



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.<sup>1</sup> 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

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<sup>1</sup> 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](http://www.epa.gov/pesticides/cumulative) and in the docket (EPA-HQ-OPP-2006-0618).

**Attachment A:**  
Organophosphates included in the OP Cumulative Assessment

<b>Chemical</b>	<b>Decision Document</b>	<b>Status</b>
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 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



United States  
Environmental Protection  
Agency

Prevention, Pesticides  
and Toxic Substances  
(7508C)

EPA 738-R-01-013  
September 2001

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# Reregistration Eligibility Decision for Acephate



# Acephate Facts

EPA has assessed the risks of acephate and reached an Interim Reregistration Eligibility Decision (IREED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted, acephate fits into its own “risk cup”-- its individual, aggregate risks are within acceptable levels. Acephate also is eligible for reregistration, pending a full reassessment of the cumulative risk from all OPs.

Acephate residues in food and drinking water do not pose risk concerns, and by reducing exposure in homes and through residential lawns, acephate fits into its own “risk cup.” EPA made this determination after the registrants agreed to drop indoor residential uses and certain turf uses. With other mitigation measures, acephate’s worker and ecological risks also will be below levels of concern for reregistration.

EPA’s next step under the Food Quality Protection Act (FQPA) is to consider risks from cumulative exposure to all the OP pesticides, which share a common mechanism of toxicity. The interim decision on acephate cannot be considered final until the cumulative risk has been considered. Further risk mitigation may be warranted at that time.

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

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

## **The OP Pilot Public Participation Process**

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

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

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

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

## Uses

- Acephate is an organophosphate insecticide currently registered for use on a variety of field, fruit, and vegetable crops (e.g., cotton, tobacco, cranberries, mint); in food handling establishments; on ornamental plants both in greenhouses and outdoors (e.g., nonbearing fruit trees, Christmas trees, and cut flowers); and in and around the home.
- Annual domestic use is approximately 4 to 5 million pounds of active ingredient per year.

## Health Effects

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

## Risks

- Dietary exposures to acephate from eating food crops treated with acephate are below the level of concern for the entire U.S. population, including infants and children. Drinking water is not a significant source of acephate exposure. However, people in the U.S. may be exposed to amounts of the acephate degradate methamidophos through food and drinking water as a result of acephate use. This exposure will be more fully addressed in the methamidophos IRED.
- EPA found risks are of concern for homeowners and children entering homes and lawn areas treated with acephate (excluding golf courses and spot or mound treatments for ant control).
- For agricultural and turf/Pest Control Operator (PCO) uses of acephate, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern. In addition, there are postapplication risks from the use of acephate in cut flowers.
- Ecological risks are also of concern to the Agency. Acephate and its degradate methamidophos are highly toxic to honey bees and beneficial predatory insects on an acute contact basis. Acute and chronic risks to birds and chronic risk to mammals are also high.

## **Risk Mitigation**

### Dietary Risk

No mitigation is necessary at this time for any dietary exposure to acephate. The acute and chronic dietary risks from acephate do not exceed the Agency's level of concern.

However, the Agency reserves the right to require further acephate mitigation to address risks from methamidophos residues resulting from acephate uses. Any additional mitigation measures will be addressed when the methamidophos interim RED is completed.

### Occupational Risk

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

- Formulate all soluble powder formulations into water soluble bags, except for soluble powders sold for fire ant, harvester ant, or hopper box seed treatment uses.
- Limit the 1 pound active ingredient per acre (lb ai/A) cotton aerial application rate to cotton grown in California and Arizona; reduce the maximum aerial application rate for cotton to 0.75 ai/A for all other areas of the United States.
- Delete aerial application to turf.
- Require enclosed cockpits and mechanical flagging for all aerial applications.
- Reduce maximum sod farm and golf course turf application rates (non-granular formulations) to 3 lb ai/A and 4 lb ai/A, respectively.
- Reduce maximum application rates for greenhouse floral and foliage plant crops, and outdoor floral and ground covers to 1 lb ai per 100 gallons water (not to exceed 0.75 lb ai/A for cut flowers and 1.0 lb ai/A for other ornamentals).
- Delete the application of acephate by low pressure handwand to treat trees, shrubs, and outdoor flora; for the control of wasps; and for perimeter treatment by PCOs.
- Delete the use of granular formulations to be applied by belly grinder, shaker can, or by hand to trees, shrubs, and 12" pots.
- Add personal protective equipment to end use product labels for workers who mix and load, and/or apply acephate.

### Residential Risk

In order to mitigate residential postapplication risk, the following risk mitigation measures are necessary:

- Delete residential indoor uses.
- Delete all turfgrass uses (except golf course, sod farm, and spot or mound treatment for ant control).
- Establish a 3 day pre-harvest interval (PHI) for the harvesting of sod.



## Ecological Risk

The Agency has determined that the following mitigation measures are needed to address ecological risk concerns:

- Establish minimum spray intervals for all agricultural crops of 3 days for application rates up to 0.5 lb ai/A and of 7 days for application rates greater than 0.5 lb ai/A.
- Require labeling to protect honeybees.
- Require labeling to reduce the potential for spray drift.

In addition, the measures to reduce occupational and residential risk will also reduce environmental loading and the potential impact to non-target organisms.

## **Next Steps**

- Numerous opportunities for public comment were offered as this decision was being developed. The acephate IRED therefore is issued in final (see [www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm) or [www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.
- In addition, further mitigation of acephate uses may be necessary to reduce risks from methamidophos residues that result from acephate applications. Once the methamidophos IRED is complete, the Agency will determine whether the methamidophos exposure resulting from acephate use poses risk concerns. Any potential further mitigation will be discussed at the time the methamidophos interim RED is released.
- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for acephate and may request further risk mitigation measures. The Agency will revoke 3 tolerances and lower 4 tolerances for acephate now. Reassessment of 14 tolerances will be made once additional residue data on cotton gin byproducts have been reviewed. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrants:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide acephate. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrants, the Agency revised the human health and environmental effects risk assessments and made them available to the public on February 22, 2000. Additionally, the Agency held a Technical Briefing on February 2, 2000, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee (TRAC), and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on February 22, 2000, and closed on April 24, 2000.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of acephate. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of acephate and associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for acephate will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The enclosed "Interim Reregistration Eligibility Decision for Acephate" was approved on September 28, 2001, and contains the Agency's decision on the individual chemical acephate.

A Notice of Availability for this Interim Reregistration Eligibility Decision (interim RED) is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Internet. See

<http://www.epa.gov/pesticides/op>.

The interim RED is based on the updated technical information found in the acephate public docket. The docket includes background information and comments on the Agency's preliminary risk assessments; the Agency's February 3, 2000, revised risk assessment for acephate; addenda to the occupational and residential risk assessments (September 15, 2000 and February 13, 2001); a revised surface water assessment (March 8, 2000); and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants and responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket also includes comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For acephate, a proposal was submitted by Valent U.S.A. Corporation (Valent), a technical registrant. All other technical registrants have agreed to the mitigation measures proposed. Comments on mitigation or mitigation suggestions were submitted by growers, agricultural extension agents, environmental organizations, university scientists, and various other organizations.

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

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

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a complete DCI, with all

pertinent instructions, is being sent to registrants under a separate cover. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

Notwithstanding the consideration of the cumulative risk from the OPs, the Agency has determined that acephate is eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that certain current uses of acephate pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section V of this interim RED describes labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section VI of this document.

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Kimberly Nesci at (703) 308-8059. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Attachment

**Interim Reregistration Eligibility Decision  
for  
Acephate**

**Case No. 0042**

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## GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC <sub>50</sub>	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 <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal. The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PCO	Pest Control Operator
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/	
EXAMS	Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing

SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for acephate. The decisions outlined in this document do not include the final tolerance reassessment decision for acephate; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. The Agency now recommends expressing the acephate tolerances in terms of acephate *per se* under 40 CFR part 180.108. Residues of methamidophos resulting from the metabolism of acephate are more appropriately placed under the tolerance expression for methamidophos in 40 CFR part 180.315(c). In addition, the Agency recommends lowering the tolerance level for cottonseed, as suggested by the data. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for acephate once the cumulative risks from organophosphates are considered. Additionally, since acephate degrades to another, registered organophosphate pesticide, methamidophos, further risk management measures for acephate may be necessary once the methamidophos assessment itself is completed.

The revised risk assessments are based on EPA's review of the all data available on the currently registered uses of acephate, including new information received during the reregistration process. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on acephate. After considering the risks from this chemical and discussing measures to address them with stakeholders and the registrants, EPA made its risk management decision on acephate. The technical registrants have to agree to the risk management measures.

Acephate is an organophosphate insecticide currently registered for use on a variety of field, fruit, and vegetable crops; in food handling establishments; on ornamental plants both in greenhouses and outdoors (including lawns, turf, and cut flowers); and in and around the home. Acephate was first registered in 1973 for ornamental uses, and in 1974 for food uses (agricultural crops). Use data from 1988 to 1997 indicate that approximately 4 to 5 million pounds of active ingredient (ai) are used domestically each year.

Acephate is registered for the control of cockroaches and fleas, which are public health pests. To ensure the public health issues associated with acephate are adequately considered as called for in FIFRA, the Agency intends to consult further with public health authorities before taking final Agency action to amend registrations of acephate.

## Overall Risk Summary

EPA has concerns about risk to humans resulting from the currently registered uses of acephate. Specifically, the Agency is concerned about risks to workers who mix, load, and/or apply acephate to agricultural sites, golf courses and home lawns, in and around residential, commercial, institutional and industrial buildings, and recreational areas. In addition, the

Agency has concerns for children exposed to acephate residues and methamidophos residues on home lawns resulting from the application of acephate.

Acute and chronic exposure to acephate residues on food does not result in risks of concern. Similarly, acute and chronic exposure to acephate concentrations in drinking water, as estimated using screening models developed by the Agency, are not of concern.

However, since residential postapplication exposures to turf alone yield high risks to children, aggregate risk combining food, drinking water, and all residential postapplication exposure is of concern to the Agency.

Postapplication occupational, residential, and recreational risks consider exposures to acephate and its degradate methamidophos. In some instances, methamidophos residues resulting from acephate applications drive the postapplication risks presented in this document.

Methamidophos is also a registered organophosphate insecticide, and is used in the U.S. on cotton, potatoes, and tomatoes. The Agency is evaluating the human health and ecological risks posed by the organophosphate methamidophos separately. However, acephate uses will contribute to the aggregate methamidophos risk cup when all exposure to methamidophos residues is considered in the methamidophos interim RED. Further mitigation of acephate uses may be necessary to reduce risks from methamidophos residues that result from acephate applications. This potential further mitigation will be discussed at the time the methamidophos interim RED is released. The relationship between these two chemicals is of particular importance in the case of drinking water risks. Based on tier I modeling data, the Agency believes that methamidophos residues in drinking water that result from acephate application alone may result in risks of concern.

In the environmental risk assessment, the EPA identified acute and chronic risks to birds, and risks to mammals and acute risk to honey bees and other beneficial insects. Acute risk to freshwater aquatic invertebrates is also of concern.

EPA has considered comments and mitigation ideas from interested parties when deciding how best to mitigate risks of concern posed by the uses of acephate. The Agency has decided on a number of label amendments to address the worker, residential, and ecological concerns. Results of the risk assessments, and the necessary label amendments to mitigate those risks, are presented in this interim RED.

### Dietary Risk

No mitigation is necessary at this time for any dietary exposure to acephate. The acute and chronic dietary risks from acephate residues on food do not exceed the Agency's level of concern. In addition, although the maximum estimated environmental concentrations of acephate from surface water sources exceed the acute DWLOC by 2 ppb (6%), the Agency considers such a marginal exceedance not of concern.

However, the Agency reserves the right to require further acephate mitigation to address risks from methamidophos residues resulting from acephate uses. Any additional mitigation measures will be addressed when the methamidophos interim RED is completed.

### Occupational Risk

Occupational exposure to acephate is of concern to the Agency, and it has been determined that a number of mitigation measures are necessary at this time. For agricultural and turf/Pest Control Operator (PCO) uses of acephate, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern. In addition, there are postapplication risks from the use of acephate in cut flowers. EPA believes these risks can be reduced to an acceptable level with the following measures:

- Formulate all soluble powder formulations into water soluble bags, except for soluble powders sold for fire ant, harvester ant, or hopper box seed treatment uses.
- Limit the 1 lb ai/A cotton aerial application rate to cotton grown in California and Arizona; reduce the maximum aerial application rate for cotton to 0.75 ai/A for all other areas of the United States.
- Delete aerial application to turf.
- Require enclosed cockpits for all other aerial applications.
- Reduce maximum sod farm application rates (non-granular formulations) to 3 lb ai/A.
- Reduce maximum golf course turf application rates (also non-granular formulations) to 4 lb ai/A.
- Reduce maximum application rates for greenhouse floral and foliage plant crops, and outdoor floral and ground covers to 1 lb ai per 100 gallons water (not to exceed 0.75 lb ai/A for cut flowers and 1.0 lb ai/A for other ornamentals).
- Delete the use of low pressure handwand to trees, shrubs, and outdoor floral, and for the control of wasps.
- Delete the application of acephate via low-pressure handwand for perimeter treatment by PCOs.
- Delete the use of granular formulations to be applied by belly grinder, shaker can, or by hand to tress, shrubs, and 12" pots.
- Add personal protective equipment to end use product labels for workers who mix and load, and/or apply acephate, as discussed in detail in Sections IV and V of this document.
- Require mechanical flagging for aerial applications.

### Residential Risk

Risks to residential handlers of acephate are not of concern to the Agency; therefore no mitigation is needed at this time. However, residential postapplication risk is of concern to children entering treated lawns, and from treated homes. In order to mitigate residential postapplication risk, the Agency has determined that the following risk mitigation measures are necessary:

- Delete residential indoor uses.
- Delete all turfgrass uses (except golf course, sod farm, and spot or mound treatment for ant control).

### Ecological Risk

Ecological risks are also of concern to the Agency. Acephate and its degradate methamidophos are highly toxic to honey bees and beneficial predatory insects on an acute contact basis. Acute and chronic risks to birds and chronic risk to mammals are also high. The Agency has determined that the following mitigation measures are needed to address ecological risk concerns:

- Establish minimum spray intervals for all agricultural crops of 3 days for application rates up to 0.5 lb ai/A and of 7 days for application rates greater than 0.5 lb ai/A.
- Reduce seasonal maximum use for cotton from 6 to 4 lb ai/A.
- Reduce aerial cotton use rates.
- Delete the aerial application to turf.
- Delete granular formulations for residential turf uses, and use on ornamental trees and shrubs and in 12 inch pots.
- Reduce turf application rates for sod and golf courses.
- Require labeling to protect honeybees.
- Require labeling to reduce the potential for spray drift.

### Conclusions

The Agency is issuing this interim Reregistration Eligibility Document (RED) for acephate, as announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for complying with any necessary label changes for products containing acephate. Note that the Agency has shortened the time period to comply with the risk mitigation measures outlined in this document so that the risks identified herein are mitigated as quickly as possible and that there is no comment period for this document. As part of the process discussed by the TRAC, the Agency's risk assessments for acephate have already been subject to numerous public comment periods in order to open up the process to interested parties, and a further comment period for acephate was deemed unnecessary. With the use deletions and the addition of label restrictions and amendments detailed in this document, the Agency has determined that, until the cumulative risk from all of the organophosphates has been considered, most of the currently registered uses of acephate may continue. Neither the tolerance reassessment nor the reregistration eligibility decision for acephate can be considered final, however, until the cumulative risk for all organophosphate pesticides is considered. The methamidophos interim reregistration eligibility decision and the organophosphate cumulative assessment may result in further risk mitigation measures for acephate.



## I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect as of August 2, 1996 (the day before FQPA was enacted). FQPA also amends the FFDCFA to require a safety finding in tolerance reassessment based on several factors, including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Acephate belongs to a group of pesticides called organophosphates that share a common mechanism of toxicity. They all affect the nervous system by inhibiting the release of the cholinesterase enzyme. Although FQPA significantly affects the Agency’s reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency’s revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the interim decision on the reregistration eligibility of acephate. It is intended to be only the first phase in the reregistration process for acephate. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for acephate.

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

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments

- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

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

In addition to the policy issues that resulted from the TRAC process, the Agency issued a Pesticide Registration Notice (PR 2000-9) on September 29, 2000, that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides, and the Agency expects that other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals, will be required for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this document are consistent with the Worker Pesticide Registration Notice.

This interim Reregistration Eligibility Decision document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment and descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page: "[www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)," and in the Public Docket.

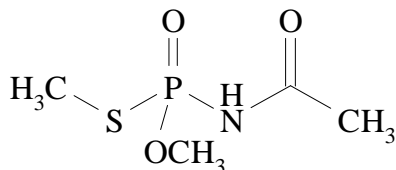
## II. Chemical Overview

### A. Regulatory History

Acephate was first registered in the United States in 1973 as an insecticide on ornamentals. The first food uses (agricultural crops) for acephate were registered in 1974. A Registration Standard was issued for acephate in 1987 that imposed several interim measures to reduce dietary, occupational, and domestic exposure from the registered uses of acephate. During the review of acephate in preparation for this document, the technical registrants agreed to drop forestry and rangeland/pastureland uses. This agreement was captured in the acephate Use Closure memo dated December 23, 1997. These uses were removed from all acephate labels by 1999.

### B. Chemical Identification

#### ! Chemical Structure:



! Common Name:	Acephate
! Chemical Name:	O, S-Dimethyl acetylphosphoramidothioate
! Chemical family:	Organophosphate
! Case number:	0042
! CAS registry number:	30560-19-1
! OPP chemical code:	103301
! Empirical formula:	C <sub>4</sub> H <sub>10</sub> NO <sub>3</sub> PS
! Molecular weight:	183.16 g/mol
! Vapor Pressure:	1.7 x 10 <sup>-6</sup> mm Hg at 24 °C
! Trade and other names:	Orthene®
! Technical registrants:	Valent U.S.A. Corporation Micro-Flo Company LLC United Phosphorous Ltd. Drexel Chemical Corporation

Acephate technical is a colorless to white solid with a melting point of 81-91° C. Acephate is highly soluble in water (79 g/100 ml), acetone (151 g/100 ml), and ethanol (>100 g/100 ml), and is soluble in methanol (57.5 g/100 ml), ethyl acetate (35.0 g/100 ml), benzene (16.0 g/100 ml), and hexane (<0.1g/100 ml) at 25° C. Acephate degrades to another, registered organophosphate chemical, methamidophos.

### **C. Use Profile**

The following information is based on the currently registered uses of acephate that were originally being supported for reregistration. Appendix A presents a summary of eligible uses and revised use conditions.

**Type of Pesticide:** Insecticide

#### **Summary of Use Sites:**

Food: Acephate is used on beans (green and lima), Brussels sprouts, cauliflower, celery, cotton, cottonseed, cranberries, head lettuce, macadamia nuts, peanuts, peppermint, peppers (bell and non-bell), soybeans (Special Local Need registrations in Mississippi and Texas only), and spearmint.

Other Agricultural Sites: Acephate is also used as seed treatment on cotton and peanuts (seed for planting), on non-bearing crops such as citrus, and on tobacco.

Residential: Acephate is used in and around residential buildings, homes, apartments, and in pantries for the control of roaches, wasps, fire ants, and crickets, among other pests. It is also used on home lawns, trees, shrubs and ornamentals.

Public Health: Acephate is used in and around residential, industrial, institutional and commercial buildings, including restaurants, food handling establishments, warehouses, stores, hotels, manufacturing plants, and ships for the control of roaches and fire ants.

Other Nonfood: Acephate is used on sod, golf course turf, field borders, fence rows, roadsides, ditch banks, borrow pits, wasteland, and greenhouse and horticultural nursery floral and foliage plants.

**Target Pests:** Armyworms, aphids, beetles, bollworms, borers, budworms, cankerworms, crickets, cutworms, fire ants, fleas, grasshoppers, leafhoppers, loopers, mealybugs, mites, moths, roaches, spiders, thrips, wasps, weevils, whiteflies, etc.

**Formulation Types Registered:** Wettable Powder, Soluble Powder, Soluble

Extruded Pellets, Granular, Liquid

**Method and Rates of Application:**

Equipment - Granular acephate can be applied by belly grinder, hand, tractor-drawn spreader, push-type spreader, and shaker can. Liquid acephate (formulated from soluble powders or soluble extruded pellets) may be applied by aircraft, airblast sprayer, backpack sprayer, chemigation, hydraulic sprayers, groundboom spray, handgun, high-pressure sprayer, hopper box (seed treatment), low-pressure handwand, seed slurry treatment, sprinkler can, transplanting in water (tobacco), or by an aerosol generator (greenhouses).

Residential applications can be made by aerosol can, backpack sprayer, hose-end sprayer, and low-pressure handwand. Residential granular applications can be made by shaker can or by hand. Residential soluble powder applications may be made by sprinkler can or compressed air sprayers.

Method and Rate - Acephate is used for seed, in-furrow, foliar spray, and soil mound (drench and dry methods for use against fire ants) treatments; and float bed, plant bed and transplant (tobacco) treatments. Acephate is also used indoors as spot, crack and crevice, and bait treatments. Rates vary according to method of application and pest. The highest registered maximum one time application rate is 5 lbs ai/A on commercial/residential turf. The highest seasonal application rate is 6 lb ai/A/year (1 lb ai/A at 6 applications per season) for cotton

Timing - For foliar applications, when eggs or insects first appear or when infestation becomes a problem. Multiple applications are allowed to maintain pest control.

**Use Classification:** Acephate products are not restricted use pesticides.

**D. Estimated Usage of Pesticide**

This section summarizes the best estimates of available pesticide usage information for acephate from 1988 to 1997. A full listing of all uses of acephate, with the corresponding use and usage data for each site, has been completed and is in the “Quantitative Usage Analysis for Acephate” document available in the public docket. The data, reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 4 to 5 million pounds of acephate are used annually, according to Agency and registrant estimates.

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

Crop	Pounds Active Ingredient Applied (000) (Wt. Avg.) <sup>1</sup>	Maximum Percent Crop Treated	Weighted Average Percent Crop Treated
Almonds	0.3	0.3%	0.1%
Apples	2	1.1%	0.2%
Apricots	6	23%	11%
Citrus, other	not available	1.6%	0.4%
Cranberries	9	51%	34%
Grapefruit	2	5%	1%
Grapes	0.4	0.3%	0.1%
Oranges	3	1.3%	0.2%
Walnuts	not available	0.06%	0.03%
Beans, Dry	40	5%	2%
Beans, Lima	37	54%	41%
Beans, Snap, Fresh	28	39%	29%
Beans, Snap, Processing	57	47%	35%
Brussels Sprouts	0.1	not available	
Carrots/Radishes	3	3%	1%
Cauliflower	7	21%	11%
Celery	23	68%	49%
Lettuce, Head	110	63%	47%
Lettuce, Other	11	28%	18%
Mint	55	42%	31%
Onions, Dry	0.2	0.4%	0.2%
Peanuts	51	10%	5%
Peppers, Bell	33	48%	24%
Potatoes	1.0	0.13%	0.10%
Soybeans	23	0.2%	0.1%
Alfalfa	3	0.06%	0.02%
Cotton	880	13%	9%
Lots/Farmsteads/etc.	3	0.05%	0.02%
Pasture	17	0.06%	0.03%
Summer Fallow	19	0.06%	0.03%
Tobacco	800	82%	61%
Woodland	6	0.04%	0.02%
Horticulture Nurseries	288	23%	17%
Institutional Turf	28	0.6%	<0.3%
Golf Courses	139	10%	<7%

Crop	Pounds Active Ingredient Applied (000) (Wt. Avg.) <sup>1</sup>	Maximum Percent Crop Treated	Weighted Average Percent Crop Treated
Landscapes by Landscape Maintenance Contractors	25	0.14%	0.06%
Lawn/Turf by Lawn Care Operators	121	0.3%	0.2%
Office/Retail Indoor by Commercial Pesticide Applicators	99	not available	
Pest Sites by Pest Control Operators	76	not available	
Residential Indoor by Commercial Pesticide Applicators	31	not available	
Residential Outdoor by Consumers	<740	not available	
Roadway Rights-of-Way	16	0.4%	<0.3%
Turf Farms	41	14%	<11%
Indoor by Commercial Pesticide Applicators	12	not available	

<sup>1</sup> Weighted Average is based on data for 1988-1997; the most recent years and more reliable data are weighted more heavily.

### III. Summary of Acephate Risk Assessment

The following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide acephate. These findings and conclusions are fully presented in the February 3, 2000 "Human Health Risk Assessment: Acephate," and two addenda to the revised occupational and residential risk assessment dated September 15, 2000, and February 13, 2001. The summary presented in this document also includes information from the August "EFED Acephate RED Chapter," dated August 25, 1999, and from an amendment to the estimated environmental concentrations of acephate in surface water titled "Revised Surface Water EECs (Incorporating the Index Reservoir and Percent Crop Area) for the HED Risk Assessment for Acephate," dated March 8, 2000.

Acephate degrades to another, registered organophosphate chemical, methamidophos. Methamidophos residues may occur in food and water as a result of the uses of acephate; however, risks from methamidophos residues from all sources will be addressed in the methamidophos interim RED. As a result, further mitigation to acephate uses may be necessary after the methamidophos interim RED is complete.

These risk assessments for acephate were presented at a February 2, 2000, Technical Briefing, that was followed by an opportunity for public comment on risk management. The risk assessments presented here form the basis of the Agency's risk management decision for acephate only; the Agency must complete a cumulative assessment of the risks of all the organophosphate pesticides before any final decisions can be made.

## A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for acephate on January 8, 1999 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. In addition, any new Agency policies were incorporated, as appropriate.

### 1. Dietary Risk from Food

#### a. Toxicity

The Agency has reviewed all toxicity studies and has determined that the toxicity database is essentially complete. The only toxicity data gap is a metabolism study in the rat (Guideline No. 85-1). Confirmatory data are being required and are included in Section V of this document. Further details on the toxicity of acephate can be found in the February 3, 2000, Human Health Risk Assessment and its supporting documents. In addition, on April 19, 2001, Valent Chemical Corporation submitted a toxicology study titled "A Single Oral Dose Study With Acephate Technical in Humans." This human study is currently in review. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 below.

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

Assessment	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor <sup>1</sup>	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary	NOAEL = 0.5 LOAEL = 2.5	Brain and plasma cholinesterase inhibition	Acute Neurotoxicity Range Finding - Rat (MRID 44203302) <sup>2</sup>	100	1X	0.005
Chronic Dietary	NOAEL = 0.12 LOAEL = 0.15	Brain cholinesterase inhibition	90-Day Feeding - Rat (MRID 40504819) <sup>3</sup>	100	1X	0.0012

<sup>1</sup>Uncertainty factor of 100 is the result of a 10x for interspecies and a 10x factor for intraspecies variability.

<sup>2</sup>In this range finding study, cholinesterase inhibition was observed after a single oral dose; therefore, the selection of this study for the purpose of acute dietary risk is justified.

<sup>3</sup>The 90-Day feeding study used to establish the chronic RfD was a special cholinesterase (ChE) study specifically designed to examine ChE effects at low doses of acephate. The values in this study were lower than that found in chronic studies, and because cholinesterase inhibition does not increase with time.

#### b. FQPA Safety Factor

The FQPA safety factor is intended to provide up to an additional 10-fold safety factor (10X) to safeguard against potential special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The Agency reduced the FQPA safety factor to 1X after evaluating the hazard and exposure data for acephate. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no



increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

**c. Population Adjusted Dose (PAD)**

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the additional FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of acephate, the FQPA safety factor is 1; therefore, the RfD is the same as the PAD. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern to the Agency.

**d. Exposure Assumptions**

Revised acute and chronic dietary risk analyses for acephate were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92. Residues used for the exposure analyses are highly refined and include anticipated residues generated from field trials, USDA Pesticide Data Program (PDP) and FDA monitoring data, adjustments for the percent crop treated, washing and cooking factors, and a probabilistic ("Monte Carlo") acute analysis.

**e. Food Risk Characterization**

A dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose (PAD; the dose at which an individual could be exposed to on any given day and no adverse health effects would result) is not of concern to the Agency. The dietary risk from acephate residues on food does not exceed the Agency's level of concern.

The percent acute PAD values for the most exposed population subgroups, children 1 to 6 years old and children 7 to 12 years old, are 33 and 31, respectively, at the 99.9<sup>th</sup> percentile of exposure. The percent chronic PAD values for the most exposed population subgroups, children 1 to 6 years old and infants (less than 1 year old), are 17 and 15, respectively.

Refinements to the dietary analyses can be made using additional monitoring data for the acute and chronic dietary analyses, cooking and processing studies, and market basket survey data. Refinements will be considered when the cumulative assessment for all of the organophosphates is conducted.

Risks from residues of methamidophos in food resulting from acephate uses are being considered and will be discussed further in the methamidophos interim RED.

## **2. Dietary Risk from Drinking Water**

Drinking water exposure to pesticides can occur through residues in ground water and surface water. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to characterize those risks. Modeling is considered to be an unrefined assessment and provides a conservative estimate of risk. In the case of acephate, the monitoring data for ground and surface water that were available were limited; therefore, modeling was used to estimate drinking water risks.

The PRZM-EXAMS model, including the recent Index Reservoir and Percent Crop Area modifications, was used to estimate surface water concentrations, and the SCI-GROW model was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than SCI-GROW.

Acephate is very soluble and mobile. It is not persistent under aerobic conditions; therefore, it is unlikely to leach to ground water.

Methamidophos residues may be present in surface and groundwater as a result of acephate uses since methamidophos is a degradate of acephate. Risk from residues of methamidophos in water that may result from acephate uses is being considered by the Agency and will be discussed further in the methamidophos interim RED.

### **a. Surface Water**

Estimated environmental concentrations (EECs) of acephate in surface water were generated using the Tier II PRZM-EXAMS screening model. This model uses available environmental fate data to generate upper-bound concentrations of pesticide in surface water. In general, it is based on more refined, less conservative assumptions than the Tier I GENEEC screening model.

Surface water EECs were determined for the use of acephate on cotton and tobacco, crops that represent the maximum yearly total applications (six aerial applications at 1 lb ai/A/application on cotton and three aerial applications at 1.33 lbs ai/A/application on tobacco). Turf is the exception, in that the application rate can be up to 5 lbs ai/A; however, the PRZM-EXAMS model used for acephate does not include a turf scenario and cannot be used to predict EECs from turf use.

Based on modeling, surface water EECs are not likely to exceed 36 ppb for peak (acute) exposure and 7.2 ppb for mean (chronic) exposure. See Tables 3 and 4 for a summary of the surface water EEC values.

**b. Ground Water**

Estimated environmental concentrations of acephate in groundwater were generated using the Tier I screening model, SCI-GROW. Groundwater EECs were determined for the use of acephate on cotton, and are not likely to exceed 0.02 ppb for acute or chronic exposures. See Tables 3 and 4 for a summary of the groundwater EEC values.

**c. Drinking Water Levels of Comparison (DWLOCs)**

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA determines how much exposure to residues in water can safely occur. This level is called the “drinking water level of comparison”(DWLOC). The DWLOC is the maximum concentration in drinking water that, when considered together with dietary exposure (and, if appropriate, residential uses), does not exceed the agency’s level of concern (the “risk cup,” or the PAD) for each population subgroup that the Agency considers. DWLOCs are then compared to the EECs to determine whether modeled or monitoring levels of pesticide in drinking water are of concern.

The results of the Agency’s drinking water analyses are summarized in Tables 3 and 4. Details of these analyses are found in the February 3, 2000, HED Human Health Risk Assessment and in the March 8, 2000, Revised Surface Water EECs for the HED Risk Assessment for Acephate.

**Table 3. Summary of DWLOC Values for Acute Risk**

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb) (SCI-GROW)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.005	0.001111	0.003889	0.02	36	136
Children 1-6 yrs.	0.005	0.001631	0.003369	0.02	36	34

For acute risk, the potential drinking water exposure to acephate alone from either ground or surface water is not of concern for any population subgroup (Table 4). Although the acute DWLOC is exceeded for one population, children (1 to 6 years old), the Agency has determined that a 6% exceedance (2 ppb) for acute drinking water from the uses of acephate is not of concern. The PRZM-EXAMS model that is used to estimate EECs is a Tier II model and a screening-level assessment. The results of the model are expected to be higher than the EECs actually found in drinking water; in other words, EECs are likely an overestimate of residues.

**Table 4. Summary of DWLOC Calculations for Chronic Risk**

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.0012	0.000089	0.001111	0.02	7.2	38
Children 1-6 yrs.	0.0012	0.000209	0.000991	0.02	7.2	10
Infants (<1 year)	0.0012	0.000185	0.001015	0.02	7.2	10

For chronic risk, potential exposure to drinking water derived from either groundwater or surface water is not of concern for any population subgroup (Table 3).

### **3. Residential Risk**

Residents and homeowners can be exposed to acephate by treating their own lawns and ornamental trees, shrubs and flowers with acephate products for pest control. The Agency considers that these residential applicators mix, load, and apply pesticides to areas around the home. Adults or children can also be exposed to acephate through contact with treated areas indoors, treated lawns or other turf areas (i.e., golf courses), or treated ornamental plants.

In addition, because acephate degrades to methamidophos, another organophosphate pesticide, people can be exposed to methamidophos as a result of the application of acephate to lawns or indoors. To consider risks from the exposure to methamidophos resulting from acephate application, the toxicity of methamidophos considered.

Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE). An MOE determines how close individuals come to a No Observed Adverse Effect Level (NOAEL), whether using the pesticide or coming into contact with pesticide residues after application. Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

#### **a. Toxicity**

The toxicity of acephate and its degradate, methamidophos, is integral to assessing the residential risk. All risk calculations are based on the most current toxicity information available for acephate and its degradate, including 21-day dermal and 4-week inhalation toxicity studies on acephate that were submitted to the Agency in May 2000. The toxicological endpoints, and other factors used in the residential risk assessment for acephate, are listed below.

Please note that the toxicological endpoints and other factors shown in Table 5a are the same as those used in the occupational risk assessment, as discussed in the Occupational Risk section of this document, Section III.A.5.a.

**Table 5a. Summary of Acephate and Methamidophos Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Acephate**

Assessment	Dose	Endpoint	Study
<b>Acephate</b>			
Dermal - Short and Intermediate-Term	NOAEL = 50 mg/kg/day LOAEL > 50 mg/kg/day	Brain cholinesterase inhibition <sup>1</sup>	21-Day Dermal - Rat MRID 45134301 MRID 44541101
Inhalation - Any Duration	NOAEL = 0.001064 mg/L (0.28 mg/kg/day) LOAEL = 0.003123 mg/L	Brain cholinesterase inhibition	4-Week Inhalation - Rat MRID 45134302
Oral - Acute	NOAEL = 0.5 mg/kg/day LOAEL = 2.5 mg/kg/day	Brain and plasma cholinesterase inhibition	Acute Neurotoxicity Range Finding - Rat MRID 44203302
<b>Methamidophos</b>			
Dermal - Any Duration	NOAEL = 0.75 mg/kg/day LOAEL = 11.2 mg/kg/day	Plasma, red blood cell, and brain cholinesterase inhibition	21-Day Dermal Toxicity - Rat MRID 44525301
Inhalation - Any Duration	NOAEL = 0.001 mg/L (0.27 mg/kg/day) LOAEL = 0.005 mg/L	Plasma, red blood cell, and brain cholinesterase inhibition	90-Day Inhalation - Rat MRID 41402401
Oral - Acute	NOAEL = 0.3 mg/kg/day LOAEL = 0.7 mg/kg/day	Brain cholinesterase inhibition	Acute Neurotoxicity MRID 43025001; 43345801

<sup>1</sup>Slight brain cholinesterase inhibition seen at 60 mg/kg/day dose in MRID 44541101

Acephate has low acute dermal and inhalation toxicity. It is non-irritating to skin, minimally irritating to the eyes and is not a skin sensitizer. It is classified under Category III for acute oral toxicity. Table 5b summarizes the acute toxicity of the active ingredient.

**Table 5b. Acute Toxicity Profile for Residential and Occupational Exposure to Acephate**

Route of Exposure	Category Basis	Toxicity Category
Oral	Acute oral LD <sub>50</sub> = 1.4 g/kg - male rat; 1.0 g/kg - female rat (MRID 00029686)	III
Dermal	Acute dermal LD <sub>50</sub> >10 g/kg - male rabbit (MRID 00055602)	IV
Inhalation	Acute inhalation LC <sub>50</sub> >61.7 mg/L (MRID 00015307)	IV
Eye Irritation	Non-irritant - rabbit (MRID 00014686)	IV
Dermal Irritation	PIS = 0.1 - rabbit (intact and abraded skin) (MRID 00015305)	IV
Dermal Sensitizer	Negative -guinea pig (MRID 00119085)	-

## **b. Exposure**

A chemical-specific monitoring study on residential handler (homeowner) exposure (MRID 40504827) was submitted to the Agency in support of the reregistration of acephate and was used in the residential risk assessment. Analyses were also performed using the *Pesticide Handlers Exposure Database* (PHED), Version 1.1 (August 1998). Standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc., were used to calculate risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from acephate labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the February 3, 2000, Acephate Human Health Risk Assessment available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling on acephate end products. Application rates specified on acephate labels for residential uses range up to 5 pounds of active ingredient per acre on residential turf.

Residential pesticide applicators of acephate, such as homeowners who treat turf and ornamentals, are likely to be exposed on a short-term basis only. For the residential exposure scenarios, the Agency assumes that no personal protective equipment is used.

The Agency also considered exposure to adults or children entering or playing on treated lawns or entering homes after application of acephate products (postapplication exposure). These activities result in potential short-term dermal acephate and methamidophos postapplication exposures. Because the degradate, methamidophos, is expected to be present following the application of acephate, the residential and postapplication assessment addresses both potential acephate and methamidophos exposures.

A submitted turf transferable residue (TTR) study was used to better define the amount of acephate and methamidophos residues on acephate-treated turf. In addition, data submitted by the Outdoor Residential Exposure Task Force (ORETF) on hose end sprayers was used in this assessment.

## **c. Residential Handler Risk Summary**

### **1) Residential Applicator Risk**

The Agency does not believe the addition of personal protective equipment to residential handlers (as used for assessing occupational handler risk) is an appropriate approach for

homeowner handler exposure assessments. Homeowners often lack access to PPE and also do not possess expertise in the proper use of PPE. As a result, homeowner handler assessments are completed using a single scenario based on the use of short-sleeved shirts and short pants (i.e., common homeowner attire during the pesticide application season). In addition, only short-term exposures were assessed, as the Agency does not believe homeowners who apply acephate will be exposed for more than a few consecutive days. The homeowner handler exposure scenarios that were assessed are summarized in Table 6.

**Table 6. Homeowner Uses and Risk Concerns (combined dermal & inhalation MOEs)**

Scenario	Crop/ Use Site	Rate lb ai/A or /gallon	Amount Used	Short-Term MOE
(1) Mixing/loading/applying using a low pressure handwand	Ornamentals, Trees, Flowers, Fire Ants	0.023	2 gallons	170
	Turf	0.035		110
	Roses, Turf	0.0076		520
(2) Mixing/loading/applying using a backpack sprayer	Ornamentals, Trees, Flowers, Fire Ants	0.023	2 gallons	7300
	Turf	0.035		4800
	Roses, Turf	0.0076		22000
(3) Mixing/loading/applying using a hose-end sprayer	Ornamentals, Trees, Flowers, Roses, Fire Ants Turf <sup>1</sup>	1.9	0.5	266
		1.9	0.25	532
		1.9	0.1	1329
		3.9	0.5	130
		3.9	0.25	259
		3.9	0.1	648
	Chemical Specific Exposure Monitoring Study MRID 40504827	0.012	50 gal.	120
(4) Mixing/loading/applying using a sprinkler can	Ornamentals, Trees, Flowers, Fire Ant	0.023	5 gal	960
	Turf	0.035		630
	Roses, Turf	0.0076		2900
(5) Loading/applying soluble powder using a hand tool or shaker can	Fire Ant	0.0069	7 mounds	140
(6) Loading/applying granules by shaker cup	Ornamentals	0.5 lb ai/1000 sq. ft.	1000 sq. ft.	14
	Roses	0.1125 lb ai/1000 sq. ft.		61
(7) Applying using an aerosol can	Crack & Crevice; Ornamentals	0.0022	2 cans	1226.5

<sup>1</sup>Please note that all of the use rates given in this row do not apply to all sites listed.

One homeowner exposure scenario, the application of granules by shaker cup (Scenario 6), has calculated risks of concern to the Agency. The MOEs of concern are driven by dermal exposure. However, the Agency believes that the MOEs presented here overestimate the risk from this residential exposure scenario. The risk estimate numbers were based on the assumption that an individual homeowner could treat 1000 square feet with the granular formulation by shaker cup. This is a conservative assumption based on the presence of other cost-effective options available to homeowners treating areas that large (i.e., hose-end sprayers). For example, if a homeowner wanted to treat a 1000 square foot flower bed with acephate, he or she would likely use a hose end sprayer over granule shaker cup.

In addition, one five pound canister of acephate granules packaged in a shaker can would only treat 150 square feet of ornamentals (667 square feet of roses). The MOE for a homeowner using an entire container is 94. To treat 1000 square feet of ornamentals would require over 6 five pound canisters. In addition, the directions for use on a container this size indicate that it is not a single use product. Therefore, risks from the use of acephate granules in shaker cups is not of concern to the Agency.

Risk estimates indicate that, when short-term dermal and inhalation exposures are combined, the Agency has no risk concerns for the remaining residential handler scenarios.

## **2) Postapplication Residential Risk**

Acephate can be used within residences for crack and crevice treatment; on home lawns, trees, shrubs and flowers, golf course turf; and on other turf areas where exposure to adults and children may occur. Exposure to acephate and its degradate methamidophos may result from entering the treated area, performing yard work (e.g., pruning, cutting and weeding), playing or performing other recreational activities (e.g., golfing) on the treated areas. Acephate and methamidophos exposures may also occur from contact (i.e., pruning, cutting and weeding) with treated ornamentals, flowers, trees, and shrubs. However, it is anticipated that these exposures would not be as significant as turfgrass exposures because of lower contact rates and the frequency and duration of potential contacts.

Both toddler and adult postapplication dermal and incidental oral risks from exposure to residential turf treated with acephate were considered. Additionally, the Agency assessed risks to adults and children exposed indoors to treated residential buildings and to golfers from exposure to treated golf course turf. The Agency does not anticipate potential inhalation exposures because of the low volatility of acephate; therefore, these exposures were not assessed.

Data from a turf transferable residue (TTR) study (MRID 44806401) submitted by the registrant were used to define available residue on recreational turf and home lawns. The maximum application rate for turf/sod farm was 5 pounds active ingredient per acre for recreational turf and home lawns; however, an application rate of 3.5 pounds of active ingredient per acre was used in the TTR study, and is reflected here. Postapplication residential and



recreational exposures were calculated on the day of treatment, in accordance with current Agency policy.

**a) Indoor Residential Postapplication Risk**

Indoor residential postapplication risks are of concern to the Agency. The MOEs for aggregate indoor residential exposure to acephate residues range from 2.8 to 9.0 for children. Additionally, risks to adults are of concern due to dermal exposure. Risks are driven by residues of acephate, not the degradate methamidophos. See Table 7 below for further information on all risk estimates given for both acephate and methamidophos residues.

These risk estimates apply to acephate use in homes. The assumptions reflect conditions and use patterns associated with residential use. Thus, these risk estimates cannot be reliably used to determine whether the Agency has risk concerns for postapplication exposure to acephate in other industrial, institutional, and commercial buildings; for example, restaurants, warehouses, stores, hospitals, hotels, manufacturing plants and ships.

**Table 7: Residential Postapplication Risk Estimates from Acephate Application Indoors**

Exposure Scenario	Acephate Application Rate (lb ai/A)	Acephate MOEs			Methamidophos MOEs		
		Dermal	Hand-to-Mouth	Aggregate	Dermal	Hand-to-Mouth	Aggregate
Toddlers on Carpets	0.5% Solution	24	14.4	9.0	94.9	2277.3	91.1
	0.75% Solution	16	9.6	6.0	63.3	1518.2	60.7
	1.0% Solution	12	7.2	4.5	47.4	1138.7	45.5
Toddlers on Hard Surfaces	0.5% Solution	24	7.2	5.5	94.9	1138.7	87.6
	0.75% Solution	16	4.8	3.7	63.3	759.1	58.4
	1.0% Solution	12	3.6	2.8	47.4	569.3	43.8
Adults on Carpets or Hard Surfaces	0.5% Solution	40.3	Not applicable		159.1	Not applicable	
	0.75% Solution	26.9			106.1		
	1.0% Solution	20.2			79.5		

**b) Residential Lawn Postapplication Risk**

Residential lawn postapplication risks are of concern to the Agency. As shown in Table 8, the MOE is 7.4 when combining the following four components of toddler exposure: hand-to-mouth; object-to-mouth; soil ingestion; and dermal exposure. Based on the available data, this risk is driven by parent acephate residues and not the degradate methamidophos.

These risks were assessed at an application rate of 3.5 lb ai/A since that is the rate used in the turf transferable residue (TTR) chemical-specific study used to determine risk. The current registered maximum application rate for residential turf is 5 lb ai/A. Thus, MOE values underestimate the risk from current labels.

**Table 8: Residential Postapplication Risk Estimates from Acephate Application to Lawns**

Scenario	Individual	Application Rate	MOE (acephate)	MOE (methamidophos)
Dermal	Adult	3.5 lb ai/A	507	2020
Dermal	Child		303	1207
Hand-to-Mouth	Child		9.6	1522
Object-to-Mouth	Child		38	6088
Soil	Child		385	454
Combined	Child		7.4	260

**c) Recreational Postapplication Risk (Golf Courses)**

Recreational postapplication risks from the use of acephate are not of concern to the Agency; MOEs from acephate residues are 3600 for child golfers and 6100 for adult golfers. MOEs from methamidophos residues resulting from acephate application are 14,000 for child golfers and 2400 for adult golfers.

**4. Aggregate Risk**

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes), and in some cases residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers). Dietary risks from exposure to acephate through food and drinking water are not of concern, as discussed above. However, since risks to children from postapplication exposure to acephate itself exceeds the risk cup (MOE = 7.4), aggregate risks are of concern.

**5. Occupational Risk**

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of acephate include: individual farmers or other growers who mix, load, and/or apply pesticides, commercial, professional, or custom agricultural applicators, commercial pest control operators and lawncare and turf management professionals. As for the residential risks, occupational risk is measured by a Margin of Exposure (MOE). An MOE determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). For acephate and methamidophos, MOEs greater than 100 do not exceed the Agency's risk concern.

**a. Toxicity**

The toxicity of acephate is integral to assessing the occupational risk. As for the residential risk assessment, all risk calculations are based on the most current toxicity information available for acephate, including 21-day dermal and 4-week inhalation toxicity studies submitted to the Agency in May 2000. The toxicological endpoints, and other factors

used in the occupational risk assessments for acephate are listed in Tables 5a and 5b in the Residential Risk Summary of this document, Section III.A.3.a.

## **b. Exposure**

A chemical-specific exposure monitoring study on pest control operator (PCO) exposure (MRID 40504823) was submitted to the Agency in support of the reregistration of acephate, and was used in the occupational risk assessment.

For other exposure scenarios, the analyses for both short- and intermediate term exposures were performed using the *Pesticide Handlers Exposure Database* (PHED), Version 1.1 (August 1998). Standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc., were used to calculate risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from acephate labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the February 3, 2000, Acephate Human Health Assessment document available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on acephate labels range depending on crop from 0.5 to 1.33 pounds of active ingredient per acre in agricultural settings, and from 0.035 pounds of active ingredient per gallon (2 gallons used per day) to 5 pounds of active ingredient per acre per application on commercial turf. The Agency typically uses acres treated per day values that are thought to represent 8 hours of application work for specific types of application equipment. New standard values for acreage treated in a day have been incorporated in this assessment, according to the Agency's Exposure Scientific Advisory Committee (ExpoSAC) interim policy 009 of June 23, 2000. In occupational exposure assessments, the Agency now assumes that 1,200 acres are treated during aerial application to major crops, such as cotton, and that 200 acres are treated by groundboom application to major crops. Acreage assumptions for other crops remain at 350 for aerial application and 80 for groundboom application.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with baseline protection and then adds additional protective measures to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest suite of PPE is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation (PPE) are applied. If MOEs are still less than 100, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from acephate activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline, chemical resistant gloves and a respirator with a protection factor (PF) of 5 (a dust mist filtering respirator).
- Maximum PPE: Baseline, an additional layer of clothing (e.g. coveralls), chemical-resistant gloves and a respirator with a protection factor of 10 (a respirator with organic vapor protection).
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a farm closed mechanical transfer system for liquids or a packaged based system (e.g., Lock n Load for granulars or water soluble packaging for wettable powders). Some engineering controls are not feasible for certain scenarios. Some formulation types qualify as engineering controls for the purpose of controlling exposure during mixing/loading, such as water soluble packets.

For the purpose of this risk assessment, the Agency has determined that the frequency and duration of acephate uses by occupational handlers result in short-term (1 to 7 days) and intermediate-term (one week to several months) exposures.

Finally, postapplication exposure to workers through entry into agricultural fields treated with acephate was also considered. These activities result in potential short-term and intermediate-term dermal acephate and methamidophos postapplication exposures. Because methamidophos is anticipated to be present following the application of acephate, the occupational, residential and postapplication assessments address both potential acephate and methamidophos exposures.

Four dislodgeable foliar residue (DFR) studies submitted by the registrant address the dissipation of acephate and methamidophos in fields/greenhouses of succulent beans, cauliflower, greenhouse roses, and tobacco. These studies were used to evaluate potential postapplication worker risks. A submitted turf transferable residue (TTR) study was used to better define the amount of acephate and methamidophos residues on acephate-treated turf.

The revised occupational risk assessment (September 15, 2000) also includes information from the Agriculture Re-Entry Task Force (ARTF) on transfer coefficients. This information has been summarized by the ExpoSAC in interim Policy 3.1.

### **c. Occupational & Residential Handler Risk Summary**

The Agency identified several major occupational handler exposure scenarios associated with the use of acephate. Numerous combined dermal and inhalation MOEs for occupational mixer/loader scenarios are less than 100 when assessed considering baseline personal protective equipment (PPE) and, therefore, are of concern to the Agency at that level of protection. However, most of these risks can be mitigated with additional levels of protection, as described below. In addition, pasture uses of acephate have previously been deleted and no registered

liquid acephate formulations for agricultural uses exist (Scenario 3); therefore, the results of these assessments are not presented here.

Only three occupational risk areas remain of concern at the highest level of mitigation available or feasible: risks to agricultural handlers who mix and load soluble powder for aerial applications to 1200 acres; risks to Pest Control Operators (PCOs) who mix, load and apply more than 5 gallons of formulated product per day; and risks to handlers who mix, load and apply granules using a belly grinder, a shaker can, or by hand (except for ant mound treatment).

The Agency could not quantitatively assess risk to occupational workers for the following scenarios due to the lack of acephate-specific or PHED exposure data for these methods of application:

- Scenario 9 Tobacco Transplanting Water “Applicator” (handlers transplanting treated tobacco plants);
- Scenario 10 Slurry Seed Treatment “Applicator” (handlers planting treated seed);
- Scenario 11 Hopper Box Seed Treatment “Applicator” (handlers planting treated seed);
- Scenario 16 Aerosol Generator Mixer/Loader/Applicator;
- Scenario 17 PCO Injector Crack and Crevice Use Mixer/Loader/Applicator; and
- Scenario 20 Tree Injection Mixer/Loader/Applicator.

Nonetheless, the Agency has qualitatively considered whether exposure is likely and attempted to describe the level of risk from these scenarios.

In Scenario 9, acephate is added to the aqueous medium that is used to start tobacco plants prior to transplanting. Two major work functions are associated with this use including preparation of the starting solution (i.e., mixing chemical with water), assessed as Scenario 1f, and workers transplanting the immature tobacco plants. Transplanting may involve exposures to people who drive a transplanting rig through fields and also to individuals involved with placing plants into the transplanting mechanism. However, based on the Agency’s understanding of the operation, it is not likely that significant exposures will occur since the formulated product is injected directly into the soil with the tobacco seedling. Plants are not handled after they are placed into the ground. Additionally, no formulated product is visible after transplanting. Therefore, this applicator scenario is not of concern to the Agency.

In Scenarios 10 and 11, acephate is used to treat cotton and peanut seed during the manufacturing/storage process or added directly to seed hoppers on application equipment during planting by growers. The Agency did not assess exposures during the actual placement of seeds into prepared soil (i.e., the tractor driver during planting). In order to consider this exposure quantitatively, the Agency would select the direct application of granules as a likely surrogate (Scenario 12). The results for that scenario indicate that, at a rate approximately 5 times higher than used for the seed treatment, baseline clothing results in acceptable risk. As

such, the Agency does not have a risk concern for the application of treated seeds at baseline levels of PPE.

For Scenario 16, the Aerosol Generator mixer/loader/applicator, there are three exposure elements that should be considered. The first component is loading the concentrated end-use product into the aerosol generator (this does not apply if the end product is being marketed in an aerosol can). The second is the initiation and monitoring of the production of aerosol in the area being treated. The last element involves venting the treated area for re-entry purposes. The mixing/loading component for greenhouse foggers would typically be addressed using the standard unit exposure values for mixing/loading liquids. Several scenarios for liquid formulations have already been completed for acephate in which a range of acephate throughput was considered. It is likely that the amount of chemical active ingredient to be used in a fogging event likely approximates the chemical throughput estimated for one of the already defined mixing/loading scenarios (5 lb ai; Scenario 3b) with acceptable MOEs at baseline PPE. As such, this exposure element can be estimated with the existing risk calculations, and is not of concern to the Agency. In addition, the Agency did calculate post-application worker risks for cut flowers and floriculture in the acephate risk assessment. These calculations can serve as the basis for any consideration of dermal exposure related to monitoring ongoing fogging events and for venting. Inhalation exposure is the only remaining element for these activities that has not been quantitatively assessed. In order to complete a quantitative assessment, more detailed information on fogging uses of acephate needs to be provided (e.g., target application concentrations, routine venting procedures, etc.).

For the PCO injector use, Scenario 17, the Agency has a potential concern for applicators using this product because it contains 96 percent active ingredient and as part of the normal use of the product, PCOs prepare the bait in an open system. Designated containers are provided with the product for this purpose and the label requires the use of gloves. As such, it is likely that exposures would be small.

For Scenario 20, Tree Injection, there are many different types of devices that can be used for this application. These range from relatively low exposure devices such as direct injection syringes that also serve as the end-use product package to higher exposure application devices such as a hypo-hatchet or other similar devices. The Agency does not have exposure data that can be used quantitatively in risk assessments for these types of devices. Qualitatively, the Agency believes that there is a potential for exposure and risk because most application methods require concentrated product and are not in closed systems.

## **1) Agricultural Handler Risk**

The occupational handler exposure scenarios that were assessed are summarized in the Table 9, and exposure scenarios that present risks of concern are explained further below.

At baseline PPE, the following handler scenarios are acceptable:

- Scenario 2 mixing and loading dry flowable formulations for slurry seed treatment (assessed as a surrogate for a new, soluble extruded pellet formulation)
- Scenario 4, 12 mixing, loading, and applying granules for drop type application to cotton;
- Scenario 6 applying to agricultural crops via groundboom;
- Scenario 7 applying to non-bearing citrus, trees and shrubs, or outdoor floral via airblast sprayer;
- Scenario 8 applying to tobacco, or trees, shrubs, or outdoor floral via handgun;
- Scenario 13a mixing, loading, and applying soluble powder by low pressure handwand to control fire ants;
- Scenario 18 mixing, loading, and applying soluble powder to ant mounds by hand tool or shaker can;
- Scenario 19 mixing, loading, and applying soluble powder to ant mounds by sprinkler can; and
- Scenario 24 mixing, loading and applying granules to ant mounds by hand.

Risks from the following handler scenarios can be mitigated by employing minimum PPE (baseline clothing plus chemical-resistant gloves and a PF 5 respirator):

- Scenario 1d mixing and loading soluble powder for airblast application to non-bearing citrus, trees and shrubs, and outdoor floral;
- Scenario 1e mixing and loading soluble powder for handgun application to tobacco, trees and shrubs, and outdoor floral;
- Scenario 1f mixing and loading soluble powder for use in tobacco transplant water;
- Scenario 1h mixing and loading soluble powder for use in a hopper box to treat cotton seed or peanut seed;
- Scenario 13a mixing, loading, and applying soluble powder by low pressure handwand to trees, shrubs, and outdoor floral (0.5 lb ai/A rate) and to control wasps;
- Scenario 14 mixing, loading, and applying soluble powder by backpack sprayer to trees, shrubs, and outdoor floral and to control wasps and fire ants;
- Scenario 15 mixing, loading, and applying soluble powder by high pressure handwand to trees, shrubs, and outdoor floral; and
- Scenario 25 flagging for aerial applications to agricultural crops *and pastures*.

Risks from the following handler scenarios can be mitigated by employing maximum PPE (double layer of clothing plus chemical resistant gloves and a PF 10 respirator):

- Scenario 1b mixing and loading soluble powder for chemigation application to cranberries;
- Scenario 13a mixing, loading, and applying soluble powder by low pressure handwand to trees, shrubs, and outdoor floral (1.0 lb ai/A rate); and
- Scenario 25 flagging for aerial applications to turf.

Risks from the following handler scenarios can be mitigated by employing engineering controls:

- Scenario 1a mixing and loading soluble powder for aerial application to agricultural crops (350 acre/day);
- Scenario 1c mixing and loading soluble powder for groundboom application to agricultural crops or turf;
- Scenario 1g mixing and loading soluble powder for slurry seed treatment of cotton seed; and
- Scenario 5 applying to agricultural crops aerially.

Risks from the following scenarios are still of concern when assuming engineering controls are employed:

- Scenario 1a mixing and loading soluble powder for aerial application to agricultural crops (1200 acres treated per day) (driven by inhalation exposure);
- Scenario 1a mixing and loading soluble powder for aerial application to turf at the 5 lb ai/A use rate; and
- Scenarios 22, 23, and 24 mixing, loading, and applying granules to trees and shrubs and 12" pots for ornamental plants.

**Table 9. Agricultural Handler Risk Assessment**

Scenario	Crop/ Use Site	Use Rate (lb ai/A)	Acres Treated /Day	Short-Term and Intermediate-Term MOEs			
				Baseline <sup>1</sup>	Min PPE <sup>2</sup>	Max PPE <sup>3</sup>	Eng. Control <sup>4</sup>
<b>Mixer/Loader Exposure Scenarios</b>							
(1a) Soluble Powder for Aerial Application	Agricultural crops	0.5	1200	0.51	3.4	6.5	91
		1	1200	0.26	1.7	3.2	46
		1	350	0.88	5.9	11	160
	Turf	5	350	0.18	1.2	2.2	31
(1b) Soluble Powder for Chemigation	Cranberries	1	30	10	68	130	1800
(1c) Soluble Powder for Groundboom	Agricultural crops	0.5	200	3.1	21	39	550
		1	200	1.5	10	19	270



Scenario	Crop/ Use Site	Use Rate (lb ai/A)	Acres Treated /Day	Short-Term and Intermediate-Term MOEs			
				Baseline <sup>1</sup>	Min PPE <sup>2</sup>	Max PPE <sup>3</sup>	Eng. Control <sup>4</sup>
	Turf	5	80	0.77	5.1	10	140
(1d) Soluble Powder/Airblast	Non-bearing citrus	0.5	40	15	100	200	2700
	Trees and shrubs (/100 gal)	1	10	31	210	390	5500
	Outdoor Floral (/100 gal)	0.5	10	62	410	780	11000
(1e) Soluble Powder/Handgun	Tobacco (/80 gal; 13 gal/A)	1	6	51	340	650	9100
	Trees, shrubs, outdoor floral (/100 gal)	1	1000 gal	31	210	390	5500
	Trees, shrubs, outdoor floral (/100 gal)	0.5	1000 gal	62	410	780	11000
(1f) Soluble Powder/Transplanting	Tobacco	0.75	20	21	140	260	3700
(1g) Soluble Powder for Slurry Seed Treatment	Cotton Seed (/100 lb seed)	0.04	200,000 lb seed	3.8	26	49	690
(1h) Soluble Powder for Hopper Box	Cotton Seed & Peanut Seed	0.1875	80	21	140	260	3700
(2) Dry Flowable Slurry Seed Treatment	Cotton Seed (/100 lb seed)	0.04	200,000 lb seed	220	470	720	11000
(4) Granule/Drop Type Spreader	Cotton	1	80	140	650	1300	7000
Applicator Exposure Scenarios							
(5) Aerial	Agricultural crops	0.5	1200	na	na	na	340
		1	1200	na	na	na	170
(6) Groundboom	Agricultural crops	0.5	200	240	860	1400	2700
		1	200	120	430	720	1400
	Pasture	0.125	80	2300	8300	14000	26000
(7) Airblast	Non-bearing citrus	0.5	40	150	440	580	1800
	Trees and Shrubs (/100gal)	1	1000 gallons	300	870	1200	3500
	Outdoor Floral (/100 gal)	0.5	1000 gallons	600	1700	2300	7000
(8) Handgun	Tobacco (/80gal; 13 gal/A)	1	6 acres	570	1500	2600	NF

Scenario	Crop/ Use Site	Use Rate (lb ai/A)	Acres Treated /Day	Short-Term and Intermediate-Term MOEs			
				Baseline <sup>1</sup>	Min PPE <sup>2</sup>	Max PPE <sup>3</sup>	Eng. Control <sup>4</sup>
	Tree, shrubs, Outdoor floral (/100gal)	1	1000 gal	340	900	1600	NF
		0.5	1000 gal	690	1800	3100	NF
(12) Granule/Drop Type Spreader	Cotton	1	80	200	870	1700	7000
Mixer/Loader/Applicator Exposure Scenarios							
(13a) Soluble Powder/Low Pressure Handwand	Trees, shrubs, outdoor floral (/100 gal)	1	1000 gal	16	73	140	NF
		0.5	1000 gal	32	150	270	NF
	Fire Ant (lb ai/5 gal)	0.047	5 gal	330	1600	2900	NF
	Wasps (lb ai/gal)	0.075	5 gal	41	200	360	NF
(14) Backpack Sprayer	Tree, shrubs, outdoor floral (/100gal)	1	40 gal	na	980	1600	NF
		0.5	40 gal	na	2000	3300	NF
	Wasps (lb ai/gal)	0.75	5 gal	na	260	440	NF
	Ant (lb ai /5 gal)	0.047	5 gallons	na	21000	35000	NF
(15) High Pressure Handwand	Tree, shrubs, outdoor floral (/100gal)	1	1000 gal	na	520	940	NF
		0.5	1000 gal	na	1000	1900	NF
(18) Hand Tool/Shaker Can	Fire Ants (lb ai/mound)	0.00694	10 mounds	660	1400	na	NF
(19) Soluble Powder Sprinkler Can	Fire Ants (0.0029 lb ai/mound)	0.047	2 gallons	18000	95000	130,000	NF
(22) Granules - Belly Grinder	Trees/shrubs (1000 sq. ft.)	0.1125	87,000 sq. ft.	17	31	53	NF
(23) Granules - Shaker Can	Trees/shrubs (1000 sq. ft.)	0.1125	10,000 sq. ft.	17	35	63	NF
(24) Granules - By Hand	12-inch pot (lb ai/pot)	0.00099	1000 pots	19	40	72	NF
	Trees, shrubs (1000 sq. ft.)	0.1125	10000 sq. ft.	17	35	63	NF
	Fire Ant	0.008	10 mounds	240	500	890	NF
Flagger Exposure Scenarios							
(25) Flagging Aerial Spray	Agricultural crops	0.5	1200	79	240	340	4000
		1	1200	40	120	170	2000
	Turf	5	350	27	82	120	1400

<sup>1</sup> Baseline: long-sleeved shirt, long pants, socks and shoes

<sup>2</sup> Minimum PPE: baseline clothing plus chemical-resistant gloves and a PF 5 respirator

<sup>3</sup> Maximum PPE: baseline clothing plus an additional layer of clothing such as coveralls, chemical-resistant gloves, and a PF 10 respirator

<sup>4</sup> Engineering controls: Closed cab tractor for application scenarios, or a closed mixing/loading system such as a farm closed mechanical transfer system for liquids or soluble packets

NF = Not feasible

## 2) Pest Control Operator and Turf Use Risk

Turf and pest control operator (PCO) uses assessed are listed in Table 10. As before, this table shows the risk estimates with increasing levels of protection.

For professional turf uses, almost all of the scenarios with risks of concern at baseline can be mitigated with additional levels of protection. However, risks to PCOs applying 40 gallons of formulated product in a day remain of concern at the highest level of protection. The Agency also considered PHED data when assessing risks to PCO (see Scenario 13a) rather than relying solely on an available chemical-specific study (see Scenario 13b). The Agency feels that PHED data are more appropriate in this instance because the operations of PCOs are so highly variable. A single study fails to represent such variability in exposure.

At baseline PPE, the following handler scenarios are acceptable:

- Scenario 6 applying to golf courses by groundboom;
- Scenario 8 applying to turf by handgun; and
- Scenario 13 PCOs mixing, loading, and applying 0.25 or 1 gallon of product formulated from a soluble powder by low pressure handwand.

Risks from the following handler scenarios can be mitigated by employing minimum PPE (baseline clothing plus chemical-resistant gloves and a PF 5 respirator):

- Scenario 3c mixing and loading liquid formulations for groundboom application to golf courses or turf;
- Scenarios 4 & 12 mixing, loading, and applying granules for drop-type spreader application to sod and golf courses;
- Scenario 6 applying to turf by groundboom;
- Scenario 13 PCOs mixing, loading, and applying 4 or 5 gallons of product formulated from a soluble powder by low pressure handwand;
- Scenario 14 PCOs mixing, loading, and applying 40 gallons of formulated product by backpack sprayer; and
- Scenario 21 mixing, loading, and applying granules to turf using a push-type spreader.

Risks from the following handler scenario can be mitigated by employing maximum PPE (double layer of clothing plus chemical resistant gloves and a PF 10 respirator):

- Scenario 1e mixing and loading soluble powder for handgun application to turf.

Risks from the following handler scenarios can be mitigated with engineering controls:

- Scenario 1c mixing and loading soluble powder for groundboom application to golf courses; and
- Scenario 5 applying to turf aerially.

**Table 10. Turf and Pest Control Operator (PCO) Handler Risk Assessment**

Scenario	Crop/ Use Site	Rate (lb ai/A)	Acres	Short- and Intermediate-term MOEs			
				Baseline <sup>1</sup>	Min PPE <sup>2</sup>	Max PPE <sup>3</sup>	Eng. Controls <sup>4</sup>
Mixer/Loader Exposure Scenarios							
(1c) Soluble Powder for Groundboom	Golf Course	5	40	1.5	10	19	270
(1e) Soluble Powder/Handgun	Turf	5	5	12	82	160	2200
(3c) Liquid/Groundboom	Golf Course	5	40	5.6	270	530	750
	Turf	5	80	3	130	270	370
(4) Granules/Drop-Type Spreader	Sod	5	80	28	130	259	2800
	Golf Course	5	40	56	260	520	2800
Applicator Exposure Scenarios							
(5) Aerial	Turf	5	350	na	na	na	120
(6) Groundboom	Turf	5	80	60	220	360	690
	Golf Course	5	40	120	430	720	1400
(8) Handgun	Turf	5	5	140	360	620	NF
(12) Granules/Drop-Type Spreader	Sod	5	80	39	180	340	2800
	Golf Course	5	40	78	350	680	2800
Mixer/Loader/Applicator Exposure Scenarios							
(13a) Soluble Powders/Low Pressure Handwand (PHED Data)	PCO (lb ai/gal)	0.088	0.25 gal	709.9	3343.2	6194.8	NF
			1 gal	177.5	835.8	1548.7	
			4 gal	44.4	208.9	387.2	
			5 gal	35.5	167.2	309.7	
			40 gal	4.4	20.9	38.7	
(13b) Wettable Powder/Low Pressure Handwand (MRID 40404823)	PCO (lb ai/gal)	0.08745	0.25 gal	242.6	1227.7	2211.2	NF
			1 gal	60.6	306.9	552.8	
			4 gal	15.2	76.7	138.2	
			5 gal	12.1	61.4	110.6	
(14) Backpack Sprayer	PCO	0.088	40 gal	na	280	470	NF
(21) Granules/Push-Type Spreader	Turf	5	5	35	91	170	NF

<sup>1</sup> Baseline: long-sleeved shirt, long pants, socks and shoes

<sup>2</sup> Minimum PPE: baseline clothing plus chemical-resistant gloves and a PF 5 respirator

<sup>3</sup> Maximum PPE: baseline clothing plus an additional layer of clothing such as coveralls, chemical-resistant gloves, and a PF 10 respirator

<sup>4</sup> Engineering controls: Closed cab tractor for application scenarios, or a closed mixing/loading system such as a farm closed mechanical transfer system for liquids or soluble packets

NF = Not feasible

### 3) Postapplication Occupational Risk

The postapplication occupational risk assessment considered exposure scenarios to workers entering treated sites in agriculture and exposure scenarios that can occur as a result of turf management activities. Workers may be exposed to acephate and its degradate methamidophos on a short-term or intermediate-term basis upon entering treated areas. All of the postapplication risk calculations for handlers completed in this assessment are included in the revised occupational and residential risk assessment dated September 15, 2000.

The Agency has incorporated dislodgeable residue data submitted by the registrant and new transfer coefficients to calculate restricted-entry intervals (REIs). These transfer coefficients were derived from Agency data and transfer coefficient studies submitted by the Agricultural Re-entry Task Force (ARTF) and summarized by OPP's Health Effects Division into an interim policy document (Policy 3.1) developed in August 2000.

In general, postapplication risk to workers from most agricultural uses of acephate is not of concern at the current 24 hour REI (Table 11). However, risk to workers exposed to treated cut flowers are of concern at the currently labeled REI of 24 hours. Risks are driven by the acephate degradate, methamidophos. MOEs are greater than 100 at day 2 after application for low exposure activities, at day 5 for medium exposure activities, and at day 9 for high exposure activities, such as harvesting. The current REI of 24 hours is of concern for workers who perform postapplication activities on cut flowers.

**Table 11: Occupational Postapplication Risk from Acephate Application.**

Exposure Activities	Days After Treatment at Which the MOE is $\geq$ 100					
	Acephate			Methamidophos		
	Low	Medium	High	Low	Medium	High
Berry, Low	0	na	na	0	na	na
Bunch/Bundle	0	0	0	0	0	0
Field Row Crop, Low/Medium	0	0	0	0	0	1
Cut Flowers	0	2	4	2	5	9
Non-Bearing Fruit Trees	0	na	na	0	na	na
Turf/Sod	0	na	1	0	0	na
Vegetable, "fruiting"	0	0	0	0	0	0
Vegetable, "head and stem Brassica"	0	0	0	0	0	0
Vegetable, "leafy"	0	0	0	0	0	1

## **B. Environmental Risk Assessment**

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the August 25, 1999, Environmental Fate and Effects Division RED Chapter for Acephate, available in the acephate public docket, and subsequent addenda. In response to comments submitted during Phases 3 and 5, the risk assessment was updated and refined.

In the Exposure and Risk Characterization sections of this chapter of the IRED, Risk Quotients (RQs) are given for several groups of species that may be affected by the use of acephate. RQs are calculated by dividing EECs by acute and chronic ecotoxicity values. Maximum EECs are used to assess acute risk, and typical EECs are used to assess chronic risk. RQs are then compared to OPP's levels of concern (LOCs) to analyze potential to cause adverse effects on nontarget organisms.

## **1. Environmental Fate and Transport**

### **a. Degradation and Mobility**

Aerobic soil metabolism is the main degradation process for acephate. Observed half-lives are less than 2 days under expected use conditions, producing the intermediate degradate methamidophos. Methamidophos is itself rapidly metabolized by soil microorganisms to carbon dioxide and microbial biomass (half-lives of < 10 days). Acephate is stable against hydrolysis except at high pH's (half-life at pH 9 of 18 days) and does not photodegrade. Acephate is not persistent in anaerobic clay sediment with a half-life of 6.6 days. The major degradates under anaerobic conditions are carbon dioxide and methane. No other significant amounts of anaerobic degradates have been found in laboratory tests.

Acephate is very soluble and very mobile under laboratory experimental conditions. Because acephate is not persistent under aerobic conditions, acephate is not expected to leach to groundwater. If any acephate were to reach ground water, it would not be expected to persist, due to its short anaerobic half-life. It appears that acephate and methamidophos are likely to be very mobile in soils.

### **b. Field Dissipation**

Acephate and its degradate methamidophos are not expected to persist in the field. Field studies conducted in Mississippi (tobacco on silt loam soil), California (bell peppers on silt loam soil), Florida (cauliflower on sand soil) and Iowa (soybeans on loam soil) found half-lives of 2 days or less with no detections of parent or the degradate methamidophos below a depth of 50 cm. Based on the vapor pressure of acephate, the Agency does not expect that volatilization from soil or water is a route of dissipation for either acephate or methamidophos.

### **c. Bioaccumulation**

Bioaccumulation of acephate residues is not of concern to the Agency. Laboratory studies showed that bioaccumulation of acephate in bluegill sunfish was insignificant.

## **2. Risk to Terrestrial Organisms**

### **a. Birds**

#### **1) Acute and Subacute Toxicity**

Avian studies indicate that acephate is moderately acutely toxic to birds (Oral LD<sub>50</sub> ranges from 51-500 mg/kg) and ranges from practically non-toxic to moderately toxic to birds on a subacute basis (Oral LD<sub>50</sub> ranges from 501 to 1000 ppm).

Avian studies indicate that methamidophos, a degradate of acephate, is highly to very highly toxic to birds on an acute basis (Oral LD<sub>50</sub> ranges from <10 to 50 mg/kg) and is slightly toxic to very highly toxic to birds on a subacute basis (Oral LD<sub>50</sub> ranges from <50 to 500 ppm).

## **2) Chronic Toxicity**

Avian reproduction studies indicate that when parents are fed between 5 and 80 ppm technical grade acephate, the survival of embryos and chicks are adversely affected. Effects seen in a study on northern bobwhite quail at 80 ppm include reduced body weight, number of eggs laid, eggs set, viable embryos, number of embryos alive at 3 weeks, number of normal hatchlings, and 14-day old survivors. Effects seen in a study on mallard ducks at 20 ppm include a reduced number of viable embryos and live 3 week embryos.

An avian reproduction study with technical grade methamidophos indicate that when northern bobwhite quail parents are fed 5 ppm, a reduction in egg thickness is seen. An avian reproduction study using methamidophos on mallard ducks showed no effect at greater than 15 ppm.

## **3) Avian Exposure and Risk Characterization**

Laboratory and exposure data indicate that there is little acute risk to birds from acephate itself (see Table 12 for calculated RQs). However, because acephate rapidly degrades to methamidophos in the environment and the degradate is highly toxic to birds, methamidophos may be responsible for the high acute risk to birds noted in reported incidents and field studies. The presented RQs are based on oral toxicity, and do not consider the highly toxic acute effects to birds from dermal and inhalation exposure.

Laboratory data indicate that the use of acephate may pose a high chronic risk to birds, both from acephate and its degradate, methamidophos. These data have shown that chronic exposure to acephate may decrease the viability of embryos and chicks, and chronic exposure to methamidophos may cause eggshell thinning. Further, literature data suggest that chronic exposure to acephate may disrupt the migratory patterns of adult birds.

The Agency expects that chronic risks to birds may be greater from the broadcast use of granular acephate formulations than from liquid formulations of acephate. Birds may be exposed to granular formulations by ingesting granules when foraging for food or grit, by walking on exposed granules, or by drinking water contaminated with acephate granules that degrade to methamidophos in the environment.

Field studies have shown that adverse effects from acephate occur one to two days after application of acephate; this delay can be interpreted as toxicity due to the degradate, methamidophos. Field studies and incidents indicate that the use of acephate may have a detrimental effect on birds, especially song birds.



Two incidents have been reported concerning an adverse impact to birds from acephate. Both incidents involved the death of birds following exposure to acephate from homeowner use.

**Table 12. Avian Risk Quotients for Acephate and Methamidophos**

Chemical and Formulation	Acute RQs	Acute High Risk LOC	Acute Restricted Use LOC	Chronic RQs	Chronic Risk LOC
Non-Granular Acephate	<0.1 to 0.4	0.5	0.2	<1 to 35.5	1
Granular Acephate	0.04 to 4.91			not calculated	
Methamidophos	0.14 to 8.19			1 to 40	

**b. Mammals**

**1) Acute and Chronic Toxicity**

Mammalian toxicity studies reviewed by the Agency indicate that acephate is characterized as moderately toxic to small mammals on an acute oral basis. However, for the degradate, toxicity studies indicate that methamidophos is highly toxic to small mammals on an acute oral and dermal basis.

**2) Mammalian Exposure and Risk Characterization**

Mammals are comparatively less sensitive to organophosphate pesticides than birds; however, field studies on acephate do show mortality and depressed cholinesterase levels. Again, because acephate degrades so quickly to methamidophos in the environment, it is likely that methamidophos causes the mortality seen from acephate applications. RQs are presented in Table 13 below. Field studies indicate that the use of acephate may have a detrimental effect on mammals, especially small animals.

Laboratory data indicate that acephate and its degradate may pose chronic risk to mammals by affecting the reproductive capacity of mammals (i.e., by reducing the viability of pups and body weight); however, there are no field data to corroborate this.

The Agency expects that chronic risks to mammals may be greater from the broadcast use of granular acephate formulations than from liquid formulations of acephate. Mammals may be exposed to granular formulations by ingesting granules when foraging for food, by walking on exposed granules, or by drinking water contaminated with acephate granules that degrade to methamidophos in the environment.

**Table 13. Mammalian Risk Quotients for Acephate and Methamidophos**

Chemical and Formulation	Acute RQs	Acute High Risk LOC	Acute Restricted Use LOC	Chronic RQs	Chronic Risk LOC
Non-Granular Acephate	<0.1 to 1.48	0.5	0.2	0.14 to 3.54	1
Granular Acephate	0.01 to 2.16			not calculated	
Methamidophos	0.1 to 21.8			0.3 to 12.2	

**c. Insects**

**1) Acute Toxicity**

Analysis of the results of honey bee acute contact studies indicate that acephate is highly toxic to bees and beneficial insects on an acute contact basis. One study indicated an LD<sub>50</sub> of 1.2 ug/honey bee. Further studies indicated that acephate is highly toxic to bees from two hours to 96 hours after foliar application at rates of 1 lb/A and from 2 hours to 24 hours at 0.5 lb ai/A rate.

EPA also reviewed a study that tried to determine a toxicity ratio of selectivity of acephate by comparing the sensitivity of beneficial predator insects to that of the pest tobacco budworm. The ratio is calculated using the LC<sub>50</sub> values for the pest divided by the LC<sub>50</sub> values for the beneficial insect and a ratio greater than 1 represents that acephate is more toxic to the predator than to the pest. Green lacewing had a calculated ratio of 6.4 and the ratio for the parasitic wasp was 10.0. Acephate is more toxic to the beneficial predator than the pest.

An acute contact toxicity study for methamidophos, a degradate of acephate, on bees indicates that methamidophos is highly toxic to bees on an acute contact basis. The LD<sub>50</sub> was 1.37 ug/bee.

**2) Non-Target Insect Exposure and Risk Characterization**

Acephate is highly toxic to honeybees and other beneficial insects. Honey bees and other beneficial insects will be exposed to acephate from use on vegetables, cotton, peanut, soybean, and ornamental plants. In addition, there are reported incidents of toxicity to bees resulting from acephate application. Based on this information, the Agency has a risk concern for beneficial and non-target insects from the use of acephate.

**3. Risk to Aquatic Organisms and Ecosystems**

**a. Freshwater Organism Toxicity**

**1) Fish Toxicity**

Acephate is considered practically nontoxic to slightly toxic to freshwater fish on an acute basis (LD<sub>50</sub> ranges from 50 to >100 ppm). Methamidophos, a degradate of acephate, is considered slightly toxic to freshwater fish on an acute basis (LD<sub>50</sub> ranges from 10 to 100 ppm). There are currently no chronic toxicity data available on fish.

**2) Freshwater Amphibian Toxicity**

Available data indicate that acephate is practically nontoxic to amphibians; therefore, the Agency has no risks of concern.

### **3) Freshwater Invertebrate Toxicity**

Acephate is considered practically non-toxic to moderately toxic to aquatic invertebrates on an acute basis ( $LC_{50}/EC_{50}$  ranges from 1.0 to greater than 100 ppm). Methamidophos, a degradate of acephate, is considered very highly toxic to aquatic invertebrates on an acute basis ( $EC_{50}$  are less than 0.1 ppm, methamidophos is categorized as. The guideline (72-2) is fulfilled (MRID 00041311, 00014110, 00014305).

Chronically, acephate affects daphnid reproduction with a NOAEC of 0.150 ppm, a LOAEC of 0.375 ppm, and an MATC of 0.237 ppm. Acephate caused reduction in the numbers of young at 0.375 ppm.

#### **b. Estuarine and Marine Organism Toxicity**

##### **1) Estuarine and Marine Fish Toxicity**

Acephate is considered practically non-toxic to slightly toxic to estuarine and marine fish ( $LC_{50}$  ranges from 10 ppm to greater than 100 ppm). Methamidophos is considered moderately toxic to estuarine/marine fish on an acute basis ( $LC_{50}$  ranges from 1 ppm to 10 ppm).

##### **2) Estuarine and Marine Invertebrate Toxicity**

Acephate is considered practically non-toxic to moderately toxic to estuarine/marine vertebrates on an acute basis ( $LC_{50}/EC_{50}$  ranges from 1.0 ppm to greater than 100 ppm). Methamidophos is considered moderately toxic to estuarine/marine invertebrates on an acute basis ( $LC_{50}/EC_{50}$  ranges from less than 0.1 ppm to 10 ppm).

Acephate effects mysid shrimp mortality with a NOAEC of 0.58 ppm, a LOAEC of 1.4 ppm, and an MATC of 0.90 ppm.

#### **c. Aquatic Exposure and Risk Characterization**

RQs calculated for acephate alone do not indicate high acute risks to fish and invertebrates; however, under certain environmental conditions (for example, high exposures in combination with elevated temperatures), there may be a concern for exposure to acephate because of its degradation to methamidophos. Although the degradate is only slightly toxic to freshwater fish, freshwater aquatic invertebrates are very sensitive. Furthermore, freshwater invertebrates appear to be more sensitive to methamidophos than estuarine or marine species (See Table 14). However, no incidents have been reported, and no field studies were conducted. Risks to freshwater and estuarine fish are expected to be minimal, based on available toxicity data.

The Agency believes that acute risks to aquatic ecosystems from the use of acephate and its degradate methamidophos will be minimal. Laboratory studies indicate that acephate itself

does not pose a high acute risk to aquatic ecosystems. However, as for aquatic organisms above, under certain environmental conditions, the use of acephate may result in risks to bivalves, invertebrates, and, indirectly, to fish. In addition, laboratory studies have shown the degradate methamidophos to be toxic to daphnids and blue shrimp. Other freshwater and estuarine invertebrate species tested in the laboratory do not appear to be as sensitive.

Chronic risks to aquatic ecosystems from the use of acephate and its degradate methamidophos are not of concern to the Agency. Information available on aquatic invertebrates show minimal chronic risk. No data are available on chronic risks to freshwater or estuarine fish; however, it is expected that effects on fish would be less than aquatic invertebrates. Data on chronic effects of methamidophos are not available. Although data on chronic effects of methamidophos are not available, chronic risk is not of concern because both acephate and methamidophos degrade rapidly in the environment.

Acephate is used in areas where runoff from agricultural fields could flow into estuaries. It is possible that acephate residues and methamidophos residues resulting from the use of acephate may be diluted to insignificant amounts by the time they reached any estuaries; in addition, acephate and/or methamidophos may degrade en route. However, the lack of information on dilution volumes and on the persistence of acephate residues in aquatic environments makes any conclusion uncertain. Areas where there could be a risk to marine and estuarine areas are the lower Rio Grande Valley in Texas, southern Florida, the Delmarva peninsula, and the North and South Carolina coasts. High amounts of rainfall in these areas exacerbate the risk to local estuarine habitats.

**Table 14. Acute Aquatic Organism Risk Quotients for Acephate (Aerial and Ground Application) and Methamidophos**

Organism	Acute RQs	Acute High Risk LOC	Acute Restricted Use LOC	Chronic RQs	Chronic LOC
<b>Acephate</b>					
Freshwater Fish	<0.05	0.5	0.1	No available data	1
Freshwater Invertebrate	<0.05 to 0.06			0.07 to 0.22	
Estuarine/Marine Fish	<0.05			No available data	
Estuarine/Marine Invertebrate	<0.05			0.02 to 0.10	
<b>Methamidophos</b>					
Freshwater Fish	<0.05	0.5	0.1	No available data	1
Freshwater Invertebrate	0.31 to 1.04				
Estuarine/Marine Fish	<0.05				
Estuarine/Marine Invertebrate	<0.05				

#### 4. Risk to Endangered Species

Endangered species LOCs except for fish (estuarine and freshwater) and estuarine invertebrates are exceeded for all uses of acephate. In addition, LOCs are exceeded for

endangered species of mammals, amphibians, birds, reptiles, insects, and freshwater invertebrates for the degradate methamidophos formed from all uses of acephate. The Agency's acute endangered species LOC for birds and mammals is 0.1; for aquatic animals is 0.05

The Agency consulted with the US Fish and Wildlife Service (FWS or the Service) on the corn use of acephate as part of the corn cluster analysis in 1983, the forest use in the forest cluster analysis in 1984, the rangeland/pastureland uses in the cluster analysis in 1984 and on several agricultural uses of acephate in the "reinitiation" of the cluster assessments in 1988. The resulting 1989 opinion found jeopardy to three bird species. The Service proposed Reasonable and Prudent Alternatives (RPAs) to avoid the likelihood of jeopardizing the continued existence of these species. In addition, the Service had Reasonable and Prudent Measures (RPMs) to reduce incidental take of two amphibians, five aquatic invertebrates and 19 fish species. There was also a formal consultation on the acephate product, Orthene 75S and its use on macadamia nut trees. The Service determined that the only species likely to be jeopardized by this use was the Hawaiian hoary bat. They provided several RPAs to remove the jeopardy determination. These consultations and the findings expressed in the Opinions, however, are based on old labels, uses, and application methods, less refined risk assessment procedures, and an older approach to consultation that is currently being revised through interagency collaboration.

EPA's current assessment of ecological risks uses both more refined methods to define ecological risks of pesticides and new data, such as that for spray drift. Therefore, the Reasonable and Prudent Measures (RPMs) in the Biological Opinion(s) may need to be reassessed and modified based on these new approaches.

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

#### **IV. Interim Risk Management and Reregistration Decision**

##### **A. Determination of Interim Reregistration Eligibility**

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

specific to an a.i.) to support reregistration of products containing acephate as the active ingredient.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the a.i. acephate, as well as an acephate-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient acephate, EPA has sufficient information on the human health and ecological effects of acephate to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that acephate products are eligible for reregistration provided that: (i) any current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the consideration of cumulative risk for the organophosphates supports a final reregistration eligibility decision. The Agency has also not fully considered risks associated with exposure to methamidophos, a degradate of acephate, resulting from acephate use. Methamidophos is a registered OP pesticide that is currently undergoing reregistration. Once the methamidophos IRED is complete, the Agency will determine whether the methamidophos exposure resulting from acephate use poses risk concerns.

Label changes are described in Section V. Appendix A lists the uses deemed eligible for reregistration by the Agency. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of acephate, and lists the submitted studies that the Agency found acceptable.

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

In addition, further mitigation of acephate uses may be necessary to reduce risks from methamidophos residues that result from acephate applications. This potential further mitigation will be discussed at the time the methamidophos interim RED is released.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For acephate, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. However, because this is an interim RED, the Agency may take any necessary further actions to finalize the reregistration eligibility decision for acephate after assessing the cumulative risk of the organophosphate class and after assessing risks from methamidophos residues resulting from the application of

acephate. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

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

If the Agency determines, before finalization of the RED, that any of the determinations described in this interim RED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this interim RED.

Acephate is registered for the control of cockroaches and fleas, which may cause or transmit diseases that are of public health concern. Therefore, any final Agency action to cancel or delete such acephate uses from product labeling may involve consultation with the Secretary, Department of Health and Human Services (HHS) under FIFRA section 4(n)(2). To facilitate the decision-making process on the residential indoor and outdoor uses of acephate and to commence the consultation process, the Agency contacted HHS's Centers for Disease Control and Prevention (CDC) and requested CDC input on the use of acephate to control public health pests, notably cockroaches in day care facilities, parks, and schools. On August 15, 2001, the CDC notified the Agency that they would be unable to provide advice on the role of acephate use to control these public health pests.

To ensure the public health issues associated with acephate are adequately considered as called for in FIFRA, the Agency intends to consult further with public health authorities before taking final Agency action to amend registrations of acephate. Under FIFRA section 6(f), the Agency provides a notice and comment opportunity for the public before finalizing a decision to cancel a registration or specific use of a pesticide. During this period, the Agency will consult with CDC and possibly other authorities, such as USDA's Animal and Plant Health Inspection Service, who has recently indicated to the Agency that they were interested in providing information on public health pest considerations in cases like acephate.

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

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process for Acephate. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Numerous letters (over 100) were received commenting on the acephate risk assessments during Phase 5 of the public process. These comments can be grouped into several categories, as described below.

Many comments were received on the benefits of acephate, primarily from nurseries and greenhouses and cotton growers. Comments noted that acephate is an economical, broad spectrum insecticide that is an important rotation tool in Integrated Pest Management (IPM) programs in greenhouses and nurseries, and that the current 24 hour REI is necessary for the use of acephate in cut flowers and non-bearing fruit trees. Cotton growers also noted that the 0.75 to 1.0 lb ai/A rate is necessary to control specific pests on cotton due to resistance development to other pesticides that are currently available.

Comments on the Ecological Risk Assessment discussed the drift deposition value of 15% that is used to determine EECs; the amount of acephate that degrades to methamidophos; regional variability in environmental conditions; cotton, tobacco, and turf use and usage estimates.

Comments on the dietary risk assessments discussed the refinement of the acute assessment and assumptions regarding food handling establishments, including percentages of establishments that are treated, the percentage of food in establishments that is exposed to residues and the levels of residues expected, and the average percentage of meals eaten at food handling establishments.

These comments have been addressed and the assessments refined as deemed appropriate by the Agency. Please see the response to comments documents available in the public docket for specifics on how the comments were addressed and the Agency's position on these issues.

## **C. FQPA Assessment**

### **1. "Risk Cup" Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate



the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to acephate is within its own “risk cup.” In other words, if acephate did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for acephate meet the FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to acephate “fit” within the individual risk cup. Therefore, the acephate tolerances remain in effect until a full reassessment of the cumulative risk from all organophosphates is completed.

## **2. Tolerance Summary**

In the individual assessment, tolerances for residues of acephate in/on plant and animal commodities [40 CFR §180.108 (a) and (b)] and in processed food [40 CFR §185.100] and feed commodities [40 CFR §186.100] are presently expressed in terms of the combined residues of acephate and its degradate methamidophos (number in parentheses in Table 15). Following evaluation of plant and animal metabolism studies, the Agency has determined that the residues that warrant regulation in plant, processed food and feed commodities are those that are currently regulated.

The Agency will propose that all acephate tolerances be expressed in terms of only acephate *per se* under 40 CFR §180.108. Residues of methamidophos resulting from acephate applications are more appropriately placed under the tolerance regulations for methamidophos as a pesticide [40 CFR §180.315 (c)]. This change is needed to achieve compatibility with CODEX in terms of residue definition.

Adequate field trial data are available to reassess the established tolerances for residues of acephate for the following commodities: beans (succulent and dry form); Brussels sprouts; cauliflower; celery; cottonseed; cranberries; lettuce (head); peanuts; peppers, and soybean; and for macadamia nuts, which is a regional registration. In addition, adequate poultry feeding data are available to reassess the established tolerances for residues of acephate in eggs and the fat, meat and meat by-products of poultry. Ruminant feeding data for acephate residues in milk and the fat, meat and meat by-products of cattle, goats, hogs, and horses are adequate, but the reassessment of these tolerances will be made when the requested residue data for cotton gin byproducts (a major livestock feed item) have been evaluated and maximum dietary burden is recalculated.

Based on available data, EPA will propose that the tolerance for cottonseed be lowered from 2 to 0.5 ppm and that the tolerance for mint hay be raised from 15 to 27 ppm. Tolerances

for grass (pasture and range) and grass hay should be revoked since these uses are no longer supported by the registrant. A tolerance for peanut hulls is no longer necessary since this commodity is not considered a significant livestock feed item according to Table 1 in OPPTS Guideline Number 860.1000, and was revoked in November 1997 (62 *FR* 66020). No changes in the established tolerances are needed for any other established tolerance for plant and animal commodities. The Agency has received residue data for acephate in/on cotton gin byproducts, and tolerances will be proposed once these data are evaluated.

Sufficient data are also available to reassess established tolerances in/on all food items resulting from the use of acephate as spot and crack and crevice treatment in food handling establishments; thus, no changes are recommended for this tolerance. Available cottonseed and soybean processing data, indicate that reductions of the cottonseed hulls and cottonseed meal tolerances are needed; from 4 to 1 ppm for cottonseed hulls and from 8 to 1 ppm for cottonseed meal. Finally, the Agency will propose that the tolerance for soybean meal be revoked, based on reevaluation of available soybean processing data. The data indicated that no concentrations of residues were observed; thus, acephate residues in soybean meal are not expected to exceed the RAC tolerance.

**Table 15. Tolerance Summary for Acephate.**

<b>Commodity</b>	<b>Current Tolerance, ppm (ppm)<sup>1</sup></b>	<b>Tolerance Reassessment (ppm)<sup>2</sup></b>	<b>Comment/ [Correct Commodity Definition]</b>
<b>Tolerances Listed Under 40 CFR §180.108 (a)</b>			
<b>Beans (succulent and dry form)</b>	3.0 (1)	3.0	Available data support the tolerance
<b>Brussels sprouts</b>	3.0 (0.5)	3.0	Available data support the tolerance
<b>Cattle, fat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Cattle, meat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Cattle, mbyp</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Goats, fat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Goats, meat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Goats, mbyp</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.

<b>Commodity</b>	<b>Current Tolerance, ppm (ppm)<sup>1</sup></b>	<b>Tolerance Reassessment (ppm)<sup>2</sup></b>	<b>Comment/ [Correct Commodity Definition]</b>
<b>Hogs, fat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Hogs, meat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Hogs, mby</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Horses, fat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Horses, meat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Horses, mby</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Milk</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Sheep, fat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Sheep, meat</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Sheep, mby</b>	0.1	to be determined	Reassessment will be made when submitted residue data for cotton gin byproducts (a major livestock feed item) have been evaluated.
<b>Cauliflower</b>	2.0 (0.5)	2.0	Available data support the tolerance
<b>Celery</b>	10 (1)	10	Available data support the tolerance
<b>Cottonseed</b>	2.0	0.5	Available data support lowering the tolerance
<b>Cranberries</b>	0.5 (0.1)	0.5	Available data support the tolerance
<b>Eggs</b>	0.1	0.1	Available data support the tolerance
<b>Grass (pasture and range)</b>	15	Revoke	This use is not supported by the registrant
<b>Grass hay</b>	15	Revoke	This use is not supported by the registrant
<b>Lettuce (head)</b>	10 (1)	10	Available data support the tolerance
<b>Mint hay</b>	15 (1)	27	Tolerance may be lowered following receipt of additional information pertaining to residues exceeding tolerance in/on samples from trials conducted before the update.
<b>Peanuts</b>	0.2	0.2	Available data support the tolerance.
<b>Peppers</b>	4.0 (1)	4.0	Available data support the tolerance
<b>Poultry, fat</b>	0.1	0.1	Available data support the tolerance
<b>Poultry, meat</b>	0.1	0.1	Available data support the tolerance

Commodity	Current Tolerance, ppm (ppm) <sup>1</sup>	Tolerance Reassessment (ppm) <sup>2</sup>	Comment/ [Correct Commodity Definition]
Poultry, mbyop	0.1	0.1	Available data support the tolerance
Soybeans	1.0	1.0	Available data support the tolerance
<b>Tolerance To Be Proposed Under 40 CFR §180.108 (a)</b>			
Cotton, gin byproducts	None	To be determined	The registrant has submitted data for cotton gin byproducts; the Agency will propose tolerance once the data are reviewed
<b>Tolerances Listed Under 40 CFR §180.108 (b)</b>			
Macadamia nuts	0.05	0.05	Available data support the tolerance
<b>Tolerances Listed Under 40 CFR §185.100</b>			
Food items in food-handling establishments as a result of spot and/or crack and crevice treatments	0.02	0.02	Available data support the tolerance
<b>Tolerances Listed Under 40 CFR §186.100</b>			
Cottonseed hulls	4	1.0	After reevaluation of available cottonseed processing data, adjustments may be required. Residues are not expected to exceed the reassessed cottonseed RAC tolerance
Cottonseed meal	8	1.0	
Soybean meal	4	Revoke	Reevaluation of available soybean processing data indicated that no concentrations of residues was observed. Acephate residues are not expected to exceed the RAC tolerance; therefore, no tolerance is needed for the processed commodity.

<sup>1</sup> Number in parentheses represents the current tolerance expression for methamidophos residues resulting from acephate applications.

<sup>2</sup> The term “reassessed” here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon consideration of cumulative risk for all of the organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment is required, that is supported by all of the submitted residue data.

The Agency will commence proceedings to revoke any necessary tolerances; modify the existing tolerances; and correct commodity definitions. The establishment of a new tolerance or raising tolerances will be deferred, pending the outcome of the cumulative assessment.

### 3. Codex Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of acephate in/on various plant and animal commodities. The Codex MRLs are expressed in terms of acephate *per se*. Harmonization of expression/definition between Codex MRLs and U.S. tolerances will be achieved when the residue definition of the U.S. tolerances is changed from combined residues of acephate and the metabolite methamidophos to acephate *per se*. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 16. Recommendations for compatibility are based on conclusions following reassessment of U.S. tolerances (see Table 15).

**Table 16. Applicable Codex MRLs and Applicable U.S. Tolerances for Acephate.**

Codex		Reassessed U.S. Tolerance, ppm <sup>1</sup>	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)		
Brussels sprouts	5	3.0	
Cattle fat	0.1	TBD	
Cattle meat	0.1	TBD	
Cauliflower	5	2.0	
Cotton seed	2	0.5	
Eggs	0.1	0.1	Compatibility exists
Lettuce, Head	5	10.0	
Milks	0.1	TBD	
Pig fat	0.1	TBD	
Pig meat	0.1	TBD	
Poultry fats	0.1	0.1	Compatibility exists
Poultry meat	0.1	0.1	Compatibility exists
Soya bean (dry)	0.5	1.0	

<sup>1</sup> TBD = To be determined; residue data remain outstanding.

Table 12 indicates that U.S. tolerances and the Codex MRLs for acephate are compatible for poultry fats, poultry meat, and eggs. The U.S. tolerance values for animal tissues (except poultry fat, poultry meat, and eggs), and milk have not been reassessed at this time because of outstanding data. Incompatibility of the U.S. tolerances and Codex MRLs remains for Brussels sprouts, cauliflower, cottonseed, lettuce (head), and soya bean (dry) presumably because of differences in agricultural practices in the U.S. upon which the residue data were developed.

#### 4. Analytical Method

Adequate methods are available for data collection and tolerance enforcement for plant and animal commodities. For tolerance enforcement, the Pesticide Analytical Manual (PAM) Vol. II lists two GLC methods (designated as Methods I and II) with thermionic detection for the determination of acephate (LOD = 0.01 ppm) and methamidophos (LOD = 0.04 ppm) residues in/on plant and animal commodities. PAM Volume II also lists a TLC method (designated as Method A) as a confirmatory method. Adequate radiovalidation data for the enforcement method using samples from the plant and animal metabolism studies have been submitted and evaluated. The enforcement method or modifications of the enforcement method were used for data collection purposes.

#### 5. Endocrine Disruptor Effects

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

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

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

#### **D. Regulatory Rationale**

The following is a summary of the rationale for managing risks associated with the current uses of acephate. The Agency has discussed these measures with the technical registrants and in all cases the registrants have agreed to the measures presented here. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

##### **1. Human Health Risk Mitigation**

###### **a. Dietary Risk Mitigation**

The acute and chronic dietary risks from acephate residues on food are below the Agency's level of concern at the 99.9th percentile of exposure with 33% of the aPAD and 17% of the cPAD used. The most highly exposed population subgroup is children 1 to 6.

The Agency is setting a Pre-Harvest Interval (PHI) of 1 day for lima bean to be consistent with the restricted entry interval (REI) for this use. No other changes to current PHIs are necessary.

Although the maximum estimated environmental concentrations of acephate from surface water sources barely exceeds the acute DWLOC for one population, children 1 to 6 years old, the Agency believes that the slight exceedance (6%) is likely to be an overestimate of acephate residues and is not of concern. The Agency believes the modeled estimates for exposure to acephate residues in surface water sources of drinking water overestimate the dietary risk for several reasons. First, the PRZM-EXAMS exposure model used to generate the EEC values for surface water, including the Index Reservoir and PCA modifications, is a Tier II model screening tool. Secondly, the environmental fate properties for acephate indicate that parent acephate residues in surface waters are unlikely to reach consumers because of the rapid aerobic dissipation in the environment. Third, the percent exceedance is minimal when considering the precision of the models used. The Agency is highly confident that surface water risks are not of concern nor is confirmatory data required at this time.

In addition, maximum estimated environmental concentrations of acephate from groundwater sources do not exceed the acute DWLOCs, and average estimated environmental concentrations of acephate from both groundwater and surface water sources do not exceed chronic DWLOCs.

Based on the above, risk mitigation is not currently required to address dietary risk. However, measures discussed below for the purpose of addressing occupational risks; i.e., the reduction in use rates for several crops, dropping aerial applications to turf, etc. (see Section IV.D.1.d.), will also serve to reduce risks from exposure to acephate in drinking water.

As discussed throughout this document, acephate degrades to another registered organophosphate pesticide, methamidophos. Methamidophos residues in food and water resulting from the use of acephate will be considered in the methamidophos interim RED. The Agency reserves the right to require further acephate mitigation measures to address risks from methamidophos residues resulting from acephate use. Any additional mitigation measures will be addressed when the methamidophos interim RED is completed.

## **b. Residential Risk Mitigation**

### **1) Residential Handler Risk**

Residential handler risks were considered for homeowners who mix, load, and apply acephate to home lawns and ornamental plants, such as roses. Handler risks were below the Agency's level of concern; thus, no risk mitigation is needed at this time.

### **2) Residential Postapplication Risk**

Postapplication risks to adults and children entering treated areas either indoors or outdoors (on treated lawns only), are of concern. To address those concerns, certain risk mitigation measures and label changes are necessary. These mitigation measures make it possible for EPA to conclude that acephate products are eligible for reregistration. The mitigation measures are as follows:

- Delete residential indoor uses.
- Delete all turfgrass uses (except golf course, sod farm, and spot or mound treatment for fire ant or harvester ant control).

#### Mitigation for Indoor Residential Postapplication Risk

Based on the indoor residential postapplication risk assessment for children and adults in homes, indoor residential risk is of concern. To mitigate risk to children and adults entering treated areas in homes, the indoor uses of acephate in residences must be removed from the label and product registrations must be cancelled. The technical registrants have notified us in writing of their intent to submit requests for voluntary cancellation of this use.

The Agency does not believe it is necessary to drop other indoor uses (i.e., within industrial, institutional, and commercial buildings, including restaurants, warehouses, stores, hospitals, hotels, manufacturing plants and ships). This is because the assumptions used to assess indoor residential risk are specific to homes (e.g., time inside the building). The Agency believes that risk to people entering industrial, institutional, and commercial buildings following acephate treatments is significantly less. Therefore, no further risk mitigation is necessary at this time for nonresidential uses.

#### Mitigation for Residential Lawn Postapplication Risk

The Agency is concerned about potential exposure to children on lawns treated with acephate and believes, in the context of this reregistration decision, changes to current product labels are necessary. The Agency's assessment showed significant residential post-application risks of concern for toddlers who are in contact with acephate-treated turf. As previously described, the assessment, combining dermal and various oral exposures, showed an aggregate MOE of 7.

While acknowledging that there are uncertainties in the hazard assessment in this case that may inflate what the risk to children might be, the existing acephate data support the Agency's conclusion that there is a risk of concern to children. Some uncertainties in the contribution of hand-to-mouth exposures to total exposure appear to make the estimate less reliable than the Agency would prefer. To explore these uncertainties the Agency conducted a review of the exposure assessment. A sensitivity analysis of the post-application risk assessment revealed that of the four types of exposure occurring to children crawling or playing on lawns, the hand-to-mouth part of the exposure assessment was the greatest contributor (see August 1, 2001, from HED titled "*Acephate - Sensitivity Analysis for Turf Risk Assessment*"). By varying the values of key input variables, most of which depend on relatively well established, peer-reviewed empirical observations of toddler behavior, the Agency found that the aggregate MOEs ranged from 7 to 224. Results at the upper end of the range were only attainable, however, when assuming the input variables were all at the lowest ranges. When considering central tendency inputs, the Agency still finds MOE values less than 100. Thus, even though the state-of-the-art of such assessments is still relatively basic, the sensitivity analysis shows that there is little doubt that young children are likely to be exposed at levels showing risks of concern.

Thus, after considering the uncertainties associated with the toddler risk assessment, the Agency is still concerned about the MOE estimate. Other factors, most notably the persistence of acephate on lawns, corroborate the risk concern and lead the Agency to conclude that any restrictions less than dropping the use patterns would make it difficult to make safety and reregistration eligibility findings. With more data on the ability of acephate residues to transfer from treated lawns to the hands or objects, the Agency may reach a different conclusion and find it unnecessary to take far-reaching actions on the results from this assessment. Absent that information, and mindful of the assessment's uncertainties, the Agency finds it prudent to reduce exposure to the maximum extent possible in line with the Agency's goal of reducing pesticide exposure to children.



The Agency discussed the potential risk concerns with the technical registrants and was able to reach consensus on the single most practical step to reduce exposure to children. The registrants have agreed to drop all formulations used on residential turf. The net effect is that all turfgrass uses will be dropped, except golf course, sod farm, and fire ant or harvester ant (mound treatment) uses. The technical registrants have notified us in writing of their intent to submit requests for voluntary cancellation of this use.

In addition, the Agency is establishing a PHI of 3 days for sod farm turfgrass so that any remaining residues in newly established lawns do not pose residential risks. After 3 days, the Agency does not believe residues are high enough to pose a risk concern for children or adults.

#### Mitigation for Recreational Postapplication Risk

Recreational postapplication risks to child golfers or adult golfers from the use of acephate are not of concern to the Agency; therefore, no mitigation is necessary at this time.

#### **c. Aggregate Risk Mitigation**

Following the deletion of certain key residential uses to mitigate residential risk, aggregate risk from acephate is not of concern to the Agency. Therefore, no further risk mitigation measures are necessary to address aggregate risk.

#### **d. Occupational Risk Mitigation**

Several occupational handler scenarios are not of concern at baseline levels of PPE; therefore, no risk mitigation is necessary at this time in order for these uses to remain eligible for reregistration. These scenarios are described in Section III.A.5. of this document.

In addition, pasture uses of acephate have previously been deleted; therefore, no mitigation is necessary. Although the consumer market includes liquid formulations, the Agency assumes that professional applicators do not use these products. These products are not suited for the types and sizes of applications that would be necessary for commercial and agricultural applicators. However, other occupational scenarios are of concern, and explained below in the Agricultural Handler Risk, PCO/Turf Risk, and Postapplication Occupational Risk sections.

#### Mitigation for Agricultural Handler Risk

For agricultural uses of acephate, the following bulleted risk mitigation measures and label changes are necessary in order to reduce mixer/loader and applicator risk in order for acephate products to be eligible for reregistration. These mitigation measures are explained in more detail below.

- Formulate all soluble powder formulations into water soluble bags, except for soluble powders sold for fire ant, harvester ant, or hopper box seed treatment uses.

- Limit the 1 lb ai/A aerial application rate to cotton grown in California and Arizona; reduce the maximum aerial application rate for cotton to 0.75 ai/A for all other areas of the United States.
- Delete aerial applications to turf.
- Require enclosed cockpits for all other aerial applications.
- Reduce maximum sod farm application rates (non-granular formulations) to 3 lb ai/A.
- Reduce maximum golf course turf application rates (also non-granular formulations) to 4 lb ai/A.
- Reduce maximum application rates for greenhouse floral and foliage plant crops, and outdoor floral and ground covers to 1 lb ai per 100 gallons water (not to exceed 0.75 lb ai/A for cut flowers and 1.0 lb ai/A for other ornamentals).
- Delete the use of low pressure handwand to apply acephate to trees, shrubs, and outdoor floral, and for the control of wasps.
- Delete the use of granular formulations to be applied by belly grinder, shaker can, or by hand to tress, shrubs, and 12" pots.
- Add personal protective equipment to the end use product labels for workers who mix and load, and/or apply acephate, as discussed in detail in Section V of this document.
- Require mechanical flagging for aerial applications.

The use of water soluble packaging, or other equivalent engineering control, is required for soluble powder formulations of acephate. This risk mitigation measure reduces mixer loader risks below the Agency's level of concern for all uses of the soluble powder formulations of acephate (Scenario 1a - 1h), except for use at the 1 lb ai/A rate on 1200 acre field crops (i.e., cotton). The MOEs of concern for the soluble powder are driven by inhalation exposure (inhalation MOEs are about half the dermal MOEs). The reduction in sod farm and ornamental use rates discussed above also decreases mixer loader and applicator risks to levels not of concern.

Equivalent engineering control methods can include the formulation of acephate into a soluble pellet formulation. Valent, one of the technical registrants of acephate, markets a patented 97% ai soluble pellet formulation that is less dusty than the standard soluble powder formulation and appears to act as an engineering control. The soluble pellet is specifically formulated to require less handling than the soluble powder and to minimize dust exposure. The patent for this formulation supports these claims. In addition, Valent is currently conducting confirmatory exposures studies to demonstrate the reduced risk from the soluble pellet formulation.

MOE calculated for the 1 lb ai/A rate and at the 0.75 lb ai/A rate for use of acephate in cotton considering engineering controls are 46 and 69, respectively, and driven by inhalation exposure. Both of these rates are above the Agency's level of concern. However, the assumptions used to calculate these MOEs; specifically, the use of 1200 acres per day continuously in conjunction with the maximum rates misrepresents how acephate is used in actual practice. The Agency understands that the maximum rate is not frequently used by cotton growers (only 25% of the total treated cotton acres), and the opportunity for continuous exposure to the maximum rate applied to 1200 acres per day is unlikely. Therefore, the Agency feels that these numbers are highly conservative and current use practices considering the 1 lb ai/A and 0.75 lb ai/A rate would often, in practice, not result in risks of concern.

In addition, acephate use on cotton at the 1 lb ai/A rate in California and Arizona and at the 0.75 ai/A rate in other parts of the country to control tarnished plant bug, stink bug, and flea beetle populations in late season cotton is supported by benefits information received from growers and extension agents. The Agency agrees that the 0.5 lb ai/A rate is not sufficient to control these pests. Following the discovery of Bt cotton and the advent of the Boll Weevil Eradication Program, the number of insecticides used on cotton to control bollworm and boll weevil have diminished considerably, and the number of applications per season have decreased from as many as 12 to as few as 2 or 3. Because of the decrease in the number of applications, and the number of different insecticides used that incidentally controlled tarnished plant bugs, stink bugs and flea hoppers, these insects have been left unchecked. For example, prior to the Bt cotton and the BWE program, stink bug infestations were spotty at best; however, since they have been left unchecked they are usually found throughout the field. The brown stink bug is especially difficult to control due to resistance.

Handlers applying acephate aerially require the use of engineering controls (enclosed cockpit) to mitigate risk. The registrants have agreed to delete aerial application to turf.

The technical registrants have agreed to drop the use of acephate low pressure handwand to trees, shrubs, and outdoor floral, and to control wasps in order to mitigate risks to handlers mixing, loading, and applying acephate by that method.

Baseline clothing plus gloves must be worn to mitigate risks to workers applying acephate by backpack sprayer to trees, shrubs, and outdoor floral; for use against wasps; for use against fire ants; and to mitigate risks to workers applying acephate by high pressure handwand.

The Agency believes that risks are acceptable at baseline PPE for mixing and loading product for use in an aerosol generator and initiating the production of aerosol, or initiating a total release aerosol can is acceptable at baseline PPE.

In order to mitigate risks to handlers applying acephate using a tree injection system, the Agency is requiring baseline PPE plus chemical resistant gloves. In addition, the Agency finds it necessary to require that these products be packaged in low exposure application devices that also serve as end use product packing and act as a closed system. Additionally, the Agency recognizes benefits to the environment from the tree injection system. By targeting the treated tree individually, the method of application appears to place less chemical into the environment. It also may pose less risk to handlers since the amount of chemical handled is less than conventional methods of application to trees.

To mitigate risks to workers mixing, loading, and applying acephate granular formulations by belly grinder, shaker can, and by hand, the registrants have agreed to delete this formulation for all uses except for use against fire ants by shaker can and by hand (both of these scenarios are adequately addressed by baseline PPE because of the low volume of product handled).

To mitigate exposure and risks to workers planting tobacco seedlings while simultaneously applying a transplant water solution of acephate by injection into the soil using a mechanical transplant system, the following label language is required:

"Transplant-water applications should be made using mechanical transplant equipment only. Using such equipment, the insecticide/water mixture is mechanically applied directly into the soil along with the transplanted plants."

#### Mitigation for Pest Control Operator/Turf Use Risk

For turf and PCO uses of acephate, the following bulleted risk mitigation measures and label changes are necessary in order for acephate products to remain eligible for reregistration. These mitigation measures are explained in more detail below.

- Delete aerial applications to turf.
- Delete the application of acephate via low-pressure handwand for perimeter treatment by PCOs.
- Reduce maximum application rates for sod farm applications (non-granular formulations) to 3 lb ai/A.
- Reduce maximum application rates for golf course turf application (non-granular formulations) to 4 lb ai/A.
- Add personal protective equipment to the end product labels for workers who mix and load, and/or apply acephate, as discussed below and in detail in Section V of this document.

The use of water soluble packaging, or equivalent engineering controls, is required for soluble powder formulations of acephate. This risk mitigation measure reduces mixer loader risks for all turf and PCO uses of the soluble powder formulations of acephate. The reduction in sod farm and golf course use rates mentioned above also decreases mixer loader and applicator risks.

To mitigate risks from the mixing, loading, and applying of granules by drop-type spreader to sod and golf courses, the technical registrants have agreed to require the use of minimum PPE. MOEs are 130 and 260, respectively, at this level of PPE. Aerial application to turf will be deleted because of risks to mixer/loaders supporting aerial applications. This action will have minimal impact on the sod and turf sector because aerial application to sod and turf is uncommon.

Risks to handlers applying acephate formulated into a liquid by groundboom to sod is mitigated by the reduction in application rates from 5 lb ai/A to 3 lb ai/A. This rate reduction results in an MOE of 84 at baseline PPE, driven by inhalation exposure. This MOE is slightly above the Agency's level of concern. However, the Agency believes that, in the interest of clarity, baseline PPE is acceptable. Since sod and golf course uses are likely to be on the same end product label, and golf course use requires only baseline PPE, to have conflicting PPE on the label could result in confusion to the user. In addition, the Agency understands that sod farms and golf courses typically treat their own acreage. Since this assessment is based on an intermediate term endpoint (7 to 30 days), the fact that applicators treating their own farms will likely not treat 80 acres a day for more than a couple consecutive days. This means that the calculated MOEs are likely conservative.

In order to mitigate risks to handlers applying granular acephate to turf with a push-type spreader at 5 lb ai/A, the Agency is requiring minimum PPE. At this rate, the calculated MOE is 91 (driven by dermal exposure). This number is calculated assuming that 5 acres of turf are treated per day. The Agency understands that granules are usually only applied as a spot treatment for specific pests; therefore, it is unlikely that applicators will treat 5 acres a day for more than a few consecutive days. In addition, this assessment is based on an intermediate term endpoint that relies on a 21-day dermal exposure study during which no toxicological effect was seen. Therefore, the Agency has no risks of concern if minimum PPE is employed for this application method and use.

To mitigate risks to PCOs mixing, loading, and applying acephate by low pressure handwand, the technical registrants have agreed to prohibit the use of a low pressure handwand method of application for perimeter treatment, since this use is the only PCO use that could result in the application of 40 gallons of formulated product in one day. To do this, the statement “Do not apply using low pressure handwand equipment” will appear on appropriate product labels associated with the perimeter treatment use. In addition, to mitigate risks from PCOs mixing, loading and applying acephate by low pressure handwand to trees, shrubs, and outdoor floral and for control of wasps, these uses are being cancelled for application in low pressure handwand equipment.

To mitigate risks from PCOs mixing, loading and applying acephate by low pressure handwand in the 4 and 5 gallon per day scenarios, the Agency is requiring minimum PPE. MOEs at this level of PPE are 209 and 167, respectively.

Risks to PCOs mixing, loading, and applying acephate by backpack sprayer are being mitigated by requiring baseline clothing plus gloves. In addition, the Agency believes the extruded pellet formulation will mitigate mixer/loader exposure to a level not of concern.

In order to mitigate risks to PCOs using acephate as a crack and crevice treatment or as an injection treatment, the Agency is requiring the use of baseline PPE and chemical resistant gloves while preparing and applying the product. The Agency believes that since designated containers are provided with the product for the purpose of mixing and loading, and the label requires the use of gloves, exposures will not be of concern.

#### Mitigation for Postapplication Occupational Risk

To mitigation postapplication occupational risk from acephate, the following bulleted risk mitigation measure and label changes are necessary in order for acephate products to remain eligible for reregistration. These mitigation measures are explained in more detail below.

- Reduce maximum application rates for greenhouse floral and foliage plant crops, and outdoor floral and ground covers to 1 lb ai per 100 gallons water not to exceed 0.75 lb ai/A for cut flowers and 1.0 lb ai/A for other ornamentals.
- All crops will require a 24 hour REI

Based on the risk assessment, there are calculated postapplication occupational risks above the Agency’s level of concern for workers entering and working in areas treated with acephate for cut flower use at the current REI of 24 hours. The cut flower MOEs for residues of

methamidophos resulting from acephate application at the current 24 hour REI are 97 (low exposure tasks); 61 (medium exposure tasks); and 35 (high exposure tasks). Low exposure tasks are irrigating, scouting, thinning, or weeding immature or low foliage plants. Medium exposure tasks are irrigating or scouting mature or high foliage plants. High exposure tasks are hand harvesting, pruning, thinning, and pinching. MOEs are greater than 100 at REIs of 2 days, 5 days, and 9 days, respectively.

To mitigate the postapplication risk to people working in cut flowers after treatment with acephate, maximum application rates for greenhouse floral and foliage plant crops, and outdoor floral and ground covers should be reduced to 1 lb ai per 100 gallons water not to exceed 0.75 lb ai/A for cut flowers (and 1.0 lb ai/A for other ornamentals). Considering this rate reduction, MOEs for high exposure tasks are 149 (acephate residues) and 99 (methamidophos residues) at the current 24 hour REI. These are not of concern.

The Agency believes that some of the assumptions used to determine MOEs for postapplication activities are conservative, and represent a worst-case exposure scenario. For example, gloves were not considered when the numbers were calculated because gloves are not required for reentry activities under the WPS; however, workers reentering to perform high exposure tasks such as pruning and thinning will likely wear gloves because of the nature of these activities. Based on this uncertainty and the rate reduction agreed to by the registrants, the Agency feels that the calculated REIs are conservative and that actual postapplication occupational risks are even less. A 24 hour REI will apply for all crops.

## **2. Environmental Risk Mitigation**

For all outdoor uses of acephate, the following measures will reduce environmental risks from the uses of acephate. These measures make it possible for the Agency to conclude that acephate products remain eligible for reregistration.

- Establish minimum spray intervals for all agricultural crops of 3 days for application rates up to 0.5 lb ai/A and of 7 days for application rates greater than 0.5 lb ai/A.
- Reduce seasonal maximum use for cotton from 6 to 4 lb ai/A
- Reduce aerial cotton use rates
- Delete granular formulations for residential turf uses, and use on ornamental trees and shrubs and in 12 inch pots.
- Reduce turf application rates for sod and golf courses.
- Require labeling to protect honeybees.
- Require labeling to reduce the potential for spray drift.

Granular formulations are of increased risk to birds, and the reduction in the amount of granular formulation available to birds in the environment helps to mitigate the risk to birds. The remaining granular turf application is a spot treatment application; therefore, the lack of a broadcast granular on residential turf will help to reduce exposure to granular formulations.

The rate reductions discussed here also help to reduce the amount of product available in the environment for ecological exposure. However, these mitigation measures do not address all of the Agency's ecological risk concerns.

### **3. Labeling**

Other use and safety information need to be placed on the labeling of all end-use products containing acephate, in addition to the mitigation measures listed above and other existing label requirements. For the specific labeling statements, refer to Section V of this document.

The Agency reserves the right to require additional label amendment to mitigate risks from methamidophos residues resulting from acephate applications. Any further amendments will be discussed in the methamidophos interim RED.

#### **a. Endangered Species Statement**

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

The Endangered Species Protection Program as described in a *Federal Register* notice (54 *FR* 27984) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at [www.epa.gov/espp](http://www.epa.gov/espp). A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the *Federal Register* before the end of 2001.

#### **b. Spray Drift Management**

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

Until EPA decides upon, and publishes the final label guidance for spray, and dust drift, registrants (and applicants) may choose to use the statements proposed in the draft PR notice. Registrants should refer to, and read the draft PR notice to obtain a full understanding of the proposed guidance, and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

For purposes of complying with the deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.

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

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

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

“For orchard and vineyard airblast applications, do not direct spray above trees and vines, and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side.”

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

For overhead chemigation:

“Apply only when wind speed is 10 mph or less.”

On all product labels:

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



For products applied as dusts—all affected products, except home and garden products:

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

“For ground rig applications, apply product no more than 4 feet above the ground or the crop canopy, and only when wind speed is 10 mph or less at the application site as measured by an anemometer.”

“For orchard and vineyard ground applications, do not direct dust above trees and vines, and shut off application at row ends, and toward outer rows. Apply only when wind speed is 3 - 10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side.”

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

On all product labels:

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

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

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

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

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

“Do not allow this product to drift.”

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

## V. What Registrants Need to Do

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

For products containing acephate, registrants need to submit the following items for each product within eight months of the date of the PDCI:

- (1) an application for reregistration (EPA Form 8570-1, filled in, with a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document);
- (2) five copies of the draft label incorporating all label amendments outlined in Table 17 of this document;
- (3) responses to the generic and/or product specific Data Call-Ins (DCIs) as instructed in the enclosed DCIs;
- (4) two copies of the Confidential Statement of Formula (CSF); and
- (5) a certification with respect to data compensation requirements.

Note that the first set of required responses for the product-specific DCI is due 90 days from the receipt of the DCI. The second set of required responses is due eight months from the date of the DCI. For questions about product reregistration and/or the product-specific DCI, please contact Bonnie Adler at (703) 308-8523.

For the generic DCI, the following items are due:

- (1) DCI response form, due 90 days from the receipt of the DCI;
- (2) Registrant response form, due 90 days from the receipt of the DCI; and
- (3) the actual generic data in response to the DCI.

### A. Manufacturing Use Products

#### 1. Additional Generic Data Requirements

The generic data base supporting the reregistration of acephate for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

#### Product Chemistry Data

830.7050      *UV/Visible Absorption*

## Toxicology Data

### *870.7485 (85-1) Rat Metabolism*

The only toxicology data gap currently is the metabolism study with rats. The existing studies, MRIDs 00014994 and 00014219 provide information on the metabolism of acephate by the rat, but do not satisfy the guideline requirements.

## Occupational Data

### *875.1100 Dermal Exposure Outdoor*

### *875.2400 (133-3) Dermal Passive Dosimetry Exposure*

An exposure study to determine the effects of the acephate extruded pellet formulation to mixer/loaders is required. MRID 45597001 has been submitted to fulfill this data requirement. This study is in review.

### *875.1700 Product Use Information*

Information on fogging/aerosol generator uses of acephate needs to be provided (e.g., target application concentrations, routine venting procedures, etc.).

## Environmental Fate and Ecological Effects Data

### *835.2120 (161-1) Aqueous Hydrolysis*

The data requirement is partially fulfilled (pH 5 and 7); data remain outstanding for the aqueous hydrolysis of acephate at pH 9.

### *835.4300 (162-4) Aerobic Aquatic Metabolism*

The data requirement for aerobic aquatic metabolism is not fulfilled.

### *835.1240 (163-1) Leaching and Adsorption/Desorption*

The data requirement for mobility of unaged and aged acephate is not satisfied.

### *850.4100 to 850.4250 (122-1 and 123-1) Non-Target Seed Germination/Seedling Emergence; Vegetative Vigor*

The guideline is not fulfilled.

## Residue Chemistry Data

### *835.1850 (165-1) Confined Rotational Crop*

Preliminary data were submitted pertaining to confined rotational crops (MRID 40504816). A new study was submitted to fill this data requirement (MRID 40874101), and this study is in review.

### *860.1300 (171-4) Nature of the Residue - Plants and Livestock*

The registration requirements for plant metabolism are partially fulfilled. To upgrade the metabolism studies, information must be submitted providing the dates of analysis of samples (bean, lettuce, and cotton) and indicating that the metabolite profile in cotton did not change over the intervals during which samples were stored.

The registration requirements for animal metabolism are partially fulfilled. The submitted poultry metabolism study is upgradable. Data must be submitted demonstrating that the metabolic profile of radioactive residues in poultry muscle did not change over the duration of the study.

## Current DCIs

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. Registrant responses are under review.

## **2. Labeling for Manufacturing Use Products**

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 17 at the end of this section.

### **B. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

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

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

## **2. Labeling for End-Use Products**

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 17 at the end of this section.

### **C. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this interim RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; Federal Register, Volume 56, No. 123, June 26, 1991.

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

### **D. Labeling Changes Summary Table**

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

**Table 17: Summary of Risk Mitigation Labeling Changes for Acephate**

Description	Risk Mitigation Labeling	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	“Only for formulation into an insecticide for the following use(s)” <i>[fill blank only with those uses that are being supported by MP registrant]</i> .	Directions for Use
	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the IRED and Agency Label Policies	<p><b>“Environmental Hazards”</b></p> <p>"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) 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 Water Board or Regional Office of the EPA."</p>	Precautionary Statements

Description	Risk Mitigation Labeling	Placement on Label
End Use Products Intended for Occupational Use (WPS Uses only on the Label or WPS Uses and Non-WPS Uses on the Label)		
Handler PPE requirements (all formulations)	<p>Note the following information when preparing labeling for all end use products:</p> <p>For <b>sole-active-ingredient</b> end-use products that contain acephate, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For <b>multiple-active-ingredient</b> end-use products that contain acephate, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	Handler PPE Statements

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Wettable Powder Formulations not packaged in Water Soluble Packaging (only products applied dry to ant mounds or hopper boxes or applied as pastes for crack and crevice treatments are eligible for reregistration without water soluble packaging).</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators applying as a paste for crack and crevice treatments.”</li> </ul> <p>“In addition, mixers and loaders supporting hopper box seed treatments must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>



Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Wetttable Powder Formulations Packaged in Water Soluble Bags. (All products with uses other than those listed above must be packaged in water soluble packaging to be eligible for reregistration).</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators using hand-held application equipment”</li> </ul> <p>“In addition, applicators using low pressure hand wand application equipment must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p>“See engineering controls for additional requirements”</p> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Soluble Pellet Formulations (Soluble Pellet Formulations must be as described in the acephate IRED)</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators using hand-held application equipment”</li> </ul> <p>“In addition, all mixers and loaders and all applicators using low pressure hand wand application equipment must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C* <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p>“See engineering controls for additional requirements.”</p> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Granular Formulations</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves”</li> </ul> <p>“In addition, mixers, loader and applicators supporting or making broadcast applications to turf must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for products applied as a total release aerosol or by aerosol generator.</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks,</li> <li>- chemical resistant gloves.”</li> </ul>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the IRED for products applied in a tree injection system</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves”</li> </ul>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>	<p>Precautionary Statements: Immediately following the PPE requirements</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>Engineering Controls for the wettable powder formulations packaged in water soluble bags that meet the specifications of the WPS</p>	<p><b>“Engineering Controls”</b></p> <p>“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <p>-- wear the personal protective equipment required above for mixers/ loaders, and</p> <p>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the following PPE: coveralls, chemical-resistant footwear and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</p> <p>"Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."</p> <p>“The use of human flaggers is prohibited.”</p> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following PPE and User Safety Requirements.</p>
<p>Engineering Controls for Soluble Pellet formulations</p>	<p>"Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."</p> <p>“The use of human flaggers is prohibited.”</p>	<p>Precautionary Statements: Immediately following PPE and User Safety Requirements.</p>

<b>Description</b>	<b>Risk Mitigation Labeling</b>	<b>Placement on Label</b>
Engineering Controls for Granular Formulations	“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)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”	Precautionary Statements: Immediately following PPE and User Safety Requirements.
User Safety Recommendations	<p><b>“User Safety Recommendations”</b></p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements: Immediately following Engineering Controls</p> <p>Must be placed in a box</p>

Description	Risk Mitigation Labeling	Placement on Label
Environmental Hazards	<p><b>“Environmental Hazards”</b></p> <p>“For terrestrial uses, 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 cleaning equipment or disposing of equipment washwaters.”</p> <p>“Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.” <i>(Use this statement only for products applied as seed treatments)</i></p> <p>“This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.”</p> <p>"This pesticide is toxic to birds"</p>	<p>Precautionary Statements: Immediately following the User Safety Recommendations</p>

Description	Risk Mitigation Labeling	Placement on Label
Restricted-Entry Interval	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.”	Directions for Use, Agricultural Use Requirements Box
Early-Entry Personal Protective Equipment (PPE) established by the RED.	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>- coveralls</li> <li>- chemical-resistant gloves made of any waterproof material</li> <li>- shoes plus socks”</li> </ul>	Directions for Use, Agricultural Use Requirements Box
Entry Restrictions for products applied as sprays that have Non-WPS uses on the label	“Do not enter or allow others to enter until sprays have dried”	Directions for Use in the Non-Agricultural Use Requirements Box.
Entry Restrictions for granular products that have Non-WPS uses on the label	“Do not enter or allow others to enter until dusts have settled”	Directions for Use in the Non-Agricultural Use Requirements Box.
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Direction for Use directly above the Agricultural Use Box.



Description	Risk Mitigation Labeling	Placement on Label
<p>Other Application Restrictions (<i>products applied as sprays</i>)</p>	<p><b>Application Rate Restrictions (Registrants must revise labels to reflect the following):</b></p> <p><u>Aerial Applications on Cotton:</u> Limit 1 lb a.i/A to cotton grown in California and Arizona. Limit 0.75 a.i/A for all other areas of the United States.</p> <p><u>Prohibit Aerial Applications to Turf:</u> Remove instructions for aerial application to turf and add the following statement: “Aerial applications to turf are prohibited.”</p> <p><u>Maximum Application Rates for Sod and Golf Course Turf:</u> Limit 3 lbs ai/A for Sod Farms. Limit 4 lbs ai/A for Golf Course.</p> <p><u>Maximum Application Rates for specified Greenhouse and Outdoor ornamental:</u> Limit 1 lb ai/A per 100 gallons of water (not to exceed 0.75 lbs ai/A for cut flowers and 1.0 lbs ai/A for all other ornamentals).</p> <p><b>Application and Preharvest Interval Restrictions (Registrants revised labels to reflect the following):</b></p> <p><u>Application Intervals for all agricultural crops:</u> Establish spray intervals of 3 days for applications rates up to 0.5 lb ai/A and 7 days for application rates greater than 0.5 lb ai/A.</p> <p><u>Pre-harvest Interval for Sod Farms:</u> Establish a 3 day pre-harvest interval (PHI) for harvesting sod.</p>	<p>Directions for Use</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>Other Application Restrictions (products applied as sprays) <i>continued</i></p>	<p><b>Use Deletions: (Registrants revised label to remove or prohibit use on the following):</b></p> <p><u>Indoor Residential Sites:</u> Delete all instructions for indoor residential applications. For use at commercial, institutional, and industrial sites only. Add a label statement prohibiting the deleted use, such as "Not for indoor residential use."</p> <p><u>Remove Specified Turf Sites:</u> Remove all instructions for use on turf grass (except for golf course, sod farm and spot or mound treatment for fire ant and harvester ant control). Add a label statement prohibiting the deleted use, such as "Use limited to sod farms and golf courses, except when applying by mound or spot treatment for fire ant and harvester ant control."</p> <p><b>Equipment Restrictions:</b></p> <p><u>Aerial Applications:</u> Remove instructions for aerial application to turf and add the following statement: "Aerial applications to turf are prohibited."</p> <p><u>Low Pressure Handwand:</u></p> <p><i>General Use Instructions:</i> "Do not apply using low pressure handwand equipment"</p> <p><i>Pest Control Operator Use Instructions:</i> "The use of low pressure handwand equipment for perimeter or wasp treatments is prohibited."</p>	<p>Directions for Use</p>

<b>Description</b>	<b>Risk Mitigation Labeling</b>	<b>Placement on Label</b>
Other Application Restrictions (granular products)	<p><b>Equipment Restrictions:</b></p> <p>“Applications to trees, shrubs and potted plants by hand or hand-held application equipment is prohibited.”</p>	Directions for Use

Description	Risk Mitigation Labeling	Placement on Label
<p>Spray Drift Restrictions/Drift Language (<i>All products as sprays</i>)</p>	<p>“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”</p> <p>“For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”</p> <p>“For airblast applications, direct spray above foliage and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 –10 mph at the application site as measured by an anemometer outside of the treated area on the upwind side.”</p> <p>“For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.”</p> <p>“For overhead chemigation, apply only when wind speed is 10 mph or less.”</p> <p>“The applicator also must use all other measures necessary to control drift.”</p>	<p>Directions for Use</p>

Description	Risk Mitigation Labeling	Placement on Label
End Use Products Intended for Occupational Use (Non-WPS Uses Only on the Label)		
Handler PPE requirements (all formulations)	<p>Note the following information when preparing labeling for all end use products:</p> <p>For <b>sole-active-ingredient</b> end-use products that contain acephate, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For <b>multiple-active-ingredient</b> end-use products that contain acephate, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	Handler PPE

<b>Description</b>	<b>Risk Mitigation Labeling</b>	<b>Placement on Label</b>
<p>PPE Requirements Established by the IRED for Wettable Powder Formulations not in Water Soluble Packaging (only products applied dry to ant mounds or applied as pastes for crack and crevice treatments are eligible for reregistration without water soluble packaging).</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators applying as a paste for crack and crevice treatments.”</li> </ul>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Wettable Powder Formulations Packaged in Water Soluble Bags.</p> <p><i>(All products with uses other than those listed above must be packaged in water soluble packaging to be eligible for reregistration).</i></p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators using hand-held application equipment”</li> </ul> <p>“In addition, applicators using low pressure hand wand application equipment must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Risk Mitigation Labeling	Placement on Label
<p>PPE Requirements Established by the IRED for Soluble Pellet Formulations (Soluble Pellet Formulations must be as described in the acephate IRED)</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for all mixers and loaders and for applicators using hand-held application equipment”</li> </ul> <p>“In addition, all mixers and loaders and all applicators using low pressure hand wand application equipment must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>



Description	Risk Mitigation Labeling	Placement on Label
PPE Requirements Established by the IRED for Granular Formulations	<p>“Personal Protective Equipment (PPE)”</p> <p>“Loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves”</li> </ul> <p>“In addition, mixers, loader and applicators supporting or making broadcast applications to turf must wear:</p> <ul style="list-style-type: none"> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul>	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals
PPE Requirements Established by the IRED for products applied in a tree injection system	<p>“Personal Protective Equipment (PPE)”</p> <p>“Handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves”</li> </ul>	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>	Precautionary Statements: Immediately following the PPE requirements

Description	Risk Mitigation Labeling	Placement on Label
<p>Engineering Controls for the wettable powder formulations packaged in water soluble bags.</p>	<p><b>“Engineering Controls”</b></p> <p>“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required above for mixers/ loaders, and</li> <li>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the following PPE: coveralls, chemical-resistant footwear and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following PPE and User Safety Requirements.</p>

Description	Risk Mitigation Labeling	Placement on Label
Engineering Controls for Granular Formulations	<p>“Engineering Controls</p> <p>“When mixers and loaders use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people <i>AND</i> the system is functioning properly and is used and maintained in accordance with the manufacturer’s written operating instructions, the handlers may choose to not wear the respirator specified in the PPE section of this label as long as the specified respirator is immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown.</p> <p>“When applicators use an enclosed cab that has a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the cab, the handlers may choose to not wear the chemical resistant gloves or the respirator specified in the PPE section of this label as long as the specified gloves and respirator are immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown.</p>	Precautionary Statements: Immediately following PPE and User Safety Requirements.
User Safety Recommendations	<p><b>“User Safety Recommendations”</b></p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following Engineering Controls)</p> <p>Must be placed in a box</p>

Description	Risk Mitigation Labeling	Placement on Label
Environmental Hazards	<p><b>“Environmental Hazards”</b></p> <p>“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) 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.”(Use statement unless exempted by PR Notice 95-01)</p> <p>“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 cleaning equipment or disposing of equipment washwaters.”</p> <p>“Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.”</p> <p>“This product and its degradate are highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.”</p> <p>"This pesticide is toxic to birds"</p>	Precautionary Statements
Entry Restrictions for products applied as sprays.	“Do not enter or allow others to enter until sprays have dried”	Directions for Use
Entry Restrictions for granular or dust products.	“Do not enter or allow others to enter until dusts have settled”	Directions for Use

Description	Risk Mitigation Labeling	Placement on Label
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Directions for Use
Other Application Restrictions	<p><b>Application Rate Restrictions (Registrants must revise labels to reflect the following):</b></p> <p><u>Maximum Application Rates for Golf Course Turf:</u> Limit 4 lbs ai/A for Golf Course.</p> <p><u>Maximum Application Rates for Outdoor ornamentals:</u> Limit 1 lb ai/A per 100 gallons of water (not to exceed 1.0 lbs ai/A).</p> <p><b>Use Deletions: (Registrants must revise label to remove or prohibit the following):</b></p> <p><u>Indoor Residential Sites:</u> Delete all instructions for indoor residential applications and add the following statement: “Do not apply to indoor residential sites. For use in indoors at non-food areas of commercial, institutional, and industrial sites only”</p> <p><u>Turf Sites:</u> Remove all instructions for use on turf grass (except for golf course turf, and spot or mound treatment for ant control).</p> <p><b>Equipment Restrictions (sprays):</b></p> <p>“The use of low pressure hand-wand equipment for perimeter or wasp treatments is prohibited”</p> <p><b>Equipment Restrictions (granulars):</b></p> <p>“Applications to trees, shrubs and potted plants by hand or hand-held application equipment is prohibited.”</p>	Directions for Use

Description	Risk Mitigation Labeling	Placement on Label
Spray Drift Restrictions/Drift Language ( <i>All products applied as sprays</i> )	<p>“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”</p> <p>“For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”</p> <p>“The applicator also must use all other measures necessary to control drift.”</p>	Directions for Use
<b>End Use Products Intended for Use by Residential Consumers Only</b>		
Environmental Hazards	<p><b>“Environmental Hazards”</b></p> <p>"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."</p>	Precautionary Statements
Entry Restrictions	“Do not allow people or pets to enter treated area until sprays have dried or dusts have settled.”	Directions for Use
General Application Restrictions	“Do not apply this product in a way that will contact people or pets”	Directions for Use
Other Application Restrictions/Risk Mitigation	<u>Remove Home Lawns Uses:</u> Remove all instructions for use on home lawns (except for spot or mound treatment for ant control).	Directions for Use

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

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

## **VI. Related Documents and How to Access Them**

This interim Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of January 8, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on February 22, 2000 .

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: "<http://www.epa.gov/pesticides/op>."

## **VII. Appendices**



## APPENDIX A: Use Patterns Eligible for Reregistration

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>FOOD/FEED USE PATTERNS</b>							
<b>Beans (Including Lima Beans and Other Dry and Succulent Beans)</b>							
Postemergence Foliar Ground/aerial	Soluble (Sol.) Powder Packaged in Water Soluble Packaging (WSP)  Soluble (Sol.) Pellets	1.0 lb ai/A	Not specified (NS)	2.0 lb ai/A per crop cycle	14 (snap beans)  1 (lima beans - succulent)	7	Initial application should be made when eggs or insects first appear using a minimum of 20 (ground) or 2 (aerial) gal of water/A. The feeding of treated vines to livestock is prohibited.
<b>Brussels Sprouts and Cauliflower</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	2.0 lb ai/A per crop cycle	14	7	Initial application should be made when eggs or insects first appear using a minimum of 25 (ground) or 5 (aerial) gal of water/A. The feeding of treated trimmings or the grazing of livestock in treated areas is prohibited.
<b>Cauliflower (See "Brussels Sprouts and Cauliflower")</b>							
<b>Celery</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	2.0 lb ai/A per crop cycle	21	7	Initial application should be made when eggs or insects first appear using a minimum of 50 (ground) or 5 (aerial) gal of water/A. All celery must be trimmed (tops removed) before shipment. The use of treated tops for food/feed is prohibited.
<b>Cotton<sup>1</sup></b>							
Preplant Seed hopper box treatment	Sol. Powder	3 oz/A or or 0.2 lb ai/A	1	3 oz/A or or 0.2 lb ai/A	Not applicable (NA)	NA	Use prohibited in AZ, CA, and the Black Lands of TX. The product should be applied evenly to cottonseed in a hopper/planter box as a dry powder. The processing of treated seed for oil or use for food/feed is prohibited.

<sup>1</sup>Total seasonal application rate for cotton is 4 lb ai/A. This includes all methods of application.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Cotton (continued)</b>							
Preplant Slurry seed treatment	Sol. Powder (WSP) Sol. Pellets	6.4 oz/100 lb seed	1	6.4 oz/100 lb seed	NA	NA	Seed treatment may be made in a slurry tank or in sufficient water for thorough coverage with approved fungicides. The processing of treated seed for oil or use for food/feed is prohibited.
At-planting In-furrow (with soil incorporation) Ground	Granular Sol. Powder (WSP) Sol. Pellets	1.0 lb ai/A	1	1.0 lb ai/A	NA	NA	Liquid formulations should be applied with flat fan nozzles using a minimum of 3 gal of water/A.
Postemergence Sidedress treatment Ground	Sol. Powder (WSP) Sol. Pellets	1.0 lb ai/A	NS	4.0 lb ai/A	21	7	Use limited to all areas of TX except the Black Lands. Application should be made beginning at the fourth or fifth node stage, and should cease after peak bloom (90 days after planting).
Postemergence Foliar Aerial	Sol. Powder (WSP) Sol. Pellets	0.75 lb ai/A (1.0 lb ai/A limited to CA and AZ)	NS	4.0 lb ai/A	21	7	Initial application should be made when eggs or insects first appear using a minimum of 1, or 3-5 (AZ, CA) gal of water/A. The feeding of treated forage or gin trash to livestock and the grazing of animals on treated areas are prohibited.
Postemergence Foliar Ground	Sol. Powder (WSP) Sol. Pellets	1.0 lb ai/A	NS	4.0 lb ai/A	21	7	Initial application should be made when eggs or insects first appear using a minimum of 10 gal of water/A. The feeding of treated forage or gin trash to livestock and the grazing of animals on treated areas are prohibited.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Cranberries</b>							
Postemergence Foliar Ground (chemigation)/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	1	1.0 lb ai/A	90	NA	Application should be made using sufficient water to achieve thorough coverage (ground) or in a minimum of 2 gal of water/A (aerial). Application should not be made from start of bloom until all berries have set. When applied via irrigation system, only sprinkler type irrigation equipment can be used.
Postemergence Foliar Ground (sprinkler)/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	1	1.0 lb ai/A	75	NA	Use limited to MA, NJ, WA, and WI. Application should be made using sufficient water to achieve thorough coverage (ground) or in a minimum of 2 gal of water/A (aerial). Application should not be made from start of bloom until all berries have set. When applied via irrigation system, only sprinkler type of irrigation may be used.
<b>Food-Handling Establishments (Including Food And Non-Food Areas Where Food And Food Products Are Held, Processed, Prepared, or Served)</b>							
Crack and crevice (pin-stream spray) Spot (coarse, low pressure spray) Paint brush (localized areas)	Sol. Powder (WSP)  Sol. Pellets	1% (by weight to weight)	NS	NS	N/A	NS	Application to food areas is limited to spot and/or crack and crevice treatment. Contamination of food or food-processing surfaces should be avoided. Spray or mist should not come in contact with food, feedstuffs, or water supplies. Use in feed-processing areas of feed-handling establishments is prohibited.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Lettuce (Crisphead Types)</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	2.0 lb ai/A	21	7	Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Applications may be made in spring, summer, and early fall in all areas; winter applications may be made in AZ, CA, FL, and TX; and late fall applications may be made in AZ. In the desert areas of AZ and CA, application should not be made after first head begins to form in crops which germinate from mid-September through November. The feeding of trimmings to livestock, and the grazing of animals on treated areas are prohibited.
<b>Lupines (Sweet Grain)</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	2.0 lb ai/A per crop cycle	14	7	Use limited to WA. Application should be made using a minimum of 20 (ground) or 2 (aerial) gal of water/A. The grazing of animals on treated areas, and the feeding of treated forage or hay to livestock are prohibited.
<b>Mint (See "Peppermint and Spearmint")</b>							

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Peanuts<sup>2</sup></b>							
Preplant Seed hopper box treatment	Sol. Powder (WSP)	3 oz 75% ai product/ 100 lb seed [SLNs AL940001 and GA960002]	1	same as single rate	NA	NA	Use limited to AL, FL, GA, and VA. The product should be applied evenly to peanut seed in a hopper/planter box as a dry powder. The processing of treated seed for oil or use for food/feed is prohibited.
	Sol. Pellets	3 oz 75% ai product/ A [SLNs FL940002, GA940001, and VA930005]					
At-planting In-furrow Ground	Sol. Powder (WSP)	1.0 lb ai/A	1	same as single rate	NA	NA	Use limited to NC, NM, TX, and VA. The feeding of treated forage or hay to livestock, and the grazing of animals on treated areas are prohibited.
	Sol. Pellets						
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)	1.0 lb ai/A	NS	4 lb ai/A per crop cycle	14 (of digging)	7	Initial application should be made when eggs or insects first appear using a minimum of 10 (ground) or 5 (aerial) gal of water/A. The feeding of treated forage or hay to livestock, and the grazing of animals on treated areas are prohibited.
	Sol. Pellets						
<b>Peppermint and Spearmint</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP)	1.0 lb ai/A	2	2.0 lb ai/A per crop cycle	14	7	Initial application should be made when eggs or insects first appear using a minimum of 20 (ground) or 5 (aerial) gal of water/A. The grazing of animals on treated areas and the feeding of spent mint hay to animals are prohibited.
	Sol. Pellets						

<sup>2</sup>Total seasonal application rate for peanuts is 4.0 lb ai/A. This includes all methods of application.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Peppers (Bell)</b>							
Postemergence Foliar Ground/aerial	Sol. Powder (WSP) Sol. Pellets	1.0 lb ai/A	NS	2.0 lb ai/A per crop cycle	7	7	Initial application should be made when eggs or insects first appear using a minimum of 25 (ground), 3 (aerial), or 5 (aerial in CA) gal of water/A.
<b>Peppers (Non-Bell)</b>							
Postemergence Foliar Ground	Sol. Powder (WSP) Sol. Pellets	0.5 lb ai/A	NS	1.0 lb ai/A	7	7	Use limited to Midwestern and Eastern states and to PR. Application should be made using a minimum of 40 gal of water/A.
<b>Peppers (Unspecified Type)<sup>3</sup></b>							
At-planting In-furrow (with soil incorporation) Ground	Granular	1.0 lb ai/A	NS	2.0 lb ai/A	NS	7	Use limited to full-season peppers (e.g., varieties that require 130-150 days to reach maturity) grown in AZ and NM. Foliar application should not be made following in-furrow application.
Postemergence Sidedress treatment (with soil incorporation) Ground	Granular	1.0 lb ai/A	NS	2.0 lb ai/A	88	7	Use limited to full-season peppers (e.g., varieties that require 130-150 days to reach maturity) grown in AZ and NM. Foliar application should <u>not</u> be made following sidedress application.
<b>Soybeans</b>							
Foliar Postemergence Ground/aerial	Sol. Powder (WSP) Sol. Pellets	1.0 lb ai/A	NS	1.5 lb ai/A per crop cycle	14	7	Use limited to MS & TX. Applications should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. The grazing or cutting of vines for hay or forage is prohibited.
<b>Spearmint (See "Peppermint")</b>							

<sup>3</sup>Total seasonal application rate for peppers (unspecified type) is 2.0 lb ai/A. This includes all methods of application.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Preharvest Interval (days)	Minimum Spray Interval (days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate			
<b>Tobacco<sup>4</sup></b>							
Foliar Floatbed/greenhouse Ground	Sol. Powder (WSP) Sol. Pellets	0.75 lb ai/A	NS	4.0 lb ai/A per crop cycle	NS	7	Use prohibited in CA [59639-89 only].
Foliar Plant bed Ground	Sol. Powder (WSP) Sol. Pellets	0.75 lb ai/A	NS	4.0 lb ai/A per crop cycle	NS	7	Use prohibited in CA [59639-89 only].
Transplant water Ground	Sol. Powder (WSP) Sol. Pellets	0.75 lb ai/A	1	0.75 lb ai/A	NS	NA	Use prohibited in CA [59639-89 only]. Application should be using a minimum of 100 gal of water/A.
	Sol. Powder (WSP) Sol. Pellets	1.5 lb ai/A	1	1.5 lb ai/A	NS	NA	Use limited to TN. Application should be using a minimum of 200 gal of water/A.
Postemergence Foliar Ground/aerial	Sol. Powder (WSP) Sol. Pellets	0.75 lb ai/A	NS	4.0 lb ai/A per crop cycle	3	7	Use prohibited in CA [59639-89 only]. Application should be made using a minimum of 10 (ground) or 3 (aerial) gal of water/A.
Mound treatment Ground	Sol. Powder Sol. Powder (WSP) Sol. Pellets	2 tsp Sol. powder/mound [dry method] or 0.75 oz/5 gal of water; 1 gal finished spray/mound - drench method]	1	13 mounds/A	3	NA	Use prohibited in CA [59639-89 only]. For dry method, product should be applied evenly over the mound as a dry powder; for drench method, finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound.

<sup>4</sup>Total seasonal application rate for tobacco is 4 lb ai/A. This includes all methods of application.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>NONFOOD/NONFEED USE PATTERNS</b>						
<b>Bermudagrass (Seed Crop)</b>						
Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1 lb ai/A	Not specified (NS)	NS	7 days	Use limited to Bermudagrass grown for seed in AZ & CA. Application should be made using a minimum of 20 (ground) or 5 (aerial) gal of water/A. The feeding of treated commodity to livestock and the grazing of animal on treated areas are prohibited.
<b>Carrots (Seed Crop)</b>						
Fall or early spring prebloom Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1 lb ai/A	2	2 lb ai/A	7 days	Use limited to carrots grown for seed in OR, ID and WA. Application should be made in 10 gal of water/A. Not for use on fields producing carrots for food. No portion of the treated field, including seed, seed screenings, and carrot waste may be used for human or animal feed. The grazing of livestock animals on treated areas is prohibited.
<b>Citrus Fruits (Non-Bearing)</b>						
Foliar	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	NS	7 days	Initial spray application should be made to individual juvenile or non-bearing trees when eggs or insects first appear using a minimum of 100 gal of water/A by ground equipment. The grazing of livestock on treated areas and the harvesting of citrus fruits for one year after treatment are prohibited.
Ground	Sol. Powder (WSP)  Sol. Pellets	4.0 lb ai/A	NS	NS	7 days	Use limited to FL. Application should be made to individual juvenile or non-bearing trees using a minimum of 100 gal of water/A by ground equipment. The grazing of livestock on treated areas and the harvesting of citrus fruits for one year after treatment are prohibited.
Mound treatment Ground	Sol. Powder (WSP)  Sol. Pellets	0.75 oz 75% ai product/5 gal of water [1 gal of finished spray/mound - drench method]	NS	NS	NS	Finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound. The grazing of livestock on treated area and the harvesting of citrus fruits for one year after treatment are prohibited.



Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>Coffee (Non-Bearing)</b>						
Mound treatment Ground	Sol. Powder  Sol. Powder (WSP)  Sol. Pellets	2 tsp dry Sol. powder (75% ai)/ mound [dry method]  0.75 oz 75% ai product/5 gal water  [1 gal finished spray/mound - drench method]	NS	NS	NS	Use limited to non-bearing coffee (<2 years old) grown in PR. For dry method, product should be applied evenly over the mound as a dry powder; for drench method, finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound. The grazing of livestock on treated area is prohibited.
<b>Commercial, Institutional, and Industrial Areas (Indoor Non-Food Areas)</b>						
Crack and crevice (pin-stream spray) Spot (coarse, low pressure spray) Paint brush (localized areas)	Sol. Powder (WSP)  Sol. Pellets	1.0% (by weight to weight)	NS	NS	NS	Contamination of food or food-processing surfaces should be avoided. Spray or mist should not come in contact with food, feedstuffs, or water supplies. Use in feed-processing areas of feed-handling establishments is prohibited.
<b>Domestic Dwellings (Outdoor)</b>						
Spot Soil band/foundation Paint brush (surfaces) Ground	Sol. Powder (WSP)  Sol. Pellets	1.2 oz 75% ai product/gal of water	NS	NS	NS	Initial application should be made when pests first appear. Not for use on residential turf. Do not apply by low pressure handwand to treat trees, shrubs, outdoor flora, for wasp control, or as a perimeter treatment.
<b>Greenhouses At The EPCOT Center (Lake Buena Vista, FL)</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	0.75 lb ai /100 gal	NS	NS	NS	Use limited to crops grown in greenhouses at the EPCOT Center (Lake Buena Vista, FL). Treated crop commodities must be destroyed following harvest and not consumed.
<b>Non-Crop Areas (Field Borders, Fencerows, Roadsides, Ditchbanks, and Borrow Pits)</b>						
Early to mid-season application Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	0.25 lb ai/A	NS	NS	NS	Application should be made using a minimum of 10 (ground), 1 (aerial), or 5 (aerial in CA) gal of water/A. The grazing or feeding of vegetation cut from treated areas is prohibited.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>Noncrop Areas (Wasteland)</b>						
Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	0.125 lb ai/A	1	0.125 lb ai/A	NS	Application should be made using a minimum of 10 (ground), 0.5 (aerial), or 5 (aerial in CA) gal of water/A. The grazing or feeding of vegetation cut from treated areas; application when lactating dairy cattle are present; and the grazing or feeding of grass or grass hay to dairy animals are prohibited. Meat animals should be removed from treated areas at least 1 day before slaughter if they were present at application or grazed treated areas within 21 days of application.
Mound Treatment Ground	Sol. Powder  Sol. Powder (WSP)  Sol. Pellets	4.5 oz 75% ai product/5 gal of water [1 gal of finished spray/mound - drench method]	1	13 mounds/A	NS	Finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound. Application should not be made when lactating dairy cattle are present. The grazing or feeding of treated grass hay to dairy animals is prohibited. Meat animals should be removed from treated areas at least 1 day before slaughter if they were present at application or grazed treated areas within 21 days of application.
<b>Noncrop Areas (Unspecified)</b>						
Mound treatment Ground	Sol. Powder  Sol. Powder (WSP)  Sol. Pellets	2 tsp Sol. powder /mound [dry method]  0.75 oz 75% ai product/5 gal water[1 gal of finished spray/mound - drench method]	1	2 tsp product/ mound [dry method]	NS	For dry method, product should be applied evenly over the mound as a dry powder; for drench method, finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound. Application should not be made when lactating dairy cattle are present. The grazing or feeding of treated grass hay to dairy animals is prohibited. Meat animals should be removed from treated areas at least 1 day before slaughter if they were present at application or grazed treated areas within 21 days of application.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>Onions (Seed Crop; Research Purposes Only)</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	NS	7 days	Use limited to onions grown for seed (research purposes only) in CA. Applications should be made in 50 gal/A of water using ground equipment. Applications should not be made when plants are in full bloom. Onions harvested from treated fields can not be used for food/feed.
<b>Turf (Sod Farm and Golf Course Use Only) and Other Ornamental Ground Covers</b>						
Foliar/Broadcast Ground	Sol. Powder (WSP)  Sol. Pellets  Granular	3.0 lb ai/A (Sod farm trt with liquid formulation)  4.0 lb ai/A (Golf course trt with liquid formulation)  5 lb ai/A (Granular)	NS	NS	7-14 days, as needed	Initial application should be made when insects or damage first appear using a minimum of 1 gal of water/1,000 sq. ft for liquid formulation. The grazing of livestock on treated area and the feeding of treated grass to livestock are prohibited.  Three (3) day Pre-Harvest Interval (PHI) for harvesting of sod.  Do not apply aerially.
<b>Ornamental Lawns, Turfs, and Other Ornamental Ground Covers</b>						
Mound treatment Ground	Sol. Powder (WSP)  Sol. Powder  Sol. Pellets  Granular	2 tsp Sol. powder/mound [dry method]  1.0 oz product/5 gal water; 1 gal finished spray/mound - [drench method]	NS	2 tsp product/ mound [dry method]	NS	For dry method [59639-26 only], product should be applied evenly over the mound as a dry powder; for drench method, finished spray should be applied until the mound is wet and to an area 4 ft in diameter around the mound.
<b>Ornamental Plants</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	0.5 lb ai/A or 1.0 lb ai/100 gal of water	NS	NS	14	Initial application should be made when insects first appear.  Do not apply by low pressure handwand.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>Ornamental Plants (Container-Grown Nursery Stock)</b>						
Foliar/broadcast Ground	Sol. Powder (WSP)  Sol. Pellets	0.75 lb ai/100 gal of water	NS	NS	NS	Thorough drench application of liquid formulation should be made by mid-September for greenhouse stock and by mid-October for outdoor stock.
<b>Ornamental Plants (Greenhouse)</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	1 lb/100 gal water (0.75 lb ai/A cut flowers; 1.0 lb ai/A other ornamentals)	NS	NS	5	Initial application should be made when eggs or insects first appear.
<b>Ornamental Trees and Shrubs (Except Flowering Crabapple)</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/100 gal of water	NS	NS	14	Initial application should be made when insects or damage first appear. Do not apply by low pressure handwand.
<b>Ornamental Trees and Shrubs (Flowering Crabapple)</b>						
Foliar Ground	Sol. Powder (WSP), Sol. Pellets	0.25 lb ai/100 gal of water	3	0.75 lb ai/300 gal of water	28 days	Initial application should be made as insects appear. Do not apply by low pressure handwand.
<b>Ornamental Trees and Shrubs (Crepe Myrtle)</b>						
Banded Paint brush	Sol. Powder (WSP), Sol. Pellets	4 tbs product/1 tbs water	NS	NS	NS	Application should be made as a paint-on slurry to the trunk in a band 6-12 inches above the ground.
<b>Ornamental Trees and Shrubs (Douglas Fir)</b>						
Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	0.5 lb/A	1	0.5 lb ai/A	NA	Application should be made no more than 2 weeks prior to bud burst using a minimum of 100 (ground) or 2 (aerial) gal of water/A. Do not apply by low pressure handwand.
<b>Ornamental Trees and Shrubs (Southern Pine Seed Orchards)</b>						
Foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	4.0 lb ai/A	2	8.0 lb ai/A	2 weeks	Use limited to Southern pine seed orchards grown in FL, GA, NC, VA, and TX. Initial application should be made when female flowers are in twig bud stage using a min. of 100 (ground) or 10 (aerial) gal of water/A. The grazing of livestock on treated areas and the harvesting of treated cover crops are prohibited. Do not apply by low pressure handwand.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Application:			Minimum Spray Interval (Days)	Use Limitations
		Single Rate	No. Per Season	Seasonal Rate		
<b>Potatoes (Greenhouse Grown Pre-Nuclear)</b>						
Foliar Ground	Sol. Powder (WSP)  Sol. Pellets	0.75 lb ai/100 gal	NS	NS	NS	Use limited to greenhouse-grown pre-nuclear potatoes in PA. Initial application should be made when insects first appear.
<b>Radishes (Seed Crop)</b>						
Postemergence Broadcast/foliar Ground/aerial	Sol. Powder (WSP)  Sol. Pellets	1.0 lb ai/A	NS	NS	7	Use limited to radishes grown for seed in WA. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Application before or during peak bloom period is not recommended. The feeding of treated crop to livestock, and the grazing of animals on treated areas are prohibited.

## APPENDIX B. Data Supporting Guideline Requirements for the Reregistration of Acephate

### GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed by Guideline Number. The Guideline Numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

A . Terrestrial Food	H. Greenhouse Food
B. Terrestrial Feed	I. Greenhouse Non-Food
C. Terrestrial Non-Food	J. Forestry
D. Aquatic Food	K. Residential
E. Aquatic Non-Food Outdoor	L. Indoor Food
F. Aquatic Non-Food Industrial	M. Indoor Non-Food
G. Aquatic Non-Food Residential	N. Indoor Medical
	O. Indoor Residential
3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

**APPENDIX B: Acephate (Case 0042) - Data Supporting Guideline Requirements for the Reregistration of Acephate**

<b>REQUIREMENT</b>			<b>CITATION(S)</b>	
<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
<b><u>PRODUCT CHEMISTRY</u></b>				
830.1550	61-1	Product Identity and Composition	All	43645001, 44005101
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	All	43645001, 44005101
830.1670	61-2B	Formation of Impurities	All	43645001, 44005101
830.1700	62-1	Preliminary Analysis	All	43645002, 44005102
830.1750	62-2	Certification of Limits	All	43645002, 44005102
830.1800	62-3	Analytical Method	All	43645002, 44005102
830.6302	63-2	Color	All	43645003, 44005103
830.6303	63-3	Physical State	All	43645003, 44005103
830.6304	63-4	Odor	All	44005103
830.7050	None	UV/Visible Absorption	All	<b>Data Gap</b>
830.7200	63-5	Melting Point	All	43645003, 44005103
830.7220	63-6	Boiling Point	All	Not Applicable
830.7300	63-7	Density	All	43645003, 44005103
830.7840 830.7860	63-8	Solubility	All	43645003, 40390601
830.7950	63-9	Vapor Pressure	All	43645003, 40645901
830.7370	63-10	Dissociation Constant in Water	All	40390601

**REQUIREMENT****CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	All	40322801
830.7000	63-12	pH	All	43645003, 44005103
830.6313	63-13	Stability	All	43645003, 44005103
830.6314	63-14	Oxidizing/Reducing Action	All	40390601
830.6315	63-15	Flammability	All	Not Applicable
830.6316	63-16	Explosibility	All	40390601
830.6317	63-17	Storage Stability	All	40390601
830.7100	63-18	Viscosity	All	Not Applicable
830.6319	63-19	Miscibility	All	Not Applicable
830.6320	63-20	Corrosion Characteristics	All	40390601
<b><u>ECOLOGICAL EFFECTS</u></b>				
850.2100	71-1	Avian Acute Oral Toxicity Test	All	43939301, 00015962, 00014701, 00014700, 00093911  For degradate methamidophos: 00014094, 00014095, 00041313, 00016000, 00093914, 00109717, 00109718, 00144428
850.2200	71-2	Avian Dietary Toxicity	All	00015956, 00015957, 00093911  For degradate methamidophos: 00093904, 00014304, 00014064, 00041658, 00146286



**REQUIREMENT**

**CITATION(S)**

New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.2300	71-4	Avian Reproduction	ABCDJK	00029692, 00029691  For degradate methamidophos: 00014113, 00014114
850.1075	72-1	Fish Acute Toxicity - Freshwater	All	40098001, 40094602, 00014705, 00014709, 00014708, 00014706, 00014707, 00014710  For degradate methamidophos: 00041312, 00014063, 05000836, 00144429, 00144432
850.1010	72-2	Invertebrate Toxicity	All	GS0042021, 00014565, 40094602, 00014861, 40098001, 00093943, 00014712  For degradate methamidophos: 00041311, 00014110, 00014305
850.1075	72-3a	Estuarine/Marine Toxicity - Fish Acute	ABCDJK	40228401  For degradate methamidophos: 00144431
850.1025 850.1035 850.1045 850.1055	72-3b and 72-3c	Estuarine/Marine Toxicity - Invertebrate Acute	ABCDJK	40098001, 00014711, 00014713  For degradate methamidophos: 00144430
850.1300 850.1350	72-4	Invertebrate Chronic Toxicity	ABCDJK	44466601, 00066341, 40228401

**REQUIREMENT**

**CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
850.4100 850.4150 850.4200 850.4225 850.4230 850.4250	122-1 and 123-1	Non-Target Seedling Emergence and Vegetative Vigor	CJ	<b>Data Gap</b>
850.4400	123-2	Aquatic Plant Growth	CJ	Not Applicable
850.3020	141-1	Nontarget Insect Acute Contact Toxicity (Honey Bee)	ABCDJK	00014714, 44038201, 05004012  For degradate methamidophos: 00036935
850.3030	141-2	Nontarget Insect Acute Residue Toxicity	ABCDJK	00014715, 05000837, 00014714
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral - Rat	All	00014675, 00029686
870.1200	81-2	Acute Dermal - Rabbit	All	00055602
870.1300	81-3	Acute Inhalation - Rat	All	00015307
870.2400	81-4	Primary Eye Irritation - Rabbit	All	00014686
870.2500	81-5	Primary Dermal Irritation - Rabbit	All	00015305
870.2600	81-6	Dermal Sensitization	All	00119085
870.6100	81-7	Delayed Neurotoxicity	All	00154884
870.6200	81-8	Acute Neurotoxicity	All	44203301, 44203302, 44203303
870.3100 870.3150	82-1	90-Day Feeding	All	40504819
870.3200	82-2	21-Day Dermal Toxicity - Rat	All	45134301
870.3250	82-3	Subchronic Dermal Toxicity - 90 Day	All	Not Applicable

**REQUIREMENT**

**CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
870.3465	82-4	Subchronic Inhalation Toxicity - 28 Day	All	45134302
	82-7	Subchronic Neurotoxicity - rats	All	44203304
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	All	00084017, 00101623
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent (dog)	All	41812001
870.4200	83-2A	Oncogenicity - Rat	All	00084017, 00101623
870.4200	83-2B	Oncogenicity - Mouse	All	00105197, 00077209, 00105198, 00129156
870.3700	83-3A	Developmental Toxicity-Rat	All	41081602
870.3700	83-3B	Developmental Toxicity - Rabbit	All	00069684, 00069683
870.3800	83-4	2-Generation Reproduction - Rat	All	40323401, 40605701
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	All	00084017
870.6300	83-6	Developmental Neurotoxicity	All	<b>Data Gap (1999 DCI)</b>
870.5140 870.5375 870.5550	84-2	Mutagenicity studies	All	00119080, 00028625, 00132948, 00132947, 000132949, 00132950, 00137738, 40209101, 00132953, 00119081, 00132955, 00132954, 00139949, 00028625
870.7485	85-1	General Metabolism	All	<b>Data Gap</b>
	85-2	Dermal Absorption	All	00154886
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>				
875.1700	90-1-SS	Product Use Information	All	<b>Data Gap</b>
875.2100	132-1A	Foliar Residue Dissipation	ABCDJ	44806401, 44763901, 44763902, 44763903, 44763904
875.2200	132-1B	Soil Residue Dissipation	ABCDJ	Waived

**REQUIREMENT**

**CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
875.2400, 875.1100	133-3	Dermal Passive Dosimetry Exposure Dermal Exposure Outdoor	ABCDJ	<b>Data Gap</b>
875.2500	133-4	Inhalation Passive Dosimetry Exposure	ABCDJ	Waived
840.1100 835.4200	201-1 202-1	Droplet Size Spectrum Drift Field Evaluation	ABCDJ	40323301, 40323302, 41023503 41023504
<b>ENVIRONMENTAL FATE</b>				
835.2120	161-1	Hydrolysis of Parent and Degradates	ABCDHIJK	41081604; <b>Data Gap (for test at pH of 9)</b>
835.2240	161-2	Photodegradation - Water	ABCD	41081603
835.2410	161-3	Photodegradation - Soil	ABJ	00015202, 40504810
835.2370	161-4	Photodegradation - Air	AB	Not Applicable
835.4100	162-1	Aerobic Soil Metabolism	ABCHIJK	00014991
835.4400	162-3	Anaerobic Aquatic Metabolism	DJ	43971601
835.4300	162-4	Aerobic Aquatic Metabolism	D	<b>Data Gap</b>
835.1240	163-1	Leaching/Adsorption/Desorption	ABCDHIJK	<b>Data Gap</b>
835-1410	163-2	Volatility-Lab	-	Not Applicable
835-8100	163-3	Volatility-Soil	-	Not Applicable
835.6100	164-1	Terrestrial Field Dissipation	ABCK	40504812, 40504813, 40504814, 41327601, 41327603, 41327604, 41327605,
None	165-4	Bioaccumulation in Fish	ABCDJ	00015243
<b>RESIDUE CHEMISTRY</b>				
835.1850	165-1	Confined Rotational Crop	ABD	<b>Data Gap</b>
860.1300	171-4A	Nature of Residue - Plants	ABDHKL	<b>Data Gap</b>

**REQUIREMENT**

**CITATION(S)**

New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
860.1300	171-4B	Nature of Residue - Livestock	ABDHKL	<b>Data Gap</b>
860.1340	171-4C	Residue Analytical Method - Plants	ABDHKL	00014579, 00014659, 00014729, 00014983, 43971606, 43971607, 44037802, 44037804
860.1340	171-4D	Residue Analytical Method - Animals	ABDHKL	00014579, 00014659, 00014729, 00014983, 43971608, 43971609, 44037804
860.1380	171-4E	Storage Stability	ABDHKL	00014984, 00015179, 40504802, 40874102, 40874103, 41081601, 41137902, 44025201, 41327601, 44251701, 44251702
860.1460	174-4I	Food Handling Establishments	L	00014654, 00014655, 00014656, 00014657, 00014568
860.1480	171-4J	Magnitude of Residues - Meat, Milk, Poultry, Eggs Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep Eggs and the Fat, Meat, and Meat Byproducts of Poultry	ABDHKL	00015183, 00015225, 00015226, 40504806 00015230, 00015245
860.1500	171-4K	Crop Field Trials - Celery	ABDHKL	00014768, 00014769, 00014770, 00014771, 00014772, 00014773, 00015323, 00015324, 00015325, 00015326, 00015327, 00015328, 00015329, 00109353
860.1500	171-4K	Crop Field Trials - Lettuce (head)	ABDHKL	00014971, 00015042, 00015190, 00015191, 00015192, 00015193, 00015194, 00015293, 00015294
860.150	171-4	Crop Field Trials - Brassica (Cole) Vegetables Grou	ABDHKL	00115240

**REQUIREMENT****CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
860.1500	171-4K	Crop Field Trials - Beans, Succulent and Dry	ABDHKL	00014540, 00014774, 00014775, 00014776, 00014777, 00014778, 00014780, 00014781, 00014783, 00014791, 00072783, 40504805
860.1500	171-4K	Crop Field Trials - Soybean Seed and Aspirated Grain Fractions	ABDHKL	00014532, 00014533, 00014534, 00015049, 00015050, 00015060, 40504805
860.1500	171-4K	Crop Field Trials - Beans, Forage and Hay	ABDHKL	00014541, 00014778, 00014780, 00014787, 00014791
860.1500	171-4K	Crop Field Trials - Peppers	ABDHKL	00014760, 00014762, 00014763, 00014764, 00014765
860.1500	171-4K	Crop Field Trials - Macadamia Nuts	ABDHKL	00138156
860.1500	171-4K	Crop Field Trials -Cotton, Seed and Gin Byproducts	ABDHKL	00014852, 00014853, 00014854, 00014855, 00015038, 00015199, 00015206, 42450501
860.1500	171-4K	Crop Field Trials - Cranberries	ABDHKL	00115589
860.1500	171-4K	Crop Field Trials -Mint Hay, Spearmint and Peppermint	ABDHKL	00029683, 00029684, 00029685, 40504803, 43971610
860.1500	171-4K	Crop Field Trials - Peanuts, Nutmeat and Hay	ABDHKL	00093722, 00093724, 44025201, 44025202
860.1500	171-4K	Crop Field Trials - Tobacco	ABDHKL	00015122, 00015125, 00109354, 40504809
860.1520	171-4L	Processed Foods (Cottonseed)	ABDHL	00015038, 00015196, 00015198, 00015199, 00015206
860.1520	171-4L	Processed Foods (Mint)	ABDHL	00029684, 00029685, 40504803
860.1520	171-4L	Processed Foods (Peanuts)	ABDHL	43971611

**REQUIREMENT****CITATION(S)**

<b>New Guideline Number</b>	<b>Old Guideline Number</b>	<b>Study Title</b>	<b>Use Pattern</b>	<b>MRID Number</b>
860.1520	171-4L	Processed Foods (Soybeans)	ABDHL	00014532, 00014533, 00014534, 00015050, 40504805, 41137903, 44777002

## **APPENDIX C: Technical Support Documents**

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

The docket initially contained preliminary risk assessments and related documents as of January 8, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on February 22, 2000.

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

[www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)

These documents include:

### **SRRD Documents:**

- Agency Response to Phase 5 Comments on Acephate. October 18, 2001
- SRRD Response to Public Comments on the Preliminary Human Health and Ecological Risk Assessments. February 18, 2000
- Acephate Use Closure Memo. December 23, 1997

### **HED Documents:**

- Acephate: Sensitivity Analysis for Turf Risk Assessment. August 1, 2001
- Acephate: Addenda to Previous Occupational and Residential Risk Assessment Completed on September 15, 2000, and on January 20, 2000. February 13, 2001
- Acephate: Addendum to Revised Occupational and Non-Occupational Exposure and Risk Assessments for the Reregistration Eligibility Decision Document. September 15, 2000
- Acephate: Support for the Toxicology Endpoint Selection - for Dermal and Inhalation Risk Assessments; Report of the Hazard Identification Assessment Review Committee (HIARC). August 30, 2000
- Acephate: Revised Human Health Risk Assessment. HED Chapter for the Reregistration Eligibility Decision (RED) Document. February 3, 2000
- Acephate: Revised Occupational and Non-Occupational Exposure and Risk Assessments for the Reregistration Eligibility Decision Document. January 20, 2000.
- Acephate: Revised Occupational and Non-Occupational Exposure and Risk Assessments for the Reregistration Eligibility Decision Document. December 15, 1999.
- Acephate. Sensitivity Analysis. November 23, 1999



- Acephate: Revised Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision. October 5, 1999
- Acephate: Revised Occupational and Non-Occupational Exposure and Risk Assessments for the Reregistration Eligibility Decision Document. September 30, 1999.
- Acephate. Revised Dietary Exposure Analysis for the HED Revised Human Health Risk Assessment. September 28, 1999
- Acephate. Response to Comments to the Draft Acephate HED Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document. Dated September 22, 1999
- Review of Acephate Incident Reports. September 8, 1999
- Acephate. Acute Anticipated Residues Assessment for the HED RED. August 18, 1999
- Acephate: Revisions of the Toxicology Chapter for the RED. June 9, 1999

**EFED Documents:**

- Response to SRRD's Questions Concerning Phase 5 Public Comments on Acephate. August 8, 2000
- Revised Surface Water EECs (Incorporating the Index Reservoir and Percent Crop Area) for the HED Risk Assessment for Acephate. March 8, 2000
- Addendum to Acephate DP Barcode: D254706. Missing text from response to comments document and acceptability of a batch equilibrium study. September 7, 1999
- EFED Response to Comments submitted to the Acephate Docket during the 60-Day Comment Period on the EFED Acephate RED Chapter. August 25, 1999
- Revised EFED Acephate RED Chapter. August 25, 1999

**APPENDIX D: Citations Considered to be Part of the Database Supporting the Acephate Interim Reregistration Eligibility Decision (Bibliography)**

**GUIDE TO APPENDIX D**

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

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
  
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
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**APPENDIX E.      Generic Data Call-In**

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







**APPENDIX F. Product Specific Data Call-In**

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

















## **APPENDIX G. EPA'S Batching of Acephate Product for Meeting Acute Toxicity Data Requirements for Reregistration.**

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

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

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

Fifty one (51) products were found which contain Acephate as the active ingredient. These products have been placed into seven batches and one “no batch” in accordance with the active and inert ingredients and type of formulation. EPA Reg. No. 239-2632 may cite Batch 4.

- Batch 2 may cite Batch 1 with the exception of eye and skin irritation data
- Batch 5 may rely on Batch 4 data
- Batches 6 and 7 may use the policy for granular pesticide products. However, due to the differences in inerts in Batch 6, products within Batch 6 may not share eye irritation data.

<b>EPA Reg. No.</b>	<b>Percent Active Ingredient</b>	<b>Formulation Type</b>
<b>Batch 1</b>		
1677-192	96.0	Solid
19713-410	99.2	Solid
19713-495	96.0	Solid
37979-1	97.0	Solid
51036-237	96.0	Solid
51036-246	98.0	Solid
59639-31	97.4	Solid
59639-41	98.9	Solid
59639-91	97.0	Solid
64014-1	98.0	Solid
70506-3	97.0	Solid
<b>Batch 2</b>		
51036-238	90.0	Solid
59639-33	90.0	Solid
59639-86	90.0	Solid
70506-2	90.0	Solid
<b>Batch 3</b>		
19713-408	80.0	Solid
34704-694	80.0	Solid
51036-262	80.0	Solid
59639-29	80.0	Solid
59639-85	80.0	Solid
<b>Batch 4</b>		
239-2406	75.0	Solid
19713-400	75.0	Solid
19713-497	75.0	Solid
51036-236	75.0	Solid
51036-252	75.0	Solid
59639-26	75.0	Solid

<b>EPA Reg. No.</b>	<b>Percent Active Ingredient</b>	<b>Formulation Type</b>
<b>Batch 4</b>		
59639-27	75.0	Solid
59639-28	75.0	Solid
59639-42	75.0	Solid
59639-89	75.0	Solid
70506-1	75.0	Solid
<b>Batch 5</b>		
59639-75	15.0	Solid
59639-87	15.0	Solid
<b>Batch 6</b>		
499-369	3.0	Liquid
499-380	3.0	Liquid
<b>Batch 7</b>		
192-210	1.5	Solid
192-211	1.5	Solid
239-2453	1.5	Solid
239-2472	1.5	Solid

<b>No Batch</b>		
<b>EPA Reg. No.</b>	<b>Percent Active Ingredient(s)</b>	<b>Formulation Type</b>
239-2436	Acephate - 15.6%	Liquid
239-2440	Acephate - 0.25% Resmethrin - 0.10%	Liquid
239-2461	9.4	Liquid
239-2476	Acephate - 0.25% Resmethrin - 0.10% Triforine - 0.10%	Liquid
239-2594	Acephate - 4.0% Triforine - 3.25% Hexakis - 0.75%	Liquid
239-2595	Acephate - 8.0% Hexakis - 0.50%	Liquid
239-2632	50.0	Solid
499-230	1.0	Liquid
499-373	1.0	Liquid
499-421	12.0	Liquid
70228-1	75.0	Solid





**APPENDIX H. List of Registrants Sent This Data Call-In**



## APPENDIX I. List of Available Related Documents and Electronically Available Forms

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

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

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

#### **Instructions**

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>
8570-27	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>

8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-35	Data Matrix (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>

**Pesticide Registration Kit** [www.epa.gov/pesticides/registrationkit/](http://www.epa.gov/pesticides/registrationkit/)

Dear Registrant:

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

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

Other PR Notices can be found at [http://www.epa.gov/opppmsd1/PR\\_Notices](http://www.epa.gov/opppmsd1/PR_Notices)

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
  
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
  - a. Registration Division Personnel Contact List
  - B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - C. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

The telephone number for NTIS is (703) 605-6000.

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

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

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

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

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

### **Documents Associated with this RED**

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

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.