is not necessary every year, but for

which dimethoate was cited as a very important tool. The alternatives to these uses were generally other organophosphates, carbamates or pyrethroids. Several regional experts stated that many of the alternatives are restricted-use products, and so dimethoate products are more attractive because dimethoate is an efficacious general use compound.

For the use sites with greater than 5% crop treated with dimethoate, the Agency assumed that the higher use frequency implied significance of use. For these sites, the Agency examined dimethoate use patterns and available alternatives and generally evaluated the feasibility of extending restricted entry intervals (but not the impacts of cancellation). Please refer to the Biological and Economic Analysis Divisions memorandum entitled *"Dimethoate application information for specific crops (DP # 291616)"* and dated March 8, 2006. Through this assessment, the Agency concluded that the required worker mitigation will effectively reduce risk without major impacts on the importance of dimethoate to users.

### 2. Spray Drift

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial, as well as other application types, where appropriate.

From its assessment of dimethoate as summarized in this document, the Agency concluded that the major source of dimethoate entering surface water bodies is through runoff. Therefore, the Agency will require that use of vegetative buffers be encouraged on product labels. The Agency is requiring mitigation that will also reduce the amount entering through spray drift. Namely, aerial applications are being cancelled for a few crops and labels will be revised to include best management practices including lowered boom height and largest effective droplet size.

### 3. Endangered Species Considerations

From the screening level assessment, RQs exceed the endangered species LOC for some of the representative exposure scenarios considered. At the rates assessed, acute and chronic RQs exceed the LOC for endangered birds and mammal across all use sites. After a single application of 0.16 lbs a.i./A, the endangered species acute and chronic risk LOCs are exceeded for birds and mammals for some use sites. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of dimethoate, can not be precluded based on the screening level ecological risk assessment.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs/IREDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this IRED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of dimethoate, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of dimethoate "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this IRED will reduce the likelihood that endangered and threatened species may be exposed to dimethoate at levels of concern. EPA is not requiring specific dimethoate label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

## V. What Registrants Need to Do

The Agency has determined that dimethoate will be eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted and (ii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. <u>For dimethoate technical grade active ingredient products</u>, the registrant needs 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. citation of any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Stephanie Plummer at (703) 305-0076 with questions regarding generic reregistration.

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

By express or courier service:
Document Processing Desk (DCI/SRRD)
Stephanie Plummer
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

B. For end-use products containing the active ingredient dimethoate, the registrant needs 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. submit any time extension or waiver requests with a full written justification.

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

1. two copies of the confidential statement of formula (EPA Form 8570-4);
2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. five copies of the draft label incorporating all label amendments outlined in Table 31 of this document;
4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
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 Venus Eagle at (703) 308-8045 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Venus Eagle
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Venus Eagle
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

## A. Manufacturing Use Products

### 1. Additional Generic Data Requirements

The generic database supporting the interim of dimethoate for the uses specified in this document has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the Interim Reregistration Eligibility Decision outlined in this document.

Studies required for dimethoate

| | |
|---|---|
| 850.1350 | Mysid life cycle |
| 850.1400 | Estuarine/marine fish early life-stage |
| 850.4225 | Seedling emergence (Tier II) |
| 850.4250 | Vegetative vigor (Tier II) |
| 850.4400 | Aquatic Plant (Tier II) |
| 860.1380 | Storage stability data for meat, milk, poultry, and eggs |
| 860.1500 | Magnitude of residue on alfalfa grown for seed |
| 860.1500 | Magnitude of residue data for cotton gin byproducts |
| 163-1 | Batch equilibrium study |
| Non-guideline study | Forestry field dissipation study (in support of poplar, spruce seed orchard, and larch uses) |
| Non-guideline study | Water treatment assay to determine percent conversion with chlorination in a variety of water chemistries |

The reregistration requirements for the magnitude of residue in plants have been fulfilled for pea vines and pea hay. The registrant must either petition the Agency for the establishment of tolerances for the total residues of dimethoate and omethoate in/on pea vines and pea hay or amend product labels to restrict the use of dimethoate to peas (not including field peas).

Studies required for metabolites

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| 850.2100 | Acute oral (bobwhite quail and mallard duck) – omethoate |
| 850.2200 | Subacute dietary (bobwhite quail and mallard duck) - omethoate |
| 850.2300 | Reproduction (bobwhite quail and mallard duck) – omethoate |

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| 860.1500 | Magnitude of residue data for metabolites of concern (O-desmethyl omethoate, O-desmethyl omethoate carboxylic acid, and O-desmethyl isodimethoate) |
| Non-guideline study | Comparative cholinesterase study on rats for metabolites of concern (O-desmethyl omethoate, O-desmethyl omethoate carboxylic acid, and O-desmethyl isodimethoate) |

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g) (2) (B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response Form provided for each product. The Agency intends to issue a separate product-specific Data Call-In outlining specific data requirements

### 2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 22.

Existing stocks time frames will be established on a case-by-case basis, depending on the number of products involved, the number of label changes, and other factors. Please refer to "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

**Labeling Changes Summary Table**

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

Table 22. Label Changes Summary Table for Dimethoate

| Description | Amended Labeling Language | Placement on Label |
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| For all Manufacturing Use Products | "Only for formulation into an insecticide for the following use(s) [alfalfa, alfalfa for seed, asparagus, beans (excluding cowpeas), broccoli, Brussels sprouts, cauliflower, celery, cherries, Chinese cabbage, Christmas tree farms, conifer seed farms, cotton, endive, field corn, grass grown for seed, herbaceous ornamentals in commercial nurseries or greenhouses, grapefruit, leaf lettuce, lemons, lentils, kale melons, mustard greens, oranges, pears, peas, pecans, peppers, popcorn, potatoes, safflower, sorghum, soybeans, Swiss chard, tangerines, tangelos, tomatoes, turnips, watermelons, wheat, and woody ornamentals in commercial nurseries or greenhouses ]."<br><br>"Not for formulation into wettable powder end use products (EUP), unless the EUP is packaged in water soluble bags."<br><br>Not for formulation into end-use products intended for use by homeowners or that permit use at residential sites. | 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 | "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 Manufacturing Use Product (MUP) label if the | Directions for Use |

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| formulator or user group | formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." | |
| Environmental Hazards Statements Required by the RED and Agency Label Policies | "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution 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 |
| End Use Products Intended for Occupational Use | | |
| PPE Requirements Established by the RED[1]<br>For Wettable Powder Formulations (wettable powder products must be packaged in water soluble bags to be eligible for reregistration) | "Personal Protective Equipment (PPE)"<br>"Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart."<br><br>"Mixers, loaders, applicators, and other handlers must wear:<br>>Long-sleeved shirt and long pants,<br>> Shoes plus socks,<br>> Chemical-resistant apron for mixers and loaders,<br>> Chemical-resistant gloves.<br><br>In addition, applicators using airblast or high pressure handwand equipment, must wear:<br>> NIOSH-approved respirator with<br>-- an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or<br>-- a canister approved for pesticides (MSHA/NIOSH approval number | Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals |

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| | prefix TC-14G), or<br>-- an organic-vapor-removing cartridge or canister with any N, R, P or HE prefilter."<br><br>"See Engineering Controls for additional requirements."<br><br>***Instruction to Registrant:*** Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil. | |
| PPE Requirements Established by the RED[1]<br>For Liquid Formulations | "Personal Protective Equipment (PPE)"<br>"Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart."<br><br>"Mixers, loaders, applicators, and other handlers; must wear:<br>Long-sleeved shirt and long pants, and<br>> Shoes plus socks,<br>> Chemical-resistant apron for mixers and loaders,<br>> In addition, all mixers and loaders, plus applicators using airblast or high pressure handwand equipment must wear chemical-resistant gloves.<br>> In addition, mixers and loaders supporting aerial and chemigation applications, and applicators using airblast or high pressure handwand equipment must wear:<br><br>> NIOSH-approved respirator with<br>-- an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or<br>-- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or<br>-- an organic-vapor-removing cartridge or canister with any N, R, P or HE prefilter." | Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals |

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| | "See Engineering Controls for additional requirements."<br><br>***Instruction to Registrant:*** Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil. | |
| 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 and 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 |
| Engineering Controls: (Water-Soluble Packaging for Wettable Powder Formulations) | "Engineering controls"<br><br>"Water-soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :<br>-- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and<br>-- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear, and the type of respirator specified in the PPE section of this label."<br><br>"Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]." | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |

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| | Flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, flaggers must:<br>-- wear long-sleeve shirt, long pants, shoes, socks and,<br>-- *either* wear the type of respirator specified in the PPE section of this labeling or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified in this labeling,<br>-- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,<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>"When applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5), the handler PPE requirements may be reduced or modified as specified in the WPS." | |
| Engineering Controls: For Liquid Formulations | "Engineering controls"<br><br>'Mixers and loaders supporting aerial or chemigation applications to alfalfa, cotton, soybeans, corn, safflower, sorghum, and wheat, must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)]. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application | Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.) |

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| | 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 the personal protective equipment required on this labeling for mixers/loaders, except that no respirator is required;<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, chemical-resistant footwear and a respirator of the type specified in the PPE section of this labeling."<br><br>"Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."<br><br>Flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, flaggers must:<br>-- wear long-sleeve shirt, long pants, shoes, socks and,<br>-- *either* wear the type of respirator specified in the PPE section of this labeling or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified in this labeling,<br>-- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,<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 | |

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| | bag, to prevent contamination of the inside of the cab."<br><br>"When handlers use closed systems, or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-5), the handler PPE requirements may be reduced or modified as specified in the WPS." | |
| 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 under: Hazards to Humans and Domestic Animals immediately following Engineering Controls<br><br>(Must be placed in a box.) |
| Environmental Hazards | "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."<br><br>"Dimethoate 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 may contaminate water through drift of spray in wind. This product has a high potential for runoff for several days after application after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product." | Precautionary Statements immediately following the User Safety Recommendations |

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| | "A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."<br><br>"A vegetative filter strip constructed and maintained in accordance with the 2000 Natural Resources Conservation Service publication "Conservation Buffers to Reduce Pesticide Losses"<br>( http://www.nrcs.usda.gov/feature/buffers/) will significantly reduce the potential for contamination of water from rainfall-runoff." | |
| Restricted-Entry Intervals for products with directions for use within the scope of the Worker Protection Standard (WPS) for Agricultural Pesticides (WPS) | "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI)." | In the Agricultural Use Requirements box |
| Early Entry Personal Protective Equipment for products with directions for use within the scope of the Worker Protection Standard (WPS) for Agricultural Pesticides | "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:<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)" | Direction for Use<br>Agricultural Use Requirements box |
| Double Notification Statement | "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area." | Direction for Use<br>Agricultural Use Requirements box |

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| General Application Restrictions | "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." | Place in the Direction for Use directly above the Agricultural Use Box. |
| Application Restriction | "This product is for use in commercial setting only. Use in residential settings is prohibited." | Near the beginning of the Directions for Use |
| Crop-Specific Application Restrictions and REIs<br>The maximum application rate also must be stated in terms of the pounds or gallons of formulation | Labels must be amended to reflect the following equipment restrictions, maximum application rates, retreatment interval, and the maximum number of treatments per year:<br><br>**High Pressure Handwand Equipment**: "When applications are made by high pressure handwand equipment, the maximum application rate for all crops and use-patterns is 0.0025 pounds active ingredient per gallon."<br><br>**Alfalfa (grown for seed and for hay)**<br>Maximum application rate: 0.5 lb ai/acre and no more than one application per crop cycle or cutting. Maximum 3 applications per year. "The REI is 48 hours."<br><br>**Asparagus, Beans (including fresh, snap, lima, and dry beans) and Cotton**<br>Maximum application rate: 0.5 lb ai/acre , 14 day retreatment interval and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Field Corn and Popcorn**<br>Maximum application rate: 0.5 lb ai/acre and no more than one | Directions for Use associated with the use directions for the specific crop to which the restriction pertains |

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| | application per year. "The REI is 48 hours. PROHIBITION: Workers are prohibited from entering the treated area to perform detasseling tasks for 4 days in nonarid areas and for 15 days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Broccoli, Brussels Sprouts, and Cauliflower**<br>Maximum application rate: 0.5 lb ai/acre, 7 day retreatment interval and no more than 3 applications per year. "The REI is 48 hours; however, the REI is increased to 72 hours in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Celery**<br>Maximum application rate: 0.5 lb ai/acre, 7 day retreatment interval, and no more than 3 applications per year. "The REI is 48 hours."<br><br>**Cherries**<br>Maximum application rate: 0.33 lb ai/acre and no more than one application per year. "The REI is 48 hours; however, the REI is increased to 4 days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Note:** There is an SLN for Cherries where the rate is 1 lb. per acre and no more than one application per year. "The REI is 10 days; however, the REI is increased to 14 days in outdoor areas where the average annual rainfall is less than 25 inches per year." This information must be placed on the SLN label<br><br>**Citrus**<br>Maximum application rate: 1 lb ai/acre and no more than one application per year. "Do not apply to citrus in Florida" "Aerial application to citrus is prohibited" "The REI is 10 days; however, the REI is increased to 14 | |

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| | days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Conifer Seed Orchards**<br>Maximum application rate: 1 lb ai/acre and no more than one application per year. "The REI is 48 hours; however, the REI is increased to 4 days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Special Exception for airblast applications to Douglas Fir Seed Orchards in WA and OR only**<br>Maximum application rate: 4.15 lb ai/acre. The limit of one application per year applies. "If airblast applications are applied at a rate greater than 1 lb a.i/ acre, the REI is 16 days; however, the REI is increased to 25 days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Grass Grown for Seed**<br>Maximum application rate: 0.5 lb ai/acre 90 day retreatment interval and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Herbaceous Ornamentals**<br>Maximum application rate: 0.25 lb ai/acre and no more than 1 application per year. "The REI is 48 hours."<br><br>**Kale**<br>Maximum application rate: 0.25 lb ai/acre, 15 day reapplication interval, and no more than 2 applications per year. "The REI is 48 hours." | |

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| | **Leaf lettuce, Swiss Chard, Endive and Escarole**<br>Maximum application rate: 0.25 lb ai/acre, 7 day reapplication interval, and no more than 3 applications per year. "The REI is 48 hours."<br><br>**Lentils, Melon, Honeydew, and Potatoes**<br>Maximum application rate: 0.5 lb ai/acre, 7 day reapplication interval, and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Safflower and Wheat**<br>Maximum application rate: 0.5 lb ai/acre and no more than 1 application per year. "The REI is 48 hours."<br><br>**Sorghum, and Soybeans**<br>Maximum application rate: 0.5 lb ai/acre, 7 day reapplication interval, and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Mustard Greens**<br>Maximum application rate: 0.25 lb ai/acre, 9 day reapplication interval, and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Pears**<br>Maximum application rate: 1 lb ai/acre and no more than one application per year. "The REI 10 days; however, the REI is increased to 14 days in outdoor areas where the average annual rainfall is less than 25 inches per year."<br><br>**Pecans**<br>Maximum application rate 0.33 lb ai/acre and no more than one application per year. "The REI is 48 hours." | |

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| | **Peppers**<br>Maximum application rate 0.33 lb ai/acre, 7 day reapplication interval, and no more than three applications per year. "The REI is 48 hours."<br><br>**Succulent peas**<br>Maximum application rate 0.16 lb ai/acre and no more than one application per year. "The REI is 48 hours."<br><br>**Note:** There are SLN registrations for succulent peas for which the total seasonal rate is not to exceed 0.5 lbs. a.i./acre.<br><br>**Tomatoes**<br>Maximum application rate 0.5 lb ai/acre, 6 day reapplication interval, and no more than 2 applications per year. "The REI is 48 hours."<br><br>**Turnips**<br>Maximum application rate 0.25 lb ai/acre, 3 day reapplication interval, and no more than 7 applications per year. "The REI is 48 hours."<br>**Woody Ornamentals and Christmas Tree Nurseries**<br>Maximum application rate 1.0 lb ai/acre, 14 day reapplication interval, and no more than 3 applications per year. "Do not apply by high pressure handwand to conifer and other ornamental tree crops" "The REI 10 is days; however, the REI is increased to 14 days in outdoor areas where the average annual rainfall is less than 25 inches per year." | |
| Spray Drift | **"Requirements for Reducing Spray Drift**<br><br>Do not apply under circumstances where possible drift to unprotected persons or to food, forage, or other plantings that might be damaged or crops thereof rendered unfit for sale, use, or consumption can occur. | Directions for Use |

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| | 1. Use the largest droplet size consistent with acceptable efficacy. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure. For groundboom and aerial applications, use medium or coarser spray nozzles according to ASAE 572 definition for standard nozzles or a volume mean diameter (VMD) of 300 microns or greater for spinning atomizer nozzles.<br>2. Make aerial or ground applications when the wind velocity favors on-target product deposition. Apply only when the wind speed is less than or equal to 10 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.<br>3. Do not make aerial or ground applications into areas of temperature inversions. Inversions are characterized by stable air and increasing temperatures with increasing distance above the ground. Mist or fog may indicate the presence of an inversion in humid areas. Where permissible by local regulations, the applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.<br>4. Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of increased spray drift. Avoid spraying during conditions of low humidity and/or high temperatures.<br>5. All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers.<br>6. For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.<br>7. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy. | |

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| | 8. For ground-boom, chemigation, orchard, or other airblast applications, do not apply within 25 feet of permanent water bodies (rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, or commercial fish ponds).<br>9. For aerial application to potatoes, do not apply within 150 feet of permanent water bodies (aquatic buffer zone).<br>10. For aerial application to crops other than potatoes, do not apply within 50 feet of permanent water bodies (aquatic buffer zone).<br>11. For aerial applications, release spray at the lowest height consistent with efficacy and flight safety. If the application includes an aquatic buffer zone, do not release spray at a height greater than 10 feet above the ground or crop canopy.<br>12. For aerial applications, the spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used and must not exceed 75% of the wingspan of 90% of rotor blade diameter. Use upwind swath displacement. | |

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