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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

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

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

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Attachment A:

Organophosphates included in the OP Cumulative Assessment

Chemical	Decision Document	Status
Acephate	IRED	IRED completed 9/2001
Azinphos-methyl (AZM)	IRED	IRED completed 10/2001
Bensulide	IRED	IRED completed 9/2000
Cadusafos	TRED	TRED completed 9/2000
Chlorethoxyphos	TRED	TRED completed 9/2000
Chlorpyrifos	IRED	IRED completed 9/2001
Coumaphos	TRED	TRED completed 2/2000
DDVP (Dichlorvos)	IRED	IRED completed 6/2006
Diazinon	IRED	IRED completed 7/2002
Dicrotophos	IRED	IRED completed 4/2002
Dimethoate	IRED	IRED completed 6/2006
Disulfoton	IRED	IRED completed 3/2002
Ethoprop	IRED	IRED completed 9/2001 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

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

OFFICE OF
PREVENTION, PESTICIDES
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April 7, 2002

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide methamidophos. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on February 3, 2000. Additionally, the Agency held a Technical Briefing on February 3, 2000, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, 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 22, 2000.

Based on its review, EPA has identified risk mitigation measures that the Agency believes mitigation measures are necessary to address the human health and environmental risks associated with the current use of methamidophos. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of methamidophos and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for methamidophos will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for methamidophos," which was approved on April 5, 2002, contains the Agency's decision on the individual chemical methamidophos.

A Notice of Availability for this Interim Reregistration Eligibility Decision for methamidophos 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.

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The interim RED is based on the updated technical information found in the methamidophos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for methamidophos (*Revised Dietary Exposure and Risk Analyses for the HED Revised Human Health Risk Assessment*, July 19, 2000, *Methamidophos: Addendum to the Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*, September 15, 2000, *Recalculated Tier II Drinking Water EECs for Methamidophos Incorporating the Index Reservoir and Percent Cropped Area*, October 17, 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, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For methamidophos, no proposal was submitted by Bayer, the technical registrant.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (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 methamidophos risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to methamidophos alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of methamidophos. 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 methamidophos. The Agency will issue the final tolerance reassessment decision for methamidophos and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophophates 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 separate cover. Additionally, for product-specific DCIs, the first set of required responses to is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

In this interim RED, the Agency has determined that methamidophos will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of methamidophos may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this interim RED.

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Special Review and Reregistration Division representative, Mark A. Hartman, at (703) 308-0734. 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

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Interim Reregistration Eligibility Decision
for
Methamidophos

Case No. 0043

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

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PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

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Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for methamidophos. The decisions outlined in this document do not include the final tolerance reassessment decision for methamidophos; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. Seven tolerances will be revoked now, because there are no currently registered uses; three tolerances will be modified, and several other commodity definitions will be corrected. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for methamidophos once cumulative risks are considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on methamidophos. After considering the revised risks and comments and mitigation suggestions from the technical registrant, Bayer, and other interested parties EPA developed its risk management decision for uses of methamidophos that pose risks of concern. This decision is discussed fully in this document.

Methamidophos is an organophosphate insecticide used on a variety of insects, first registered in 1972 for cotton, potatoes and numerous other crops. Use data from 1999 and 2000 indicate an average annual domestic use of approximately 640,000 pounds of active ingredient (lbs ai) of methamidophos.

The methamidophos risk assessments are different than those for most organophosphate pesticides because methamidophos is a metabolite of the organophosphate pesticide acephate. Consequently, the dietary (food) assessments, and to some extent the drinking water assessment, encompass the risk of methamidophos from applications of methamidophos only, and from "all sources" which includes applications of acephate. Methamidophos is not registered for use in residential settings. Previously, acephate had numerous residential, recreational and institutional uses which were evaluated in the acephate IRED. To mitigate risks of concern, acephate use in these settings have been limited to indoor use in institutional settings such as schools and hospitals, use on ornamentals in the residential settings, spot or mound treatments for fire ant control, and use on golf course turf. The risks associated with the degradation of acephate to methamidophos for these uses were evaluated in the acephate IRED and were found to be negligible.

Overall Risk Summary

EPA's human health risk assessment for methamidophos indicates some risk concerns. Food risk, both acute and chronic, is below the Agency's level of concern. Drinking water risk estimates

based on screening models, from surface water for acute and chronic exposures, is of concern for all populations. Conversely, drinking water risk estimates based on screening models, from ground water for acute and chronic exposures, is not of concern for all populations. There are concerns for workers who mix, load, and apply methamidophos to agricultural sites and to workers who re-enter treated areas. Also, EPA has identified acute and chronic risk to birds and mammals that are of concern, and some risk to freshwater invertebrates.

To mitigate risks of concern posed by the uses of methamidophos the Agency has decided on a number of label amendments to address the worker, drinking water 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 (food)

Acute and chronic dietary risk assessments for food do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for dietary (food) exposure to methamidophos from food.

Dietary (drinking water)

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

Based on model predictions of currently registered uses, the EECs for methamidophos from the application of methamidophos in surface water range from 28.6 to 61.8 ppb for acute exposure, and from 1.5 to 3.8 ppb for chronic exposure. The only surface water EEC calculated for methamidophos from the application of acephate, using the Tier I GEENEC model is 22 ppb. The acute and chronic EEC for methamidophos in groundwater is 0.028 ppb. The SCI-GROW model was also used to estimate ground water concentrations for methamidophos resulting from the application of acephate. The modeled EEC for methamidophos in ground water from the application of acephate to cotton is 0.005 ppb. Table 3 summarizes the modeled EECs for the respective crop scenarios. The DWLOCs for methamidophos from all sources are 2.9 for acute exposure and 0.6 for chronic exposure. The Agency is therefore concerned with possible exposure to methamidophos residues in surface water sources of drinking water and is requiring confirmatory monitoring data to evaluate actual acute and

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chronic concentrations of methamidophos. The Agency does not have risk concerns for exposure to drinking water from ground water sources.

Aggregate Risk

The acute aggregate risk assessment for methamidophos from all sources combines exposure from food and drinking water sources only. Acute dietary (food) risk estimates are below 100% of the aPAD for the US population and all population subgroups. Infants is the most highly exposed population subgroup and has an acute drinking water level of comparison (DWLOC) of 2.9 ppb. Based on screening-level model predictions of the remaining supported uses, the acute (peak) drinking water estimated concentration in surface water is 61.8 ppb which is of risk concern to the Agency. The screening-level model predictions of acute concentrations in ground water is 0.033 ppb for methamidophos, which is less than the DWLOC and not of risk concern to the Agency.

However, due to the uncertainties and limitations of the model predictions, the Agency believes that actual acute concentration of methamidophos in surface water is likely to be less than the DWLOC. To demonstrate this, confirmatory surface water monitoring data is to be generated to address this risk concern.

Similarly, the chronic aggregate risk assessment for methamidophos combines exposure from food and drinking water sources only. Chronic dietary (food) risk estimates are well below 100% of the cPAD for the US population and all population subgroups. Children 1-6 years old is the most highly exposed population subgroup and result in a chronic DWLOC of 0.9 ppb. Based on screening-level model predictions of the remaining supported uses, the average (chronic) estimated concentration in surface water is 3.8 ppb, which is of risk concern to the Agency. Similarly, due to the same uncertainties and limitations of the model predictions for acute exposure, the Agency also believes that actual chronic concentrations of methamidophos in surface water is likely to be less than the DWLOC. To demonstrate this confirmatory surface water monitoring data is to be generated to address the risk concern.

The screening-level model predictions of acute concentrations in ground water is 0.033 ppb for methamidophos, which is less than the DWLOC and not of risk concern to the Agency.

Occupational Risk

Occupational exposure to methamidophos is of concern to the Agency, and it has been determined that a number of mitigation measures are necessary at this time. For the agricultural uses of methamidophos, several mixer/loader/ applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than 100). EPA believes that most of these risks can be mitigated to an acceptable level by phasing out use on cotton and with the following label restrictions: use of closed cabs by applicators; use of enclosed vehicles for flaggers or the use of ground positioning system (GPS)

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equipment that negates the need for flaggers for aerial application.; and increased Restricted Entry Intervals (REIs).

Ecological Risk

Ecological risks are also of concern to the Agency. The Agency's assessment suggests the potential for the liquid formulation to cause acute effects to birds for broadcast applications. The avian acute RQs range from 0.38 to 6.63. The highest avian acute RQ is from nine 1 lb ai/A ground or aerial applications to tomatoes. For the same use patterns, mammalian acute RQs range from 0.2 to 20.3. Regarding chronic risk to birds, the RQs range from 2.49 to 32.87. Again the same use patterns resulted in chronic RQs for mammals ranging from 0.75 to 9.86. All use patterns are of concern to the Agency for acute and chronic effects to birds and mammals.

Acute risk to freshwater fish and estuarine fish is not of concern for any use patterns, with RQs ranging from <0.05 to 0.07. The acute high risk, restricted use risk and endangered species risk is of concern for freshwater invertebrates at the maximum application rate of 1.0 lb ai/A with RQs ranging from 1.1 to 3.0 and may be of concern for estuarine invertebrates. No chronic risk assessment was conducted since there are no chronic data for aquatic species.

Because of the toxicity of methamidophos, to help protect terrestrial birds, mammals and freshwater invertebrates, it is very important to reduce their potential exposure to methamidophos products that have been applied. In additional to the phase out of the cotton use to mitigate occupational risks of concern which will also serve to reduce risk to birds and mammals, reductions in the maximum number of applications allowed per season are needed to reduce risks to birds, mammals and fresh water invertebrates.

The Agency has determined that, with the phase-out of the cotton use and the addition of the label restrictions and amendments detailed in this document, until the outcome of cumulative risks for all of the organophosphates has been considered, other currently registered uses of methamidophos may continue.

The Agency is issuing this Interim Reregistration Eligibility Document (IRED) for methamidophos, 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 methamidophos. Note that there is no comment period for this document, and that the time frames for compliance with the label changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for methamidophos have already been subject to numerous public comment periods, and a further comment period for methamidophos was deemed unnecessary. Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period,

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depending on the content of the risk management decision. With regard to complying with the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for methamidophos can be considered final, however, until the cumulative risks for all organophosphate pesticides is considered. The cumulative assessment may result in further risk mitigation measures for methamidophos.

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I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment 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 on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Methamidophos belongs to a group of pesticides called organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. 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 methamidophos. It is intended to be only the first phase in the reregistration process for methamidophos. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for methamidophos.

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.

In addition to the policy issues that resulted from the TRAC process, the Agency issued, on Sept. 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker Risk Mitigation

for Organophosphate Pesticides 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 necessary 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 interim RED are consistent with the Worker Risk PR Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management. 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 lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides/op, and in the Public Docket.

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II. Chemical Overview

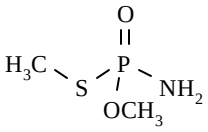
A. Regulatory History

Methamidophos was first registered in the United States in 1972 under the trade name Monitor. It was used principally on potatoes, cotton, and cole crops to control a broad spectrum of insects through contact, and systemic action inhibiting cholinesterase. A Registration Standard, which describes the terms and conditions for the continued registration of methamidophos, was issued for methamidophos in 1982.

In 1997, the technical registrant, Bayer Corporation, voluntarily cancelled all uses of methamidophos except for use on cotton, potatoes, and tomatoes (special local need only). In 1998, a special local needs registration was issued for use on alfalfa grown for seed in California. By December 1999, the registrant had also voluntarily phased-in closed mixing and loading systems for all remaining uses to address potential worker exposures.

B. Chemical Identification

Methamidophos:



- **Common Name:** Methamidophos
- **Chemical Name:** O,S-dimethyl phosphoramidothioate
- **Chemical family:** Organophosphate
- **Case number:** 0043
- **CAS registry number:** 10265-92-6
- **OPP chemical code:** 101201
- **Empirical formula:** $C_2H_8NO_2PS$
- **Molecular weight:** 141.1
- **Trade and other names:** Monitor

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- **Basic manufacturer:** Bayer Corporation, Valent U.S.A.

Methamidophos is a colorless to white crystalline solid with a strong mercaptan-like odor, and a melting point of 46.1°C. It is readily soluble (>200 g/L) in water, acetone, dimethylfomamide, dichloromethane, and 2-propanol, and is soluble in n-octanol at 50-100 g/L, toluene at 2-5 g/L, and n-hexane at <1 g/L. The vapor pressure of methamidophos is approximately 1.725×10^{-5} mm Hg.

C. Use Profile

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

Type of Pesticide: Insecticide/acaricide.

Summary of Use Sites:

Food/Feed Crop: Cotton, potato, and tomato.

Other Agricultural Sites: None.

Residential: None.

Public Health: None.

Nonfood Crop: Alfalfa grown for seed

Target Pests: Broad spectrum of insects including: aphid, Colorado potato beetle, green peach aphid, leafhopper, leafminer, lygus bug, stink bug, tomato pinworm, and whitefly.

Formulation Types Registered:

Technical Grade/Manufacturer-Use Product (MUP): liquid 60-72% ai.

End-Use Product: emulsifiable concentrate (EC) 40% ai.

Method and Rates of Application:

Equipment: Aircraft, ground sprayer, and sprinkler irrigation.

Method and Rate: Chemigation (potatoes only), high volume spray (dilute), and low volume spray (concentrate). Maximum use rate for all crops is 1.0 lb

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ai/A. The label allows four applications per season on cotton and potatoes, and up to nine applications per season on tomatoes.

Timing: Methamidophos end-use products are applied at various times including at-plant, and foliar timings.

Use Classification: Restricted Use

D. Estimated Usage of Pesticide

Table 1 summarizes the best available estimates for the pesticide uses of methamidophos. These estimates are derived from a variety of published and proprietary sources available to the Agency for 1999 and 2000. A full listing of all uses of methamidophos, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment," dated 5-9-2000 and the "Use and Usage Analysis for Methamidophos," dated November 20, 2001, which are available in the public docket. Approximately 640,000 pounds of active ingredient (lbs ai) of methamidophos are used annually, according to Agency estimates. Methamidophos use is highest on potatoes (87% of total methamidophos pounds applied), followed by tomato (8% of total methamidophos pounds applied), and cotton (5% of total methamidophos pounds applied).

Table 1. Methamidophos Usage Summary in the United States[1]

Crop	Percent Crop Treated	Base Acres Treated (1000 acres)[2]	Average Number of Applications Per Year	Average Application Rate (lbs ai/A)	Pounds Active Ingredient Applied (1000 lbs.)
Alfalfa for Seed (CA only)	50%	33*	1.0	0.8	36
Cotton	2%	288*	1.0	0.3	84
Potatoes	29%	322*	1.7	0.9	520
Tomatoes (Fresh)	15%	18*	2.5	0.6	28
Tomatoes (Processed)	3%	9*	1.0	0.9	8

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[1]Source: USDA 1999 and 2000 Agricultural Chemical Use (May, 2000, May 2001, July, 2001) and California Department of Pesticide Regulation, Pesticide Use Report (2000)..
[2]Base acres treated derived from estimate of acres grown in USDA 1999 and 2000 Agricultural Chemical Use (May 2000, May 2001, July, 2001).
*Base acres treated for California derived from harvested acreage; other states based on USDA 2000 Agricultural Chemical Use.

III. Summary of Methamidophos Risk Assessment

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

These risk assessments for methamidophos were presented at a February 3, 2000 technical briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for methamidophos only; the Agency must consider a cumulative assessment of the risks of all the OP pesticides before any final decisions can be made.

Human Health Risks

- *Human Health Risk Assessment-Methamidophos Revised Risk Assessment*, February 3, 2000.
- *Revised Dietary Exposure and Risk Analyses for the HED Revised Human Health Risk Assessment*, July 19, 2000.
- *Methamidophos: Addendum to the Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*, September 15, 2000.
- *Recalculated Tier II Drinking Water EECs for Methamidophos Incorporating the Index Reservoir and Percent Cropped Area*, October 17, 2000.

Environmental Fate and Ecological Effects

- *Amended EFED Methamidophos RED Chapter*, September 15, 1999.

A. Human Health Risk Assessment

The methamidophos risk assessments are different than those for most organophosphate pesticides because methamidophos is a metabolite of the organophosphate pesticide acephate.

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Consequently, the assessments encompass the risk of methamidophos from applications of methamidophos only, and from "all sources" which includes applications of acephate. Acute probabilistic and chronic dietary (food) risk assessments were conducted as well as a qualitative assessment of the potential exposure to all methamidophos sources through drinking water. EPA issued its preliminary risk assessments for methamidophos on October 30, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3 and Phase 5, the risk assessments were updated and refined. Major revisions to the human health risk assessment are listed below:

- Refinement of the acute dietary (food) risk assessment to use probabilistic (Monte Carlo) techniques;
- Incorporation of data from USDA's Pesticide Data Program (PDP) into the dietary (food) risk assessment;
- Adjustment to percent crop treated estimates;
- Incorporating washing and cooking factors into the dietary (food) assessment;
- Revised anticipated residues were calculated for use in the dietary risk assessment;
- Use of residue data from a potato processing study was incorporated into the dietary risk assessment;
- Information concerning a submitted import tolerance petition for peppers, squash, and strawberries was incorporated.
- 1999 PDP monitoring data on canned tomatoes was incorporated in the dietary assessment.
- Use of new toxicological endpoints for dermal risk assessment. These data affect the lowest observed effect level, and no observed effect level in the dermal risk assessments.
- Use of three dislodgeable foliar residue studies submitted by Bayer to assess post-application exposure to agricultural workers, and set restricted entry intervals.
- Recalculated Tier II drinking water EECs incorporating the Index Reservoir and Percent Cropped Area.

1. Dietary Risk from Food

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a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim RED for all currently registered uses. Further details on the toxicity of methamidophos can be found in the February 3, 2000 "Human Health Risk Assessment" and subsequent addenda**.** A brief overview of the studies and safety factors used for the dietary (food) risk assessment is outlined in Table 2 in this document.

b. FQPA Safety Factor

The FQPA Safety Factor (SF) was reduced from 10x to 3x. A weight-of-the-evidence approach indicated neuropathology in hens and humans reported in the open scientific literature. This led the Agency to conclude that an FQPA safety factor is appropriate. In studies from the open scientific literature, ingestion of methamidophos has been shown to result in delayed peripheral neuropathy in humans. Similarly, adult hens developed poly neuropathy. The Agency determined that the 10x factor can be reduced to 3x primarily because: 1) there was no increased susceptibility of the offspring of rats or rabbits to pre- and/or post-natal exposure 2) a two-generation reproductive toxicity study in rats showed no increased sensitivity in pups when compared to adults 3) the toxicology database is complete; and 4) the dietary food exposure assessment does not underestimate the potential exposure for infants and children from residues in food. However, based on this evidence, the requirement of a developmental neurotoxicity study has been triggered. This study will in turn provide additional data (e.g., potential increased susceptibility, and effects on the development of the fetal nervous system, etc.). More information can be found in the document "FQPA Safety Factor Recommendations for the Organophosphates," dated August 6, 1998.

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the reference dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). The RfD is calculated by taking the no observed adverse effect level (NOAEL) from an appropriate study and dividing it by an uncertainty factor (i.e., NOAEL/UF). A risk estimate that is less than 100% of the acute PAD (aPAD) or chronic PAD (cPAD) does not exceed the Agency's risk concern. In the case of methamidophos, the FQPA safety factor is 3x; therefore the acute and chronic PADs are equivalent to the acute and chronic RfDs divided by 3, respectively. The aPAD for methamidophos is 0.001 mg/kg/day. The cPAD for methamidophos is 0.0001 mg/kg/day. The basis for the aPAD and the cPAD are summarized in Table 2 below.

Table 2. Summary of Toxicological Endpoints Used in the Dietary Risk Assessment

Exposure Scenario	Dose	Endpoint	Toxicology Study	UF	FQPA Safety Factor	PAD (mg/kg/day)
Acute dietary	NOAEL = 0.3 mg/kg/day LOAEL = 0.7 mg/kg/day	Plasma, erythrocyte and brain cholinesterase inhibition.	Acute neurotoxicity study in rats (MRIDs 43025001, 43345801)	100	3	0.001
Chronic dietary	NOAEL = 0.03 mg/kg/day LOAEL = 0.06 mg/kg/day	Brain cholinesterase inhibition.	8- week subchronic oral toxicity cholinesterase study in rat (MRID 41867201)	100	3	0.0001

d. Exposure Assumptions

The Agency conducts dietary (food) risk assessments using the dietary exposure evaluation model (DEEM™), which incorporates consumption data generated in USDA's continuing survey of food intakes by individuals, 1989-1992. For the assessment of dietary (food) exposure to residues of methamidophos resulting from the use of methamidophos, monitoring data generated through the USDA Pesticide Data Program (PDP) for potatoes and tomatoes, and through the Food and Drug Administration (FDA) Surveillance Monitoring Program for peppers, squash, and strawberries were used. Anticipated residue values from crop residue field trial studies, and percent crop-treated data were used for cotton. For the assessment of dietary (food) exposure to residues of methamidophos resulting from the use of acephate, PDP or FDA monitoring data were used for succulent beans, cauliflower, celery, lettuce and peppers. Anticipated residue values from crop residue field trial studies, and percent crop-treated data were used for dry beans, Brussels sprouts, cotton, cranberries, macadamia nuts, mint, peanuts and soybeans.

For acute probabilistic dietary risk assessments, the entire distribution of single-day food consumption events is combined with a distribution of residues to obtain a distribution of exposure in mg/kg/day. Chronic dietary (food) risk assessments use the three-day average of consumption for each subpopulation combined with residues in commodities to determine average exposure in mg/kg/day. For probabilistic assessments, the Agency regulates at the 99.9th percentile of exposure. Both assessments included the dietary (food) risk from methamidophos exposure from use of methamidophos and from the use of acephate.

Valent U.S.A. Corporation has submitted an import tolerance petition in support of uses of methamidophos on squash, strawberries and peppers. There is an existing tolerance for methamidophos on peppers, but none has been established for the latter two commodities. The dietary

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risk assessment includes these proposed uses. Otherwise, these proposed tolerances are not addressed in this IRED.

e. Food Risk Characterization

Generally, a dietary (food) risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed EPA's risk concerns. Acute dietary (food) exposure to methamidophos from applications of methamidophos alone, and from "all sources" (applications of methamidophos and acephate) result in risk estimates that are below the Agency's level of concern—that is, less than 100% of the acute PAD is used. For example, for exposure resulting from applications of methamidophos alone, for the most exposed subpopulation, children 7-12 years old, the percent acute PAD value is 33% at the 99.9th percentile of exposure from consumption of food alone. For exposure resulting from applications of methamidophos from "all sources", for the most exposed subpopulation, all infants, the percent acute PAD value is 76% at the 99.9th percentile of exposure from consumption of food alone.

Chronic dietary (food) exposure estimates are also below the Agency's level of concern for all subpopulations. For the most highly exposed subpopulation, children 1-6 years old, the percent chronic PAD values are 15% for methamidophos alone and 37% when including methamidophos residues from the application of acephate, from consumption of food alone.

2. Dietary Risk from Drinking Water

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

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW 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 the other two.

As in the dietary risk assessment for food, separate drinking water risk assessments were conducted for both exposure to methamidophos as a result of the application of methamidophos and exposure to methamidophos from all sources including the application of acephate.

Although the environmental fate data base for methamidophos is not complete, supplemental information from ungradable laboratory studies indicate that methamidophos is not persistent in aerobic

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environments but may be persistent in anaerobic aquatic environments where it will be associated with the aqueous phase. No acceptable data are available on the behavior of methamidophos under field conditions, but information from acceptable terrestrial field dissipation studies for acephate indicated that methamidophos is not persistent.

a. Surface Water

The Tier II PRZM-EXAMS screening model is used to estimate upper-bound environmental concentrations (EECs) in drinking water derived from surface water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. Acute modeled EECs for methamidophos in surface water from the application of methamidophos alone range from 29 ppb to 48 ppb, depending on the crop site. Chronic modeled EECs for methamidophos in surface water from the application of methamidophos alone range from 3.9 ppb to 6.9 ppb, depending on the crop site.

The Agency also used the recently implemented Index Reservoir (IR) and Percent Crop Area (PCA) modifications to the Tier II PRZM-EXAMS model to calculate upper-bound EECs for methamidophos in drinking water derived from surface water. Applying the IR and PCA modifications, acute modeled EECs for methamidophos in surface water from the application of methamidophos alone range from 28.6 ppb to 61.8 ppb depending on the crop site. Chronic modeled EECs for methamidophos in surface water from the application of methamidophos alone range from 1.5 ppb to 3.8 ppb, depending on the crop site.

The surface water model assumes methamidophos applications are made at the maximum rate for each crop on the current label, using the labeled methods of application. The model results are also based on four applications per season with a seven day retreatment interval. The lack of acceptable aerobic aquatic metabolism data increase the uncertainty of the chronic estimated environmental concentrations (EECs).

To estimate the potential exposure to methamidophos from the application of acephate, the Agency relied upon the Tier I GENEEC screening model. A higher-tiered model was not used in this case due to the high level of uncertainty surrounding any estimate of the decay rate for acephate and the transformation rate of acephate to methamidophos which are needed to use the PRZM-EXAMS model. The acute modeled EEC for methamidophos in surface water from the application of acephate to cotton is 22 ppb. The chronic modeled EEC for methamidophos in surface water from the application of acephate to cotton is 12 ppb. This analysis assumes a 25% conversion efficiency from acephate to methamidophos at time of application resulting in the equivalent of six applications at 0.25 lb methamidophos/ai./A on cotton. EECs for other crops were not developed.

For the purposes of assessing drinking water risks from exposure to methamidophos from all sources (i.e. including both methamidophos and acephate applications) the Agency will rely upon the

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model estimates generated using the PRZM-EXAMS model with the Index Reservoir (IR) and Percent Crop Area (PCA) modifications described above which are based upon the application of methamidophos alone. The Agency believes that the conservative default PCA used for the scenario with the highest EEC (potatoes in ME) would most likely account for methamidophos residues from both methamidophos and acephate applications in a given watershed. For this scenario, the default PCA value of 0.87 was used to calculate the EEC. This assumes that 87% of the watershed being evaluated is cropped in potatoes and/or other crops that methamidophos can be applied to. In this particular case, it is estimated that 65,000 acres of potatoes are grown in the state of Maine each year. Cotton is not grown in Maine and there is not a SLN for tomatoes there so all methamidophos use in that state would be on potatoes. If it was assumed that all that acreage fell into any one of the nine watersheds in Maine as a worst-case scenario, the range of PCA values would likely be 0.04 to 0.16 or 4% to 16%, significantly lower than the 87% assumption. The effect of the PCA value on EECs has a linear relationship. Consequently, using these values would reduce EECs by a factor of 5 to 20. Further, the main crop uses of acephate (beans, cotton, lettuce and tobacco) are either not grown in Maine or are not likely to have significant acreage. Therefore, additional contribution of methamidophos residue from the application of acephate in this scenario is very unlikely. Even though this analysis has not been deemed to be sufficient to change the PCA quantitatively, it does support the belief that this EEC likely provides a sufficiently protective estimate of exposure to methamidophos from all sources in drinking water. Further, the information is not currently available to enable the Agency to use a Tier II model to estimate concentrations of methamidophos from the application of acephate, as described above, and it is not considered appropriate to combine the results of a Tier II assessment (methamidophos applications) with the results of a Tier I assessment (acephate applications).

Monitoring for methamidophos in surface water is limited. No residues were detected in the available samples (328 samples primarily from Florida and Mississippi) but the limits of detection for this sampling are uncertain and it is unclear if these samples were taken in areas where methamidophos was being used. Given these limitations, the existing surface water monitoring database cannot be used to estimate concentrations of methamidophos in surface water. The U.S. Geological Survey (USGS) in its National Water Quality Assessment (NAWQA) program is not currently analyzing for methamidophos.

b. Ground Water

The Tier I screening model, SCI-GROW, was used to estimate drinking water concentrations derived from groundwater. The acute and chronic EEC for methamidophos in groundwater is 0.028 ppb. The ground water modeling assumes the maximum yearly total application of methamidophos (nine applications at 1.0 lb/a.i./A on tomatoes in Florida) per the current labels. Methamidophos is not expected to leach significantly to groundwater given that it is not persistent under aerobic conditions. This expectation is reflected in the results of the model. Further, a majority of use areas will have ground water that is less vulnerable to contamination than that in areas used to derive the SCI-GROW

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estimate. Very limited ground water monitoring data for methamidophos is available. Four detections were recorded in these data which were collected between 1984 and 1993.

The SCI-GROW model was also used to estimate ground water concentrations for methamidophos resulting from the application of acephate. The modeled EEC for methamidophos in ground water from the application of acephate to cotton is 0.005 ppb. This analysis assumes a 25% conversion efficiency from acephate to methamidophos at time of application resulting in the equivalent of six applications at 0.25 lb methamidophos/ai./A on cotton. EECs for other crops were not developed.

Since the same model was used to develop both the EECs from methamidophos applications and methamidophos resulting from applications of acephate, the Agency has decided to combine the estimates for the purposes of assessing drinking water risks from exposure to methamidophos from all sources.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary (food) exposure, does not exceed a level of concern.

The results of the Agency's drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the HED Human Health Risk Assessment dated February 3, 1999, the EFED Environmental Risk Assessment dated September 15, 1999, and the Recalculated Tier II Drinking Water EECs for Methamidophos Incorporating the Index Reservoir and Percent Cropped Area, October 17, 2000.

For acute risk, surface water EECs exceed the acute DWLOCs for all subpopulations (Table 3). Even if it is assumed that there are no food exposures to methamidophos, drinking water alone, based on model estimates, would result in exceedences of the risk cup, particularly for infants and children. Ground water EECs do not exceed the acute DWLOCs for any subpopulations. Therefore, the Agency does not have a risk concern for ground water sources of dietary exposure for the general U.S. population or the most highly exposed subpopulation. The table below presents the calculations for the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Acute Risk

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Population Subgroup	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Available Water Exposure (mg/kg/day)	DWLOC (ppb)	Maximum Surface Water EECs (ppb)	Maximum Groundwater EECs (ppb)
Methamidophos						
U.S. Population	0.001	0.000269	0.000731	25.6	61.8	0.028
Children 7-12 years old	0.001	0.000334	0.000684	6.8	61.8	0.028
Methamidophos from all Sources						
U.S. Population	0.001	0.000429	0.000571	20	61.8	0.033
All Infants	0.001	0.000762	0.000238	2.4	61.8	0.033

For chronic risk, surface water EECs slightly exceed the chronic DWLOCs for all subpopulations (Table 4). Ground water EECs do not exceed the chronic DWLOCs for any subpopulations. Therefore, the Agency does not have a risk concern for ground water sources of dietary exposure for the general U.S. population or the most highly exposed subpopulation. The table below presents the calculations for the chronic drinking water assessment.

Table 4. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Available Water Exposure (mg/kg/day)	DWLOC (ppb)	Maximum Surface Water EECs (ppb)	Maximum Groundwater EECs (ppb)
Methamidophos						
U.S. Population	0.0001	0.000007	0.000093	3.3	3.8	0.028
Children 1-6 years old	0.0001	0.000015	0.000085	0.9	3.8	0.028
Methamidophos from all Sources						
U.S. Population	0.0001	0.000023	0.000077	3	3.8	0.033
Children 1-6 years old	0.0001	0.000037	0.000063	0.6	3.8	0.033

The acute and chronic dietary risks from drinking water exposure are above the Agency's level

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of concern for most subpopulations.

3. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and any non-occupational exposures (residential use). Acute and chronic aggregate risk assessments were conducted for methamidophos. Methamidophos is not registered for use in residential settings. Previously, acephate had numerous residential, recreational and institutional uses which were evaluated in the acephate IRED. To mitigate risks of concern, acephate use in these settings have been limited to indoor use in institutional settings such as schools and hospitals, use on ornamentals in the residential settings, spot or mound treatments for fire ant control, and use on golf course turf. The risks associated with the degradation of acephate to methamidophos for these uses were evaluated in the acephate IRED and were found to be negligible. Therefore, aggregate short-term exposures were not estimated. Results of the aggregate risk assessment are summarized here, and are discussed in the methamidophos human health risk assessment.

The Agency was only able to quantify food sources of dietary exposure to methamidophos because dietary exposures through drinking water have only been estimated using models. Neither adequate groundwater or surface water monitoring data were available to estimate potential drinking water exposures to methamidophos.

Acute Aggregate Risk Assessment: Potential acute dietary risks from food sources alone do not exceed the Agency's level of concern. The most exposed subpopulation, all infants, consume 76% of the acute PAD at the 99.9th percentile of exposure, based on highly refined exposure estimates. Further, potential drinking water risks from exposure to water from ground water sources does not exceed the acute DWLOCs and, therefore, do not exceed the Agency's level of concern. However, when drinking water exposure concentrations, derived from surface water models, are added to the acute dietary risk assessment, the potential exists for acute dietary exposures through drinking water that exceed the acute DWLOCs, resulting in acute aggregate risks of concern.

Chronic Aggregate Risk Assessment: In the case of the food component of the chronic aggregate risk assessment, risks are well below the Agency's level of concern. No more than 37% of chronic PAD is consumed for children 1-6. Further, potential drinking water risks from exposure to water from ground water sources does not exceed the chronic DWLOCs and, therefore, do not exceed the Agency's level of concern. However, based on modeled estimates of methamidophos concentrations in surface water, the potential exists for chronic dietary exposures through drinking water that exceed the chronic DWLOCs, resulting in chronic aggregate risks of concern.

4. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a

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pesticide, or re-entering treated sites. Methamidophos is a restricted use pesticide and has no uses in residential areas. However, methamidophos is a degradant of the pesticide acephate which does have residential uses. Methamidophos residential exposure risk resulting from acephate applications in residential areas was evaluated in the Interim Reregistration Eligibility Decision for Acephate dated September 30, 2001. Occupational handlers of methamidophos include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of methamidophos is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for methamidophos, including a 21-day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for methamidophos are listed below. Due to the use patterns of methamidophos, long-term exposure is considered highly unlikely.

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

Route and Duration of Exposure	Toxicological Endpoint and Dose	Study	Absorption Factor
Short-Term Dermal	NOAEL = 0.745 mg/kg/day, LOAEL = 11.2, mg/kg/day, based on plasma, red blood cell, and brain cholinesterase inhibition	21-day dermal toxicity in rats	NA
Intermediate-Term Dermal	NOAEL = 0.745 mg/kg/day, LOAEL = 11.2, mg/kg/day, based on plasma, red blood cell, and brain cholinesterase inhibition	21-day dermal toxicity in rats	NA
Short-Term Inhalation	NOAEL = 0.001 mg/l, LOAEL = 0.005 mg/l, based on plasma, red blood cell, and brain cholinesterase inhibition	90-day inhalation toxicity study-rats	NA

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Intermediate-Term Inhalation	NOAEL = 0.001 mg/l, LOAEL = 0.005 mg/l, based on plasma, red blood cell, and brain cholinesterase inhibition	90-day inhalation toxicity study-rats	NA

Methamidophos is acutely toxic, causing death to laboratory animals shortly after exposure to relatively low oral, dermal, or inhalation doses. Methamidophos is only moderately irritating to the eyes and mildly irritating to the skin. Death and other signs of systemic toxicity occurred shortly after dermal or ocular application. These findings suggest that methamidophos is rapidly absorbed via these routes.

Table 6. Acute Toxicity Profile for Occupational Exposure for Methamidophos

Study Type (MRID)	Results	Toxicity Category
Acute Oral-Rat (00014044)	LD_{50}=15.6 mg/kg **%** LD_{50}=13.0 mg/kg **&**	I
Acute Dermal-Rabbit (00014049)	LD_{50}=118 mg/kg **%**	I
Acute Inhalation-Rat (00148449)	LC_{50}=0.052-0.079 mg/l **%** LC_{50}=0.062-0.128 mg/l **&**	I
Primary Eye Irritation-Rabbit (00014221)	Corneal opacity and pannus present in 2/6 rabbits for 10 days post-treatment. One death.	I
Primary skin irritation-Rabbit (00014220)	PIS=0.6. Test material was lethal to 5/9 animals within 24 hrs. of treatment.	I
Dermal Sensitization-Guinea Pig (00147929)	Not a skin sensitizer.	NA

b. Exposure

Three chemical-specific dislodgeable foliar residue studies that were submitted to the Agency by the technical registrant were used to evaluate post-application exposures. Chemical-specific exposure data for handlers were not available for methamidophos, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). In addition, standard assumptions about average body weight, work day, area treated daily and volume of pesticide handled were used to calculate risk estimates. The quality of the data and exposure factors represents the best

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sources of data currently available to the Agency for completing these kinds of assessments. The application rates are derived directly from methamidophos 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 Human Health Assessment document for methamidophos, which is 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 methamidophos labels range to a maximum of 1.0 pounds of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest suite of personal protective equipment (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. The levels of protection that formed the basis for calculations of exposure from methamidophos activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves and a respirator if risk is driven by inhalation.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a closed mechanical transfer system for liquids. Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

For methamidophos, since the same toxicological endpoint and uncertainty factors are being used for both short-term and intermediate-term (1-30 days to several months) exposure durations, both risk estimates are identical. Although information is not available to determine what percentage of applicators apply methamidophos continuously for more than 30 days, it is believed to be a very small segment of commercial applicators.

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c. Occupational Handler Risk Summary

Inhalation and dermal exposure to methamidophos can result from occupational use. The Agency assessed dermal and inhalation risks (MOEs) for each crop currently registered for methamidophos. Since the toxicological endpoints used for dermal and inhalation exposures are the same; plasma, red blood cell, and brain cholinesterase inhibition, the MOEs for each route of exposure were combined to create a single MOE for each scenario. For methamidophos, occupational MOEs greater than 100 are not of risk concern to the Agency.

1) Agricultural Handler Risk

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during typical use-patterns associated with methamidophos. All the MOEs in the tables below are based on combined dermal and inhalation MOEs. The scenario numbers correspond to the scenario numbers detailed and discussed in Appendix A of the Occupational and Residential Exposure Chapter. The current labels require use of a dry-coupling mixing/loading system. Based on the use patterns, five major exposure scenarios (each assessed at the same maximum application rate of 1.0 lb ai/A) were identified for methamidophos:

- (1a) mixing/loading of liquid formulation for aerial application and chemigation (potato only);
- (1b) mixing/loading of liquid formulation for groundboom application;
- (2) applying sprays with an aircraft;
- (3) applying sprays with groundboom equipment; and
- (4) flagging aerial spray applications.

As summarized in Table 7, occupational risks are of concern (i.e., MOEs < 100) for most scenarios, even when maximum PPE are utilized. Handler risks are also of concern for many scenarios with engineering controls. Engineering controls are considered to be the maximum feasible mitigation. It is notable that dermal exposures are driving the Agency's risk concern for the occupational scenarios in question rather than inhalation exposures especially in the case of applicators and flaggers. For example, the MOE of 51 for groundboom applicators for cotton using enclosed cabs is composed of an MOE of 53 for the dermal component and an MOE of 2198 for the inhalation component.

Table 7. Agricultural Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)

			Total MOEs for Short- and Intermediate-Term Risks			
Exposure Scenario	**Crop**	**Area Treated (A/day)**	**Baseline**	**Min. PPE**	**Max. PPE**	**Engineering Controls**

Mixer/Loader						
(1a) Mixing/loading liquid formulation for aerial application or chemigation	Cotton/Alfalfa	1200	0.015	1.8	2.5	5
	Potato/Tomato	350	0.052	6.3	8.7	17
(1b) Mixing/loading liquid formulation for groundboom application	Cotton/Alfalfa	200	0.090	11	15	30
	Potato/Tomato	80	0.23	28	38	74
Applicator						
(2) Applying sprays with an aircraft	Cotton/Alfalfa	1200	NA	NA	NA	8.4
	Potato/Tomato	350	NA	NA	NA	29
(3) Applying sprays with groundboom equipment	Cotton/Alfalfa	200	16	18	23	51
	Potato/Tomato	80	41	46	59	128
Flagger						
(4) Flagging aerial spray applications	Cotton/Alfalfa	1200	3.7	3.6	3.9	183
	Potato/Tomato	350	13	12	14	626

2) Post-Application Occupational Risk

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

The Agency completed a post-application exposure assessment for methamidophos for the following scenarios: irrigating, scouting, thinning, and weeding immature plants for cotton, potatoes and tomatoes; irrigating, scouting, and weeding mature plants for potatoes and tomatoes; and pruning, staking, tying and hand harvesting for tomatoes. The dermal NOAEL of 0.745 mg/kg/day based on a 21-day dermal toxicity study in rats (Table 5) was used to assess potential dermal exposure to workers

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re-entering treated fields. The post-application assessment is also based on 8 hours of worker daily exposure and the default transfer coefficients (Tcs) shown in Table 8. Also, three chemical-specific dislodgeable foliar residue (DFR) studies were conducted for methamidophos which were used to determine the DFR values used in conducting the post-application risk assessment.

For post-application risks to methamidophos, an MOE of 100 or greater is not of concern to the Agency. Table 8 summarizes the occupational post-application risks following foliar applications of methamidophos. In summary, except for methamidophos use on cotton, which resulted in a MOE >100 within one day after being treated, all crops are of post-application risk concern with REIs as high as 18 days after being treated, such as foliar use of methamidophos on tomatoes in Florida.

Table 8. Occupational Post-application Risks from Foliar Applications of Methamidophos

Crop	Task	Transfer Coefficient (cm^2/hr)	DAT* where MOE > 100
Cotton	Irrigating, scouting, thinning, and weeding immature plants	100	DAT 0
Potato	Irrigating, scouting, thinning, and weeding immature plants	300	DAT 4 (KA) DAT 1 (MO) DAT 2 (WA)
	Irrigating and scouting mature plants	1500	DAT 11 (KA) DAT 4 (MO) DAT 7 (WA)
Tomato	Irrigating, scouting, thinning, and weeding immature plants	500	DAT 12 (FL) DAT 4 (CA) DAT 6 (GA)
	Irrigating and scouting mature plants	700	DAT 15 (FL) DAT 5 (CA) DAT 8 (GA)
	Hand harvesting, pruning, staking, tying	1000	DAT 18 (FL) DAT 7 (CA) DAT 9 (GA)

* DAT = Day after treatment

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 Amended EFED Methamidophos RED Chapter, September 15, 1999, available in the public docket. The only revision to this publicly available document is a revised drinking water assessment discussed in the dietary risk section above.

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1. Environmental Fate and Transport

Although the environmental fate database for methamidophos is not complete, supplemental information from upgradable laboratory studies indicate that methamidophos is not persistent in aerobic environments but may be persistent in anaerobic aquatic environments where it will be associated with the aqueous phase. No acceptable data are available on the behavior of methamidophos under field conditions, but information from acceptable terrestrial field dissipation studies for acephate indicate that methamidophos is not persistent.

Aerobic soil metabolism is the main degradative process for methamidophos. Methamidophos degraded with a calculated half-life of 14 hours in a sandy loam soil at exaggerated applications rates. Its major degradates also rapidly degrade in soil (half-life < four days). Methamidophos photodegrades rapidly on soil (half-life of 63 hours) but photodegrades very slowly in sterile aqueous solutions (half-life of > 200 days) and is stable against hydrolysis under acidic conditions.

Laboratory studies show that methamidophos is very soluble and very mobile. The methamidophos degradate DMPT is also expected to be very mobile. Because methamidophos and its degradate are not persistent under aerobic conditions, little methamidophos residue could be expected to leach to groundwater. Volatilization from soil water is not expected to be a major route of dissipation for methamidophos because of its rapid metabolism in soil and its calculated Henry's constant of 1.6×10^{-11} mole/m^3.

2. Ecological Risk Assessment

The Agency's ecological risk assessment compares toxicity endpoints from ecological studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of methamidophos products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs) which indicates whether a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. In general, the higher the RQ the greater the concern. When the RQ exceeds the LOC for a particular category (e.g. endangered species), the Agency presumes a risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 9.

Table 9. LOCs and Associated Risk Presumptions

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5,	Acute risk
The acute RQ >LOC of 0.2,	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1,	Acute effects may occur in Endangered species

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

a. Ecological Hazard Profile

Avaian/Mammaliam

Based on a review of the available toxicity database, data for birds showed methamidophos to be highly to very highly toxic for acute oral exposure and slightly to very highly toxic for subacute dietary exposure. Table 10 summarizes selected acute toxicity information for birds.

Table 10. Acute Oral Toxicity to Birds

Species	LD_{50} (mg/kg)	Toxicity Category
Acute Oral (Single dose by gavage)		
Mallard Duck	8.48	Very highly toxic
Northern Bobwhite Quail	8	Very highly toxic
Common Grackle	6.7	Very highly toxic
Dark eyed Junco	8	Very highly toxic
Subacute dietary[1] (five days of treated feed)		
Mallard Duck	847.7	Moderately toxic
Northern Bobwhite Quail	42	Very highly toxic

The effects in avian reproduction testing included reduced egg thickness. Table 11 summarizes the results of the chronic toxicity tests for avian species.

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Table 11. Avian Reproductive Toxicity

Species/ Study Duration	NOEC (ppm ai)	LOEC (ppm ai)	LOEC Endpoints
Northern bobwhite	3	5	Egg thickness
Mallard duck	>15	>15	No Effect

Wild mammal testing is not required for methamidophos. Rat toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Acute and chronic rat toxicity data relevant to ecological effects show that methamidophos is highly toxic to small mammals on an acute oral and dermal basis and is considered highly toxic to bees.

Aquatic

Data for freshwater fish showed methamidophos to be slightly toxic for acute exposure. For freshwater aquatic invertebrates, data indicated that methamidophos is very highly toxic for acute exposure. Data for estuarine and marine fish showed methamidophos to be moderately toxic for acute exposure. For estuarine and marine aquatic invertebrates, data indicated that methamidophos is slightly to very highly toxic for acute exposure. Data was either not required (fish) or unavailable (invertebrates) to assess the chronic effects of methamidophos. Table 12 summarizes invertebrate toxicity.

Table 12. Acute Toxicity to Aquatic Invertebrates

Species, Study Type	EC_{50} (ppb ai)		Toxicity Category
	48-hr	96-hr	
Freshwater			
Waterflea	0.026	-	Very highly toxic
Estuarine/Marine			
Oyster	-	39	Slightly toxic
Blue Shrimp	-	0.00016	Very highly toxic
Mysid Shrimp	-	5.6	Moderately toxic

b. Risk to Birds and Mammals

EPA uses models to estimate exposure of nontarget plants and animals to methamidophos. For terrestrial birds and mammals, the Agency first estimates initial levels of pesticide residues on various wildlife food items. Acute and chronic risks to birds and mammals were predicted for the liquid

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formulations of methamidophos.

The Agency's assessment suggests the potential for the liquid formulation to cause acute effects to birds for broadcast applications. The avian acute RQs range from 0.38 to 6.63. The highest avian acute RQ is from nine 1 lb ai/A ground or aerial applications to tomatoes. Regarding chronic risk to birds, the RQs range from 2.49 to 32.87. Table 13 summarizes the risk quotients for birds.

Table 13. Avian Acute and Chronic Risk Quotients Based on Bobwhite Quail

# of Applications	Diet	EEC (ppm)		Risk Quotient	
		Max.	Mean	**Acute**	**Chronic**
Tomatoes at 5 app at 1.0 lb ai	Short grass	256	91	6.10	30.22
	Tall grass	117	38	2.79	12.80
	Broad Leaf	144	48	3.43	16.00
	Seed Fruit	16	7	0.38	2.49
Tomatoes at 9 app at 1.0 lb ai	Short grass	278	99	6.63	32.87
	Tall grass	128	42	3.04	13.92
	Broad Leaf	157	52	3.73	17.40
	Seed Fruit	17	8	0.41	2.71
Potatoes/Cotton at 4 app at 1.0 lb ai	Short grass	256	91	6.10	30.22
	Tall grass	117	38	2.79	12.80
	Broad Leaf	144	48	3.43	16.00
	Seed Fruit	16	7	0.38	2.49

For the same use patterns, mammalian acute RQs range from 0.2 to 20.3 and in chronic RQs for mammals ranging from 0.75 to 9.86. All use patterns are of concern to the Agency for acute and chronic effects to birds and mammals.

c. Risk to Aquatic Animals

To assess potential risk to aquatic animals, the Agency uses a computer model to generate EECs of methamidophos in surface water. However, unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the index reservoir and percent crop area factor. These refinements are solely used to assess pesticide exposure to humans from drinking water sources. Hence, the EECs used to assess exposure to aquatic animals are not the same as the EEC values used to assess human dietary exposure from drinking water sources.

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Acute risk to freshwater fish and estuarine fish is not of concern for any use patterns, with RQs ranging from <0.05 to 0.07. The acute high risk, restricted use risk and endangered species risk is of concern for freshwater invertebrates at the maximum application rate of 1.0 lb ai/A with RQs ranging from 1.1 to 3.0. Risk may be of concern for some estuarine invertebrates based on supplemental data on blue shrimp. No chronic risk assessment was conducted since there are no chronic data for aquatic species.

d. Incidents

Approximately six wildlife mortality incidents likely not to be associated with misuse have been reported to the Agency since 1980. Four of these incidents involved crops which are no longer registered. Three of these incidents involved adverse impacts on bee colonies including two from use on potatoes.

e. Endangered Species

Endangered species LOCs are exceeded for acute and chronic risks to birds and mammals and acute risks to freshwater invertebrates for all currently registered uses of methamidophos.

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

C. Benefits

The Agency has assessed the benefits of all registered uses of methamidophos. A summary of the Agency's benefits findings is presented below; for more information, see the following documents: *Use and Usage Analysis for Methamidophos,* dated November 20, 2001, and *Methamidophos Use on Cotton, Tomatoes and Potatoes*, dated December 6, 2001. All of these documents are available in the public docket and on the internet.

Alfalfa for Seed

In 2000, more than 50% of the alfalfa seed acreage in California was treated with

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methamidophos. The primary target pest of methamidophos applications is lygus bug, which is a key pest in alfalfa seed. Lygus bug can cause significant economic damage to alfalfa grown for seed throughout the growing season. Methamidophos is an important element of a resistance management program for this pest early in the season, before introducing pollinators into the fields. It is the most effective chemical for lygus bug control at this time of the season. The alternatives to methamidophos include methidathion, which is less effective; and synthetic pyrethroids, which have limited use due to problems with resistance. Methamidophos is applied once per season at an average rate of one pound per acre.

Cotton

In 2000, an estimated 2% of the U.S. cotton acreage was treated with methamidophos. Arkansas and Louisiana reported 4% of state cotton acreage treated in that year, while California reported 2%. The average number of applications made to cotton per year is one at an average application rate of 0.3 pounds of active ingredient per acre. In California, methamidophos use is targeted primarily for the control of lygus bugs. State cotton specialists have indicated that methamidophos is an important part of their IPM programs in California and also noted that lygus bugs are developing resistance to some alternatives to methamidophos. The alternatives to methamidophos for lygus bug control include acephate, aldicarb, bifenthrin, cyfluthrin, cypermethrin, dimethoate, oxamyl, and zetamethrin.

In Louisiana and Arkansas methamidophos applications are targeted primarily for control of whiteflies and thrips. State experts in Louisiana have indicated that a shifting thrip species population in that state has increased the importance of methamidophos use there. For thrip control, the alternatives to methamidophos include acephate, aldicarb, dicrotophos, imidacloprid and phorate. For the control of whiteflies the alternatives include acephate, buprofezin, chlorpyrifos, fenpropathrin, profenofos, and pyriproxifen.

Potatoes

In 2000, an estimated 29% of the U.S. potato acreage was treated with methamidophos. Washington reported 80% of state acreage treated in that year, while Idaho, Oregon and Pennsylvania all reported greater than 28% of state acreage treated. The average number of applications made to potatoes per year ranged from 1 to 3.2 at an average application rate of between 0.6 and 1.0 pound of active ingredient per acre. Methamidophos application in potatoes is generally a 7 -10 day preventative program and cannot be applied within 14 days of harvest.

The three primary target pests for use of methamidophos on potatoes are green peach aphid, Colorado potato beetle and leafhoppers. Pre- and post-emergence control of the green peach aphid, a vector for the potato leafroll virus, is the critical methamidophos use in most areas of the country. Alternatives for pre-emergence control include aldicarb, imidacloprid and phorate. Only imidacloprid is a potential alternative for post-emergence control but it is significantly more costly and does not have

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the period of residual effectiveness that methamidophos has that is necessary in some potato growing regions. There is also concern for potential resistance in some regions for imidacloprid. Aldicarb's use for pre-emergence control is limited due to a 150 day pre-harvest interval (PHI). These circumstances make methamidophos critical to potato production, especially in the production of potatoes for seed, where there is zero tolerance for aphids or the viruses they carry.

For Colorado potato beetle control, alternatives to methamidophos include carbofuran, esfenvalerate, endosulfan, imidacloprid and phosmet. The effectiveness of the alternatives vary by region. In the major production areas, carbofuran and methamidophos are the most efficacious pesticides for controlling this pest. For the control of leafhoppers in potatoes, there are a number of registered alternatives to methamidophos, however, only carbaryl may provide acceptable efficacy.

Tomato (Fresh)

In 2000, an estimated 15% of the U.S. fresh market tomato acreage was treated with methamidophos. This is down from an estimated 60% of the U.S. fresh tomato crop treated with methamidophos in 1994. In Florida, which accounts for more than 40% of U.S. fresh market tomato production, 14% of the fresh tomato acreage was treated with methamidophos in 2000. In California, which accounts for 30% of U.S. fresh market tomato production, 8% of the fresh tomato acreage was treated with methamidophos in 2000. In Georgia, North Carolina, South Carolina and Tennessee, which account for a combined 10% of U.S. fresh market tomato production, 86%, 58%, 46% and 22% of the tomato acreage in each state was treated with methamidophos in 2000, respectively. The average number of applications made with methamidophos to fresh market tomatoes per year ranged from 1.2 to 3.3, with average application rates ranging from 0.5 and 1.0 pound of active ingredient per acre.

Methamidophos is used primarily to control Western flower thrips in fresh tomatoes in the Southeastern U.S. This pest a primary vector of Tomato Spotted Wilt Virus, which can reduce the marketable yields on fresh tomatoes by up to 50%. Methamidophos applications are critical for the control of this pest because growers target as many as 5-6 insecticide applications per season for this pest, and the only effective alternative to methamidophos, spinosad, is limited to two applications per season. Without methamidophos, growers would not achieve sufficient control of the pest, and would likely face significant yield losses from the virus.

Methamidophos is also used to control silverleaf whitefly in the Southeastern U.S. This is a difficult pest to manage and it transmits Tomato Mottle Virus and Tomato Yellow Leaf Curl Virus, which can cause significant tomato damage. Methamidophos is considered to be important as a cost-effective synergist mixed with a synthetic pyrethroid insecticide to control this pest. The alternatives to methamidophos to control silverleaf whitefly include endosulfan, esfenvalerate, fenpropathrin, imidacloprid, permethrin, pymetrozine, pyriproxifen and thiamethoxam.

In California, the primary target pest for methamidophos on fresh tomatoes is stink bug.

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Methamidophos is the only effective insecticide available for controlling this economically important pest. The primary alternatives to methamidophos for the control of this pest are limited in their effectiveness. Imidacloprid is only effective against low populations, dimethoate is a severe hazard to bees, and endosulfan has waterway restrictions which limit its use. Without methamidophos, growers would not achieve sufficient control of the pest, and would likely face significant yield losses.

Methamidophos is applied to fresh tomatoes late in the growing season in California. Therefore, many cultural activities such as weeding, pruning, staking and tying are completed well in advance of application of this material. By contrast, in the Southeastern U.S., methamidophos is applied throughout the season, resulting in applications before or soon after these activities occur in the field. Current labels require a 7 day PHI.

Tomato (Processed)

California accounts for more than 95% of the U.S. production of processed tomatoes. In 2000, an estimated 3% of the California processed tomato acreage was treated with methamidophos. Methamidophos usage on processed tomatoes has seen a steady decline since the mid-1990's. An average of one application is made with methamidophos to California processed tomatoes per year, and slightly less than one pound of active ingredient is applied on average per acre per application.

As in the case of fresh tomatoes in California, the primary target pest of methamidophos application to processing tomatoes is stink bug. The limitations mentioned earlier on the primary alternatives to methamidophos for control of this pest, make methamidophos an important tool in processed tomato production.

Methamidophos is applied to processed tomatoes late in the growing season in CA. Therefore, many cultural activities such as weeding, pruning, staking and tying are completed well in advance of application of this material. Current labels require a 14 day PHI in CA.

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IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient methamidophos , as well as a methamidophos-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 methamidophos, EPA has sufficient information on the human health and ecological effects of methamidophos to make an interim decision as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that methamidophos products are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted including the phase out of the cotton use, and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision.

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

Although the Agency has not yet considered its final cumulative risk assessment for 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 methamidophos. Based on its current evaluation of methamidophos alone, the Agency has determined that methamidophos 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 methamidophos.

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At the time that the cumulative assessment is finalized, the Agency will address any outstanding risk concerns. For methamidophos, if all changes outlined in this document are incorporated into the labels, then all currently recognized risks will be adequately managed. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for methamidophos after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk mitigation measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

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

If the Agency determines, before finalization of the RED, that any of the determinations described in this 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.

Label changes for methamidophos are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of methamidophos, and lists the submitted studies that the Agency found acceptable.

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 Public Participation Process. These comments in their entirety are available in the docket. The Agency received comments from the technical registrant, Bayer Corporation. Comments were also received from the National Potato Council, the California Tomato Research Institute, the National Agricultural Aviation Association, Florida Fruit and Vegetable Association, Washington State University, California Tomato Commission and Environmental Focus. The Agency also received approximately 10 comments from various agri-business companies and associations, commodity groups, farm bureaus, universities, extension, and state agencies, as well as private citizens, supporting the use of methamidophos. A brief summary of the comments and the

Agency response is noted here.

Registrant Comments

Comment: Bayer noted differences between dietary assessment conducted by EPA versus the Bayer assessment. The three main differences noted were (1) processing factors used, particularly in tomato residue assessment, (2) percent crop treated data used and (3) imputation of composite residue data appears to be inappropriate and exaggerates high-end predictions for residues.

Response: The dietary assessment was conducted with the best available data and in accordance with Agency policy. The most recent dietary assessment reflects some of the concerns noted by the registrant. These include changes to the % crop treated and the use of processed tomato data.

Comment: Some assumptions used by the Agency in the assessment appear not to be reflective of assumptions supported by data the Agency has on hand. The risk assessment uses transfer coefficients ranging from 2500 to 10000 whereas recent studies have shown that more realistic values range from 100 to 650 for activities such as scouting and harvesting.

Response: The risk assessment has been revised to incorporate updated TC's which were generated as a result of the ARTF data. The range of TC's used is 300 to 1500 depending on the crop involved and the activity being evaluated.

Comment: The assessment also appears to have inadequately considered the personal protective equipment requirements specified on the product label. The revised assessment failed to use NIOSH exposure reduction factors for the label specified respiratory protection. The revised assessment also used dermal exposure reduction factors that are not consistent with exposure reduction factors used by other regulatory agencies or with exposure reduction factors derived from PHED data.

Response: Where possible, the labeled PPE was accounted for in the various PPE scenarios evaluated in the risk assessment. There are some PPE, such as chemical-resistant aprons, that the Agency views as qualitative measures because there are no recognized protection factors (PF) to assess their effectiveness. The Agency has no protection factors to assess headgear. Face and neck wipe monitoring data constitutes dermal head exposure values. All occupational handlers were assessed as wearing footwear (socks plus shoes or boots), foot exposure is not traditionally monitored, and therefore, a 100 percent protection factor is implied. Finally, inhalation exposures were not the most significant risk factor, (if protection factors were increased, little change in combined MOEs would result).

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Comment: The uncertainty attributed to interspecies variability for the selected endpoint is not supported by available human and animal data. Therefore Bayer believes that an MOE of 10 provides an adequate margin of safety for the product and should be used for the methamidophos occupational exposure and risk assessment.

Response. Consistent with the Agency's policy announced on December 14, 2001, this assessment does not consider or rely on any third-party studies which intentionally dose human subjects with toxicants to identify or quantify their effects. Therefore, the Agency continues to employ the uncertainty of 100.

Washington State University

Comment: Comments that EPA rejected a human exposure study and indicated that if these results were used, the 100-fold uncertainty factor applied to the chronic RfD could be confidently reduced.

Response: Consistent with the Agency's policy announced on December 14, 2001, this assessment does not consider or rely on any third-party studies which intentionally dose human subjects with toxicants to identify or quantify their effects. Therefore, the Agency continues to employ the 100-fold uncertainty factor.

Comment: The potato processing study, although submitted by the manufacturer, has some serious methodological flaws as pointed out by the Agency. Consequently, the 10X concentration factor for potato chips is completely unrealistic. The DEEM analysis for tomato puree has an ambiguous entry. The stated processing factor for tomato puree is 0.7, yet the acute DEEM analysis shows that there are several puree types with factors of 3.3.

Response: Although some irregularities were noted in the potato processing study, the Agency concluded that these actions did not likely affect the overall conclusions of the study. Unless additional information is provided, the 10X concentration factor will continue to be used in the dietary assessment. With respect to tomatoes, a revised dietary assessment has been conducted which incorporates monitoring data for processed tomatoes. Since actual processed commodity data was used, a processing factor was not applied. Consequently, the concerns about the tomato processing factor is no longer applicable.

Comment: The post application exposure scenario included hand harvesting of potatoes. This is a situation that is a remote exception rather than the rule. Further, a question was raised as to the use of different transfer coefficients for different compounds having the same post occupational activity.

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Response: The current policy on transfer coefficients lists potatoes under Vegetables, "root". Within the root vegetable category, mechanical potato harvesting exposure was assigned a value of 0. Hand harvesting was listed as out of scope of the transfer coefficient table. Therefore, hand harvesting is no longer a scenario for which risk estimates are developed.

California Tomato Research Institute

Comment: The commentor states that the PDP data are not representative of California's 95% portion of the US processed crop and that using the PDP data coupled with a processing factor does not deliver a relevant or accurate processed methamidophos exposure. Use information and residue data collected by California Department of Pesticide Regulation was provided.

Response: As discussed earlier, a revised dietary assessment which includes USDA monitoring data for processed tomatoes and percent crop treated information which separates processed and fresh tomato has been conducted.

Environmental Focus

Comment: Environmental Focus has concerns pertaining to assigning a 15% default value for drift when applying methamidophos next to surface water. The AgDRIFT model does not specify a drift default value associated with aerial application.

Response: The 15% value is the result of the adoption of the AgDRIFT model, which when used with default values for droplet size, pond size and wind speed gives that result. The modeling conducted by the Agency is intended to be a conservative screening assessment. The assumptions made are not considered unreasonable and fall within the range of allowed use of the chemical.

Comment: Environmental Focus has concerns that the Agency uses a scenario in its assessment that assumes an aerial applicator will apply next to a drinking water supply when wind speed is 10 mph.

Response: The models are used as a screening tool and, as such, are intended to simulate situations that could occur in the field. The modeling is done according to the label, and in conditions that are not intended to be typical but are realistic.

National Agricultural Aviation Association

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Comment: NAAA is concerned that the data the EPA uses to determine the occupational risk associated with the aerial application are outdated and overly conservative. Specifically, PHED does not include data on worker exposure subsequent to 1992- which is before the Worker Protection Standards went into effect at a time when many techniques and equipment to protect workers became commonplace. NAAA believes that if more current data that takes into account technological advancements that enhance worker protection, any exposure assessment would demonstrate an adequate margin of safety for those involved aerial application including new technological advances.

Response: The Agency considered this comment during the risk mitigation process. The Agency would consider any data that the NAAA would submit.

Comment: NAAA has concerns pertaining to assigning a 15% default value for drift when applying methamidophos next to surface water. The AgDRIFT model does not specify a drift default value associated with aerial application.

Response: See earlier response to similar question.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment is 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 fully developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to methamidophos is within its own "risk cup." In other words, if methamidophos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for methamidophos meet the FQPA safety standards, provided the risk mitigation measures outlined in this document are implemented and additional data needs are addressed. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and

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drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels. While the combined risks from all exposures to methamidophos "fill" the aggregate risk cup, the water exposures are based on screening-level modeling estimates. The Agency has determined that actual drinking water exposures are likely to be lower than predicted by these models and has made a regulatory determination that combined risks from all exposures to methamidophos "fit" within the individual risk cup. Except for those tolerances that are to be lowered or revoked, the current methamidophos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered later this year.

b. Tolerance Summary

Tolerances for residues of methamidophos in/on plant commodities [40 CFR §180.315 (a) and (b)] are currently expressed in terms of residues of methamidophos *per se*.

The available plant and animal metabolism studies indicate that the residue of concern is the parent methamidophos. Methamidophos is also a metabolite of acephate. It is recommended that residues of methamidophos resulting from the metabolism of acephate be included under the tolerance regulations for methamidophos as a pesticide [40 CFR §180.315(c)]. This change is needed to achieve compatibility with the MRLs of the Codex Alimentarius Commission, if only in terms of residue definition. Such a change in the residue definition requires deletion of paragraph (d) (8) of 40 CFR §180.3 which states that methamidophos residues may not exceed the higher of the two tolerances established for the use of acephate or methamidophos as a pesticide.

The listing of methamidophos tolerances under 40 CFR §180.315 should be subdivided into parts (a), (b), and (c). Part (a) should be reserved for permanent tolerances, part (b) for tolerances with regional registration, and part (c) for tolerances reflecting use of acephate formulations alone (i.e., no methamidophos formulations are registered for use on these commodities).

The Agency will commence proceedings to revoke and modify existing tolerances, and correct commodity definitions. The establishment of a new tolerance or raising tolerances will be deferred, pending consideration of cumulative risk for the organophosphates. "Reassessed" does not imply that all of the tolerances have been reassessed as required by FQPA, since these tolerances may only be reassessed once the cumulative risk assessment of all organophosphate pesticides is considered, as required by the statute. Rather, this IRED provides reassessed tolerances for methamidophos in/on various commodities, supported by all the submitted residue data, only for the single organophosphate chemical methamidophos. EPA will finalize these tolerances after considering the cumulative risks for all organophosphate pesticides. The Agency's tolerance summary is provided in Table 14. This table lists several tolerances associated with uses that are no longer registered, as announced in FIFRA 6(f)(1) Notices of Receipt of Requests from the registrant for cancellation and/or use deletion, which EPA approved. Therefore, the associated tolerances should be revoked.

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Table 14. Tolerance Summary for Methamidophos

Commodity	Tolerance Listed Under 40 CFR §180.315	Reassessed Tolerance	Tolerance Listed Under 40 CFR §180.108	Comment *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.315 (a)				
Beets, sugar, roots	0.02	Revoke	--	The registrants are not supporting methamidophos use on sugar beets and there are no registered acephate uses.
Beets, sugar, tops	0.50	Revoke	--	
Broccoli	1.0	Revoke	--	The registrants are not supporting methamidophos use on broccoli and there are no registered acephate uses.
Brussels sprouts	1.0	1.0	0.5	This tolerance must be moved to §180.315(c).
Cabbage	1.0	Revoke	--	The registrants are not supporting methamidophos use on cabbage and there are no registered acephate uses.
Cauliflower	1.0	0.5	0.5	This tolerance must be moved to §180.315(c).
Cottonseed	0.1 (N)	0.2	--	[*Cotton, undelinted seed*]
Cucumbers	1.0	Revoke	--	The registrants are not supporting methamidophos use on cucumbers and there are no registered acephate uses.
Eggplant	1.0	Revoke	--	The registrants are not supporting methamidophos use on eggplant and there are no registered acephate uses.
Lettuce, head	1.0	1.0	1	This tolerance must be moved to §180.315(c).
Melons	0.5	Revoke	--	The registrants are not supporting methamidophos use on melons and there are no registered acephate uses.

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Commodity	Tolerance Listed Under 40 CFR §180.315	Reassessed Tolerance	Tolerance Listed Under 40 CFR §180.108	Comment *[Correct Commodity Definition]*
Peppers	1.0	1.0	1	This tolerance must be moved to §180.315(c). *[Pepper, bell and non-bell]*
Potatoes	0.1(N)	0.1	--	
Tomatoes	1.0	2.0	--	
Tolerance To Be Proposed Under 40 CFR §180.315 (a)				
Cotton, gin byproducts	--	10	--	
Tolerance Listed Under 40 CFR §180.315 (b)				
Celery	1	1.0	1	This tolerance must be moved to §180.315(c).
Tolerances to be Listed Under 40 CFR §180.315(c)				
Beans (succulent and dry form)	--	1.0	1	[*Beans, dry and succulent*]
Brussels sprouts	1.0	1.0	0.5	
Cauliflower	1.0	1.0	0.5	
Celery	1	1.0	1	
Cranberries	--	0.1	0.1	
Lettuce	1.0	1.0	1	[*Lettuce, head*]
Mint hay	--	2	1	[*Mint, tops (leaves and stem)*]
Peppers	1.0	1.0	1	*[Peppers, bell and non-bell]*
Soybeans	--	–	1	

Tolerances Listed Under 40 CFR §180.315 (a)

Pending label amendments for some crops, adequate field trial data are available to reassess the established tolerances for cottonseed, potatoes, and tomatoes. The available data suggest that the tolerance levels for cottonseed and tomato should be raised to 0.2 ppm and 2.0 ppm, respectively.

The use of methamidophos on Brussels sprouts, cauliflower, lettuce, and peppers was cancelled in 1997. Because there are registered acephate uses on these crops, methamidophos tolerances for these crops should be moved to 40 CFR §180.315(c).

The following tolerances should be revoked as the registrants are not supporting methamidophos

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uses and there are no registered acephate uses on these commodities: beets, sugar, roots; beets, sugar, tops; broccoli; cabbage; cucumbers; eggplant; and melons.

Tolerance to be Proposed Under 40 CFR §180.315 (a)

A tolerance for residues of methamidophos in/on cotton gin byproducts must be proposed. The available data support a tolerance level of 10 ppm.

Tolerance Listed Under 40 CFR §180.315 (b)

The use of methamidophos on celery was cancelled in 1997. Because there are registered acephate uses on this crop, the methamidophos tolerance for this crop should be moved to 40 CFR §180.315(c).

Tolerances to be Listed Under 40 CFR §180.315(c)

The basic producer of acephate (Valent U.S.A. Corporation) intends to support use of acephate on the following food/feed crops: beans (snap, dry, and lima); Brussels sprouts; cauliflower; celery; cotton; cranberries; lettuce, head; peanut; pepper, non-bell; pepper, bell; peppermint/spearmint; soybean; and tobacco. Therefore, tolerances for residues of methamidophos in/on these commodities (except tobacco) resulting from use of acephate should be established under 40 CFR §180.315(c). The tolerance expression in this section should read: "Tolerances are established for residues of methamidophos in or on the following raw agricultural commodities as a result of the application of acephate:".

Tolerances for combined residues of acephate and methamidophos in cottonseed meal and hulls have been established (40 CFR §180.108). However, based on a cottonseed processing study submitted to satisfy methamidophos reregistration requirements, methamidophos residues do not concentrate in cottonseed processed commodities. Therefore, tolerances for methamidophos residues in cottonseed processed commodities are not required under 40 CFR §180.315(c).

A tolerance for the combined residues of acephate and methamidophos in soybean meal has been established (40 CFR §180.108). Data for soybean processed commodities were reviewed in the Acephate Reregistration Standard Update (dated 1/29/92). In one study conducted in 1978, soybeans were treated with three applications of a 75% SC/S formulation at 1 or 2 lb ai/A/application (2x or 4x the maximum seasonal rate Valent wishes to support). Methamidophos residues were found to concentrate slightly in soybean meal (average concentration of 1.2x) and hulls (average concentration of 1.9x) but not in crude oil. In a second study conducted in 1987, soybeans were treated with 11 applications of a 75% SC/S formulation at 2 lb ai/A/application (- 15x the maximum seasonal rate Valent wishes to support). Methamidophos residues were 0.01-0.02 ppm in/on soybeans, 0.02 ppm in meal, 0.02 ppm in hulls and <0.01 ppm in refined oil. Based on the exaggerated application rates used in the studies and the resulting residues in processed commodities, the Agency concludes that no

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tolerances are required for methamidophos residues in soybean processed commodities.

For mint hay, data submitted by the registrant since the tolerance was set support an increase in the tolerance.

Tolerances Listed Under 40 CFR §180.315(a) and (b)

Tolerances have been established for residues of methamidophos in/on various raw agricultural commodities [40 CFR §180.315(a) and (b)]. In addition, tolerances have been established for combined residues of acephate and its metabolite methamidophos in/on various plant and animal commodities [40 CFR §180.108(a) and (b)]. Tolerances established for acephate in/on several commodities (beans, Brussels sprouts, cauliflower, celery, cranberries, lettuce, mint hay, and peppers) include limits on residues of methamidophos.

Residue Analytical Methods

Adequate methods are available for data collection and tolerance enforcement for plant commodities. For tolerance enforcement, the Pesticide Analytical Manual (PAM) Vol. II lists a GLC method (designated as Method I) with thermionic detection for the determination of methamidophos (LOD = 0.01 ppm) residues in/on plant commodities. PAM Vol. 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 metabolism studies have been submitted and evaluated.

Because no tolerances are required for animal commodities, no enforcement method for animal commodities is required.

CODEX Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of methamidophos in/on various plant and animal commodities. The Codex MRLs are expressed in terms of methamidophos *per se*. The expression of residues for Codex MRLs and U.S. tolerances is harmonized. A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in Table 15. Further harmonization of U.S. tolerances and Codex MRLs are not feasible at this time because of differences in agricultural practices.

Table 15. Codex MRLs and Applicable U.S. Tolerances for Methamidophos.

Codex		Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)		
Alfalfa forage (green)	2 [1]	--	No U.S. registrations.
Brussels sprouts	1	1.0	
Cabbages, Head	0.5 [2]	--	U.S. registrants not supporting use.

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Codex		Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)		
Cattle fat	0.01 (*) [3]	--	
Cattle meat	0.01 (*)	--	
Cauliflower	0.5 [2]	0.5	
Celery	1	1.0	
Cotton seed	0.1 [4]	0.2	
Cucumber	1	--	U.S. registrants not supporting use.
Goat fat	0.01 (*)	--	
Goat meat	0.01 (*)	--	
Hops, dry	5	--	No U.S. registrations.
Lettuce, Head	1	1.0	
Melons, except Watermelon	0.5	--	U.S. registrants not supporting use.
Milks	0.01 (*)	--	
Peach	1 [2]	--	No U.S. registrations.
Peppers, Chili	2	1.0	
Peppers, Sweet	1	1.0	
Pome fruits	0.5	--	No U.S. registrations
Potato	0.05 [4]	0.1	
Rape seed	0.1	--	No U.S. registrations
Sheep fat	0.01 (*)	--	
Sheep meat	0.01 (*)	--	
Soya bean (dry)	0.05 [1]	0.01	
Sugar beet	0.05	--	U.S. registrants not supporting use.
Sugar beet leaves or tops	1	--	U.S. registrants not supporting use.
Tomato	1 [2]	2	
Tree tomato	0.01 (*) [1]	--	No U.S. registrations.
Watermelon	0.5	--	U.S. registrants not supporting use.

[1] Based on treatment with acephate.

[2] The MRL is based on residues from the use of methamidophos, not acephate (1996 JMPR).

[3] (*) = At or about the limit of detection.

[4] Including residues resulting from the use of acephate.

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2. Endocrine Disruptor Effects

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

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

3. Labels

A number of label amendments, in addition to the existing label requirements, are necessary in order for methamidophos products to be eligible for reregistration. The Agency has determined that these measures, in addition to the existing label requirements, will adequately reduce risks to handlers.

Provided the following risk management measures are incorporated in their entirety into labels for methamidophos-containing products, the Agency finds that all currently registered uses of methamidophos are eligible for interim reregistration, pending consideration of cumulative risks of the organophosphates. While all uses are eligible at this time, the cotton use will be phased out over five years. The regulatory rationale for each of the risk management measures outlined below is discussed immediately after this list of required risk management measures.

a. Agricultural Use Exposure Reduction Measures

For agricultural use, the following measures are required, in addition to the existing labeling requirements to address drinking water, occupational handler and ecological risks of concern. The registrant has not yet agreed to these measures.

- Require all labels be amended to indicate that applications must be made using enclosed cab tractors or enclosed cockpits.
- Require all labels be amended to indicate that flaggers must be in enclosed vehicles or mechanical flaggers be used; or the use of ground positioning system (GPS) equipment that negates the need for flaggers for aerial application.
- Require all labels to reduce maximum # of applications to 2 per season during phase out period

for cotton.

- Require all labels to reduce maximum # of applications to 4 or less per season for tomatoes (current SLNs that have maximum # of applications less than 3 would retain that number of applications).
- Require all labels to increase REIs for all activities to 4 days for potatoes.
- Require Section 24(c) labels to increase REIs for all activities to 4 days for tomatoes except in CA where the REI will remain at 3 days.

b. Homeowner Use Exposure Reduction Measures

There are no residential uses for methamidophos.

D. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

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

1) Acute Dietary (Food)

Acute dietary (food) exposure to methamidophos from applications of methamidophos alone, and from "all sources" (applications of methamidophos and acephate) result in risk estimates that are below the Agency's level of concern—that is, less than 100% of the acute PAD is used. For example, for exposure resulting from applications of methamidophos alone, for the most exposed subpopulation, children 7-12 years old, the percent acute PAD value is 33% at the 99.9th percentile of exposure from consumption of food alone.. For exposure resulting from applications of methamidophos alone and methamidophos residues from the application of acephate, for the most exposed subpopulation, all infants, the percent acute PAD value is 76% at the 99.9th percentile of exposure from consumption of food alone. No mitigation measures are necessary at this time to address acute dietary risk from food.

2) Chronic Dietary (Food)

Chronic dietary (food) exposure estimates are below the Agency's level of concern for all subpopulations. For the most highly exposed subpopulation, children 1-6 years old, the percent

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chronic PAD values are 15% for methamidophos alone and 37% when including methamidophos residues from the application of acephate, from consumption of food alone. No mitigation measures are necessary at this time to address chronic dietary risk from food.

3) Drinking Water

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

Based on model predictions of currently registered uses, the EECs for methamidophos from the application of methamidophos in surface water range from 28.6 to 61.8 ppb for acute exposure, and from 1.5 to 3.8 ppb for chronic exposure. The only surface water EEC calculated for methamidophos from the application of acephate, using the Tier I GEENEC model is 22 ppb. The acute and chronic EEC for methamidophos from all sources in groundwater is 0.033 ppb. Table 3 summarizes the modeled EECs for the respective crop scenarios.

The acute and chronic dietary risks from drinking water exposure from ground water sources are not of concern because the groundwater EECs are well below the DWLOCs. The acute and chronic dietary risks from drinking water exposure from surface water sources are above the Agency's level of concern for all subpopulations. However, there are uncertainties which lead the Agency to expect that actual exposure from drinking water is unlikely to be as high as the levels used in the development of the risk assessment which are based on screening models. Based on these uncertainties and the anticipated reduction in water contamination implementing the risk reduction measures contained in this document, the Agency believes that the risks from drinking water are not of concern.

The drinking water risk assessments are based on screening level models that are conservative in their estimates of drinking water exposure. Actual exposure is expected to be lower than the EEC's reported in the IRED. An example of the type of assumptions used in the model that can contribute to conservative estimates involves rainfall levels. To determine what rainfall level to use in the model, the Agency identifies a peak rainfall level for each of 36 years of daily rainfall data. The model then assumes that rainfall will equal the 90th percentile of these 36 annual peak values when estimating concentrations, a conservative assumption. Also, the percent cropped area (PCA) assumption for potatoes used in the model is 0.87, the default assumption. This means the model assumes that 87% of a watershed is planted with one of these crops and that 100% of this crop is treated with methamidophos, which appears unlikely to occur especially considering that the PCA calculated for major crops like corn and cotton using data submitted to the Agency are 0.46 and 0.20 respectively. For example, with respect to the scenario with the highest calculated EEC, potatoes in Maine, it is estimated that 65,000 acres of potatoes are grown in the state of Maine each year. If it was assumed that all that acreage fell into any one of the nine watersheds in Maine as a worst-case scenario, the range of PCA values would likely be 0.04 to 0.16 or 4% to 16%, significantly lower than the 87%

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assumption. The effect of the PCA value on EECs has a linear relationship. Consequently, using these values would reduce EECs by a factor of 5 to 20. Even though this analysis has not been deemed to be sufficient to change the PCA quantitatively, it does provide a sense of the potential uncertainty of the modeled water concentrations in this case.

With regard to the potential risks associated with acephate application, the model used to estimate water concentrations is a tier I model and, as such, is not as refined as the tier II PRZM-EXAMS model. A higher-tiered model was not used in this case due to the high level of uncertainty surrounding any estimate of the decay rate for acephate and the transformation rate of acephate to methamidophos which are needed to use the PRZM-EXAMS model. This increases the level of uncertainty associated with these estimates. For the purposes of assessing drinking water risks from exposure to methamidophos from all sources (i.e. including both methamidophos and acephate applications) the Agency will rely upon the model estimates generated using the PRZM-EXAMS model with the Index Reservoir (IR) and Percent Crop Area (PCA) modifications described above which are based upon the application of methamidophos alone. The Agency believes that the conservative default PCA used for the scenario with the highest EEC (potatoes in ME) discussed above would most likely account for methamidophos residues from both methamidophos and acephate applications in a given watershed. As mentioned above, these estimates may be as much as a factor of 5 to 20 times greater than actual water concentrations. Further, the main crop uses of acephate (beans, cotton, lettuce and tobacco) are either not grown in Maine or are not likely to have significant acreage. Therefore, additional contribution of methamidophos residue from the application of acephate in this scenario is very unlikely. These considerations support the belief that this modeled EEC likely provides a sufficiently protective estimate of exposure to methamidophos from all sources in drinking water. Further, the information is not currently available to enable the Agency to use a Tier II model to estimate concentrations of methamidophos from the application of acephate, as described above, and it is not considered appropriate to combine the results of a Tier II assessment (methamidophos applications) with the results of a Tier I assessment (acephate applications).

The risk reduction measures contained in this IRED, including a phase out of the cotton use and the reduction in the maximum number of applications allowed per season for all crops, are expected to reduce the amount of methamidophos available to reach surface waters. This supports the Agency's belief that drinking water risks will be reduced to a level at which the risk cup is not exceeded.

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

b. Homeowner Risk Mitigation

Methamidophos is not registered for use in residential settings. Previously, acephate had

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numerous residential, recreational and institutional uses which were evaluated in the acephate IRED. To mitigate risks of concern, acephate use in these settings have been limited to indoor use in non-residential institutional settings such as schools and hospitals, use on ornamentals in the residential settings, spot or mound treatments for fire ant and harvester ant control, and use on golf course turf. The risks associated with the degradation of acephate to methamidophos for these uses were evaluated in the acephate IRED and were found to be negligible. Therefore, no further risk mitigation is needed with respect to the residential uses of acephate to address risks associated with methamidophos exposure.

c. Aggregate Risk Mitigation

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

Acute Exposure

The acute aggregate risk assessment for methamidophos from all sources combines exposure from food and drinking water sources only. Acute dietary (food) exposure estimates are below 100% of the aPAD for the US population and all population subgroups. Infants are the most highly exposed population subgroup and result in an acute drinking water level of comparison (DWLOC) of 2.9 ppb. Based on screening-level model predictions of the remaining supported uses, the acute (peak) drinking water estimated concentration in surface water is 61.8 ppb which is of risk concern to the Agency. The screening-level model predictions of acute concentrations in ground water is 0.033 ppb for methamidophos, which is less than the DWLOC and not of risk concern to the Agency.

However, due to the uncertainties and limitations of the model predictions, the Agency believes that actual acute concentration of methamidophos in surface water is likely to be less than the DWLOC. To demonstrate this, confirmatory surface water monitoring data is to be generated to address this risk concern.

Short-Term Exposure

As mentioned above, methamidophos is not registered for use in residential settings. Previously, acephate had numerous residential, recreational and institutional uses which were evaluated in the acephate IRED. To mitigate risks of concern, acephate use in these settings have been limited to indoor use in institutional settings such as schools and hospitals, use on ornamentals in the residential settings, spot or mound treatments for fire ant control, and use on golf course turf. The risks associated with the degradation of acephate to methamidophos for these uses were evaluated in the acephate IRED and were found to be negligible. Therefore, no further risk mitigation is needed with respect to the residential uses of acephate to address risks associated with methamidophos exposure.

Chronic Exposure

Similarly, the chronic aggregate risk assessment for methamidophos combines exposure from food and drinking water sources only. Chronic dietary (food) risk estimates are well below 100% of

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the cPAD for the US population and all population subgroups. Children 1-6 years old is the most highly exposed population subgroup and result in a chronic DWLOC of 0.9 ppb. Based on screening-level model predictions of the remaining supported uses, the average (chronic) estimated concentration in surface water is 3.8 ppb, which is of risk concern to the Agency. Similarly, due to the same uncertainties and limitations of the model predictions for acute exposure, the Agency also believes that actual chronic concentrations of methamidophos in surface is likely to be less than the DWLOC. To demonstrate this confirmatory surface water monitoring data is to be generated to address the risk concern.

The screening-level model predictions of acute concentrations in ground water is 0.033 ppb for methamidophos, which is less than the DWLOC and not of risk concern to the Agency.

d. Occupational Risk Mitigation

1) Agricultural Uses

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

Handlers

As summarized in Table 7, occupational risks are of concern (i.e., MOEs < 100) for all scenarios, even when maximum PPE (i.e, double layer clothing, gloves, and a respirator) are utilized. Handler risks are also of concern for many scenarios with engineering controls (closed mixing/loading, enclosed cabs). Engineering controls are considered to be the maximum feasible mitigation. For workers wearing the maximum PPE described above, MOEs range from 2.5 to 38 for mixer/loaders and from 3.9 to 59 for applicators and flaggers. For workers using the engineering controls described above, MOEs range from 5 to 74 for mixer/loaders and from 8.4 to 626 for applicators/flaggers. Current labels require closed mixing/loading systems to be used. To mitigate occupational risks associated with the use of methamidophos, the following measures are to be implemented for the alfalfa, cotton, tomato and potato uses to be eligible for reregistration.

- Applicators must be in an enclosed cab or cockpit.
- Flaggers must be in enclosed vehicles or mechanical flaggers; or the use of global positioning system (GPS) equipment that negates the need for flaggers for aerial application must be used.
- The cotton use must be cancelled.

Even with maximum engineering controls (closed mixing/loading system and enclosed cabs) the MOEs for all mixer/loader scenarios, the groundboom applicator for cotton scenario and all aerial

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application scenarios remain less than the Agency's target of 100. For cotton scenarios, the Agency has determined that the benefits of this use do not offset the risks. However, the benefits discussed above are significant enough that a 5-year phase out rather than immediate cancellation of this use is justified to allow ample time for transition to alternatives.

For the alfalfa seed use of methamidophos, the Agency has determined that significant benefits exist to support reregistration for this use. Methamidophos is critical for the control of lygus bug in California alfalfa seed fields. It is an important element of California's lygus bug resistance management program, and is the most effective control of lygus pest early in the season, prior to introducing pollinators into the fields.

For the potato uses, the Agency has determined that significant benefits exist to support reregistration for this use. As mentioned earlier, post-emergence control of the green peach aphid, a vector for the potato leafroll virus, is the critical use in most areas of the country. Only imidacloprid is a potential alternative for post-emergence control but it is significantly more costly and does not have the period of residual effectiveness that methamidophos has that is necessary in some potato growing regions. There is also concern for potential resistance in some regions for imidacloprid. These circumstances make methamidophos critical to potato production, especially in the production of potatoes for seed where there is zero tolerance for aphids or the viruses they carry.

For the tomato uses of methamidophos, the Agency has determined that significant benefits exist to support reregistration for this use. In the Southeastern U.S., methamidophos is one of only two chemicals available for the control of the Western flower thrip, which is a vector for Tomato Spotted Wilt Virus, which can cause significant economic damage to a tomato crop. For fresh and processed tomatoes in California, methamidophos is the only effective insecticide available for controlling the economically important stink bug. The limitations mentioned earlier on endosulfan, dimethoate and imidacloprid make methamidophos an important tool in fresh and processed tomato production in California.

In addition to the benefits outlined above, there is some uncertainty associated with the Agency's risk estimates for methamidophos. This uncertainty is explained in the following section on post application risk.

Post-Application Risk

EPA develops exposure assessments on post-application workers for various crops and activities at intervals following the application until risk falls below a target level. For methamidophos, the target level for risk concerns is an MOE of 100.

In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target MOE. Occupational risks are regulated under the FIFRA section 3(c)(5) standard - "without unreasonable adverse effects on the environment" - which means that both risks and benefits must be considered in making a risk management decision. This standard may be met at a level below the target MOE when there are significant benefits associated with a specific activity. As the worker exposure database has improved, risk assessments are now conducted for a variety of post-application activities based on the level of exposure for each worker activity. For a specific crop/pesticide combination, the duration

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required to achieve the target MOE can vary depending on the activity assessed.

In general, EPA prefers to set a single REI for all activities related to a crop or crop group without additional activity-based labeling. This approach is favored because handlers and workers are more likely to understand and comply with simpler labels. Also, permitting entry for some activities during the REI could cause confusion and compromise the effectiveness of the Worker Protection Standard (WPS). However, when the consideration of risks and benefits indicate that a single REI is unworkable, EPA may consider either setting an REI with early entry exceptions for one or more critical tasks or establishing an entry prohibition for a specific task after the REI has expired. For methamidophos, no critical activities have been identified to warrant the use of an activity-based exception or prohibition.

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

To mitigate post-application occupational risks associated with the use of methamidophos, the following measures are to be implemented for the tomato and potato uses to be eligible for reregistration.

- Increase REIs for all activities for tomatoes to 4 days in all states except California where the REI would remain at 3 days per the current labels.

- Increase REIs for all activities for potatoes to 4 days.

For tomatoes in California, hand harvesting re-entry risks are adequately addressed by the 7-day and 14-day PHIs currently on labels. Methamidophos is applied late season to tomatoes in California therefore pruning, staking, tying and activities associated with immature plants are not a re-entry issue there. An REI of 3 days would result in an MOE of 70 for irrigation and scouting of mature plants which are the key activities of concern.

For tomatoes in Florida, an REI of 4 days would result in an MOE of 31 for irrigation and scouting of mature plants and an MOE of 22 for hand harvesting tying, pruning and staking which are the key activities of concern. Re-entry risks for hand harvesters are not adequately addressed by the 7-day PHI currently on labels (MOE = 30).

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For tomatoes in other areas of the country, an REI of 4 days would result in an MOE of 45 for irrigation and scouting of mature plants and an MOE of 32 for hand harvesting, tying, pruning and staking which are the key activities of concern. Re-entry risks for hand harvesters are not adequately addressed by the 7-day PHI currently on labels (MOE = 66).

For potatoes, an REI of 4 days would result in an MOE of 44 for irrigation and scouting of mature plants which are the key activities of concern.

While the MOEs that result from these mitigation steps do not fully address the risks of concern (i.e. MOEs are not greater than 100), the following information was taken into consideration in making these risk management decisions. These considerations are in addition to the benefits that have been discussed previously in this document.

In the case of tomatoes, as mentioned earlier, the Agency evaluated reentry risk based on data available from CA, FL and GA. More specifically, the data from FL was developed in the southern part of the state while the GA data was collected in the southern part of that state. The test area in GA is significantly closer to the areas in FL where methamidophos use is critical, which are predominantly in the northern areas of the state, than the test fields where the data were developed in southern FL. Therefore, it is likely that the GA data and the associated REIs would be more appropriate when considering the re-entry risks in the major methamidophos use areas in FL resulting in significantly increased MOEs for the FL scenario.

Further, there is some uncertainty associated with the Agency's worker risk estimates from the endpoint selected for methamidophos. MOEs are calculated by dividing the hazard endpoint by the estimated exposure. At present time, the Agency selects endpoints based on NOAELs and LOAELs from available toxicology studies. By definition, NOAELs and LOAELs are actual dose levels tested in these studies. The value of the NOAEL or LOAEL is determined solely by the dose selection in the toxicity study. NOAELs and LOAELs may be numerically close (e.g., 5 mg/kg/day vs. 6.5 mg/kg/day); or they may also be orders of magnitude apart (e.g., 5 mg/kg/day vs. 500 mg/kg/day). The use of NOAELs and LOAELs as toxicological endpoints is an established and scientifically accepted method of performing risk assessments and will continue to be used in risk assessments performed by the Agency. However, the Agency is considering the use of benchmark dose modeling techniques for determining toxicological endpoints for use in risk assessment. Benchmark dose modeling involves the use of statistical and mathematical curve fitting procedures to refine the endpoints used in risk assessment

In the case of methamidophos, a short-term dermal endpoint of 0.75 mg/kg/day was selected for use in occupational exposure assessments. As mentioned earlier, this endpoint is based on the NOAEL from a 21-day dermal toxicity study. The LOAEL from this study is 11.2 mg/kg/day based on brain, plasma and RBC cholinesterase inhibition. For this dermal toxicity study, the value of the NOAEL is approximately 15-fold smaller than the LOAEL.

Methamidophos was selected as the index chemical in the Preliminary Cumulative Risk Assessment (PCRA) for the OPs. This selection was based on the availability of high quality dose-response data for brain, plasma, and RBC cholinesterase inhibition and also the availability of data for all of the exposure routes of interest (oral, dermal, and inhalation). Due to the complexity of issues surrounding the estimation of cumulative risk of a large group of chemicals, it was determined that

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benchmark dose modeling was preferred over using NOAELs/LOAELs for determining endpoints for use in cumulative risk extrapolations. In the PCRA the BMD_{10}, or the estimated dose to cause a 10% reduction brain cholinesterase activity, was selected as an appropriate endpoint. Because methamidophos is being used as the index chemical in the cumulative risk assessment of OPs, BMD_{10}s and also the respective BMDLs (the lower 95% confidence limit on the BMD_{10}) have been calculated from the methamidophos 21-day dermal toxicity study mentioned above for male and female rat brain cholinesterase. These BMD_{10}s and BMDLs for male and female rat brain cholinesterase activity are shown in the table below.

Table 16. BMD10s and BMDLs from the methamidophos 21-day dermal study for brain cholinesterase activity measured in female and male rats

Route of Administration	Sex	BMD_{10} (mg/kg/day)	BMDL (mg/kg/day)	NOAEL (mg/kg/day)
Dermal	F	2.12	1.77	0.75
	M	1.88	1.41	

It is notable that the BMDLs are very close to the BMD_{10}s indicating very narrow confidence limits. Although the BMD_{10} s and BMDLs have not been calculated for plasma and RBC cholinesterase inhibition, based on the results of other toxicity studies in methamidophos, the Agency does not expect the benchmark dose calculations for the BMD_{10}s or the BMDLs from the blood compartments to be significantly different from the results shown in Table 16.

The Agency's draft guidance on use of benchmark dose specifies that the BMDL, and not the BMD_{10}, should be used as the endpoint for risk extrapolation. As the Agency expands its use of benchmark dose modeling techniques in its single chemical risk assessments, the BMDLs, not BMD_{10}s, are likely to be used.

The BMDL for male brain cholinesterase inhibition (1.44 mg/kg/day) is approximately 1.9 times larger than the NOAEL of 0.75 mg/kg/day being used to estimate short-term dermal occupational risk. In order to better characterize the potential risks to persons entering treated fields and being exposed to methamidophos residues, the Agency looked at the effect of using the BMDL instead of the NOAEL as is customary in deriving MOEs. For example, using the NOAEL of 0.75, the resulting MOE for short-term post application risk for potatoes at day 4 after treatment is 44. If the more refined endpoint (i.e., the BMDL of 1.44 mg/kg/day) were used instead the resulting MOE would be approximately 84. Based on this comparison, the Agency believes that the short-term dermal occupational risk would not exceed 44 but may be as high as 84.

In summary, when deciding whether the benefits of use provided by methamidophos outweigh the risk the Agency takes into consideration all available information. This includes the effects of the use of the BMDL versus the NOAEL on MOEs, dislodgeable foliar residue data specific to those regions of the country where methamidophos is most likely to be used, and the need for growers to enter treated fields at a particular time to perform specific activities and the consequences of not being able to complete those activities. Therefore, the Agency believes that the REIs set forth as mitigation in this IRED are appropriate.

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2. Environmental Risk Mitigation

The Agency has ecological risk concerns regarding the acute risks of methamidophos to terrestrial birds and mammals, and to freshwater and estuarine invertebrates; and chronic risk concerns to birds and mammals and freshwater and estuarine invertebrates. The ecological risk assessments exhibit RQ values which exceed the various target levels of concern (LOCs).

Birds and Mammals

The Agency's assessment suggests the potential for the liquid formulation to cause acute effects to birds for broadcast applications. The avian acute RQs range from 0.38 to 6.63. The highest avian acute RQ is from nine 1 lb ai/A ground or aerial applications to tomatoes. For the same use patterns, mammalian acute RQs range from 0.2 to 20.3. Regarding chronic risk to birds, the RQs range from 2.49 to 32.87. Again the same use patterns resulted in chronic RQs for mammals ranging from 0.75 to 9.86. All use patterns are of concern to the Agency for acute and chronic effects to birds and mammals.

Because of the toxicity of methamidophos, to help protect terrestrial birds and mammals, it is very important to reduce their potential exposure to methamidophos products that have been applied. In additional to the phase out of the cotton use previously described in this document to mitigate occupational risks of concern which will also serve to reduce risk to birds and mammals, several additional mitigation measures are needed to reduce risks to birds and mammals. These are:

- Require all labels to reduce maximum # of applications to 2 per season during phase out period for cotton.

- Require all labels to reduce maximum # of applications to 4 per season for tomatoes.

It should also be noted that significant benefits exist for both the tomato and potato uses as described earlier.

Aquatic Organisms

Acute risk to freshwater fish and estuarine fish is not of concern for any use patterns, with RQs ranging from <0.05 to 0.07. The acute high risk, restricted use risk and endangered species risk is of concern for freshwater invertebrates at the maximum application rate of 1.0 lb ai/A with RQs ranging from 1.1 to 3.0. No chronic risk assessment was conducted since there are no chronic data for aquatic species.

Many of the measures previously described in this document to reduce occupational and terrestrial risks will also serve to reduce aquatic risks of concern. It should also be noted that significant benefits exist for both the tomato and potato uses as described earlier.

E. Other Labeling

In order to remain eligible for reregistration, other use and safety information need to be placed

on the labeling of all end-use products containing methamidophos. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. 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 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, will soon be proposed for public comment in the Federal Register.

2. Spray Drift Management

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

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

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

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

<u>For products applied outdoors as liquids</u>:

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

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

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

<u>For overhead chemigation</u>:

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

<u>On all product labels</u>:

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

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

Or

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

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

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

"Do not allow this product to drift."

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

F. Methamidophos Risk Mitigation Summary

Based on the rationale for the interim decisions associated with the use of methamidophos, the following risk mitigation measures are also necessary to be incorporated in their entirety into labels for methamidophos-containing products in order for methamidophos to be eligible for reregistration. Registrants may propose, and EPA will consider, alternative mitigation measures that provide appropriate mitigation of the identified risks. Specific language of these revisions is set forth in the summary tables of Section V of this document. Likewise, the data required to be provided to the Agency to confirm these regulatory decisions are also listed in Section V.

1. Dietary Risk

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

2. Occupational Risk

The following measures are necessary to mitigate handler risk:

- Applications must be made using enclosed cab tractors or enclosed cockpit aircraft.
- Mechanical flaggers for aerial application; or the use of global positioning system (GPS) equipment that negates the need for flaggers.

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

- For foliar application of the liquid formulation, a 4 day REI is necessary for tomatoes in all states except CA
- For foliar application of the liquid formulation, a 4 day REI is necessary for potatoes.

The following additional measures are necessary to mitigate risks of concern for specific crops:

Cotton: Implement a 5-year phase out of the use on cotton.

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3. Ecological Risks

EPA has determined that remaining uses are eligible for reregistration provided that:

- The maximum # of applications on all labels be reduced to 2 per season during phase out period for cotton.

- The maximum # of applications on all labels be reduced to 4 per season for tomatoes.

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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, which include submission of the following:

A. Data Call-In Responses

For methamidophos technical grade active ingredient products, registrants need to submit the following items.

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

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

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

Within the time limit specified in the generic DCI:

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

Please contact Mark Hartman at (703) 308-0734 with questions regarding reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

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

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

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

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

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

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

Within eight months from the receipt of the PDCI:

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

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

(3) five copies of the draft label incorporating all label amendments outlined in Table 17 of this document;

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

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

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

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

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

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

B. Manufacturing Use Products

1. Additional Generic Data Requirements

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

1. Drinking water monitoring data for surface water sources for methamidophos in potato and tomato growing regions. This data is requested in order to confirm that the level of methamidophos is lower than predicted in the Agency's water models (OPPTS 167-1-SS)

2. Chronic Estuarine Invertebrate Study using Mysid shrimp (OPPTS 850.1350)

3. Photolysis on Soil (OPPTS 161-3)

4. Anaerobic Aquatic Metabolism (OPPTS 835.4400)

5. Terrestrial Field Dissipation (OPPTS 164-1)

6. Daphnid Chronic Toxicity Study (OPPTS 850.1300)

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7. Terrestrial Plant Toxicity, Seedling Emergence (OPPTS 850.4100)

8. Terrestrial Plant Toxicity, Vegetative Vigor (OPPTS 850.4150)

9. Dermal Passive Dosimetry Exposure (OPPTS 133-3)

10. Mixer/Loader exposure data for dry coupling closed mixing/loading system (OPPTS 875.1100 and 875.1300)

11. Confined Accumulation in Rotational Crops (OPPTS 860.1850)

12. Product chemistry data requirements for all technical and manufacturing use products have not been fulfilled. (830 series\60 series)

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; the developmental neurotoxicity study is currently in review. Acceptable acute and subchronic studies have been received and reviewed by the Agency.

2. Labeling for Manufacturing Use Products

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

C. 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.

D. Existing Stocks

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Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this interim RED. 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 registrant may distribute and sell methamidophos products bearing old labels/labeling for 26 months from the date of issuance of this interim RED. Persons other than the registrant 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 registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

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E. 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 Labeling Changes for methamidophos

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into an insecticide for the following use(s): alfalfa grown for seed, cotton, tomatoes and potatoes."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "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)."	Directions for Use

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Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by Agency Label Policies	"Environmental Hazards" "This chemical is extremely toxic to birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE" Due to Acute Toxicity. "For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification."	Top of Front Panel

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Description	Amended Labeling Language	Placement on Label
Handler PPE requirements	**"Personal Protective Equipment (PPE)** Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and flaggers using engineering controls must wear: Long-sleeved shirt and long pants Shoes plus socks In addition, mixers and loaders must wear chemical-resistant gloves and a chemical resistant apron." "See engineering controls for additional requirements. "Handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear: Coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical resistant footwear plus socks, Chemical-resistant headgear if overhead exposure, In addition, handlers exposed to the concentrate must wear: A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or He prefilter; Chemical-resistant apron"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

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Description	Amended Labeling Language	Placement on Label
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

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Description	Amended Labeling Language	Placement on Label
Engineering Controls	"Engineering Controls "Mixers and loaders must use a closed system that provides dermal and inhalation protection and must use and maintain this system in a manner that meets the requirements specified in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 mL. per disconnect point." Mixers and loaders must also: -- wear the personal protective equipment required above for mixers/loaders using engineering controls, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the PPE specified above for handlers engaged in those activities for which use of an engineering control is not possible." "Applicators using motorized ground equipment and flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators and flaggers must: -- wear the personal protective equipment required above for applicators using engineering controls, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the PPE specified above for handlers engaged in those activities for which use of an engineering control is not possible. -- take off any extra PPE that was put on and worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "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)];"	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

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Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This pesticide is extremely toxic to birds, mammals, and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate." "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product." "This pesticide is toxic to bees. Application should be timed to coincide with periods of minimum bee activity, usually between late evening and early morning."	Precautionary Statements immediately following the User Safety Recommendations

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Description	Amended Labeling Language	Placement on Label
Restricted-Entry Interval (all products except those listed below)	"Do not enter or allow workers to enter into treated areas during the restricted entry interval (REI). The REI for cotton and alfalfa is is 48 hours. The REI for cotton and alfalfa is 72 hours in areas where average rainfall is less than 25 inches a year. The REI for potatoes is 4 days.	Directions for Use, Agricultural Use Requirements Box
Special Local Needs Registrations in California (CA78016300; CA79009600)	The REI for tomatoes is 3 days**.**	
Special Local Needs Registrations in states other than California (AL89000800; AR97000400; DE91000200; DE92000200; FL80004600; FL89000700; FL89004100; FL90000300; FL92000400; GA86000400; GA90000100; IN79000100; IN93000300; LA91000800, LA99001100; MD91000900; MI78001600; MI93000300; NC89000700; NJ96001000; OH79000800; OH79001000; PR92000100; SC78001600; TN89000700; TN93000300; TN96000600; TX91001200; TX91001600; VA91000500; VA93000200)	The REI for tomatoes is 4 days**.**	

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Description	Amended Labeling Language	Placement on Label
Early Re-entry Personal Protective Equipment established by the IRED.	**Early Entry PPE (WPS)** "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: * coveralls worn over long-sleeve shirt and long pants, * chemical-resistant gloves made of any waterproof material, * chemical-resistant footwear plus socks, and * chemical-resistant headgear (if overhead exposure) * protective eyewear" **"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area."	
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 Directions for Use directly above the Agricultural Use Box.
Other Application Restrictions	**Crop-Specific Application Restrictions** (labels must be amended to reflect the requirements specified below) All Crops: An advisory that application of methamidophos products after applications of acephate may result in illegal residues. Tomatoes: The different use directions for tomatoes destined to be processed is not considered to be practical and must be removed from the label. Cotton: The cotton grazing/feeding restrictions are not considered practical and must be removed. Cotton: Maximum number of applications per season is two.	Directions for Use

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Description	Amended Labeling Language	Placement on Label
Other Application Restrictions (SLNs)	Tomatoes: Maximum number of applications per season is four.	
Other Application Restrictions (SLNs currently w/ < 3 apps)	Tomatoes: Maximum number of applications per season is two.	
Spray Drift Restrictions for Outdoor Products Applied as a Liquid	"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."	Directions for Use in General Precautions and Restrictions
Spray Drift language	"Aerial Spray Drift Management" " 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 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. If application includes a no-spray zone, do not 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." "For ground boom applications, apply with nozzle height no more than four 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. "The applicator also must use all other measures necessary to control drift."	Directions for Use in General Precautions and Restrictions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The

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more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should 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 following sections indicate the means to view or obtain copies of paper or electronic versions of these documents and lists titles of documents that are now in the docket files.

A. Availability at OPP Docket Room

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 p.m.

The docket initially contained preliminary risk assessments and related documents as of 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.

B. Availability on the Internet

Many of the supporting documents may be viewed or downloaded from the Internet. The web site is as follows: http://www.epa.gov/oppsrrd1/op/.

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VII: Appendices

Appendix A. Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, (Days)	Use Directions and Limitations
Alfalfa						
Foliar Ground or aerial	4 lb/gal EC [CA980013]	1.0 lb/A	1	1.0 lb/A	N/A	Applications may be made in a minimum of 25 gal/A by ground, 3 gal/A by air. Do not feed refuse to livestock. Alfalfa seed from treated fields may not be used for growing sprouts for human or animal consumption. Do not apply through any type of irrigation system.
Cotton						
Foliar (Before bolls open) Ground or aerial	4 lb/gal EC [3125-280] [AR870007] [MS810014]	1.0 lb/A	2	2.0 lb/A	50	Applications may be made in a minimum of 25 gal/A by ground, 3 gal/A by air, or by irrigation systems. The feeding of gin trash to livestock or grazing of animals on treated fields is prohibited.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, (Days)	Use Directions and Limitations
	4 lb/gal EC [59639-56]	1.0 lb/A	2	2.0 lb/A	50	Applications may be made in a minimum of 25 gal/A by ground or 3 gal/A by air. The feeding of gin trash to livestock or grazing of animals on treated fields is prohibited.
Foliar Ground or aerial	4 lb/gal EC [AR810044] [AR890005] [CA780189] [CA790188] [LA830018] [MS810055] [MS830013] [TN880004]	1.0 lb/A	2	2.0 lb/A	NS	Use limited to AR, CA, LA, MS, and TN. Applications after 65% of the bolls are open are prohibited. Applications may be made in a minimum of 25 gal/A by ground or 1 gal/A by air (MS810055 only). The feeding of gin trash to livestock or grazing of animals on treated fields is prohibited.
Potato						
Foliar Ground or aerial	4 lb/gal EC [3125-280] [59639-56]	1.0 lb/A	4	4.0 lb/A	14	Applications may be made in a minimum of 25 gal/A by ground, 3 gal/A by air, or by sprinkler irrigation systems with a retreatment interval of 7- to 10-days as a preventative program or as needed.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, (Days)	Use Directions and Limitations
Tomato						
Foliar Ground	4 lb/gal EC [FL890041]	1.0 lb/A	4	4.0 lb/A	7	Tank mix use limited to FL.
	4 lb/gal EC [FL920004]	1.0 lb/A	4	4.0 lb/A	7	Use limited to FL. Applications may be made in a minimum of 25 gal/A by ground with a retreatment interval of 5- to 7-days.
	4 lb/gal EC [IN790001] [IN930003] [MI780016] [MI930003] [OH790008] [OH790010]	1.0 lb/A	3	3.0 lb/A	7	Use limited to IN, MI, and OH. Applications may be made in a minimum of 25 gal/A by ground with a retreatment interval of 7- to 10-days.
	4 lb/gal EC [SC780016]	1.0 lb/A	4	4.0 lb/A	14	Use limited to SC. Applications may be made in a minimum of 50 gal/A by ground with a retreatment interval of 7- to 10-days.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, (Days)	Use Directions and Limitations
	4 lb/gal EC [AL890008]	0.75 lb/A	4	3.0 lb/A	7	Use limited to AL and GA. Applications may be made in a minimum of 25 gal/A by ground with a retreatment interval of 5- to 7-days.
	4 lb/gal EC [PR920001]	0.75 lb/A	4	3.0 lb/A	7	Use limited to PR. Applications may be made in a minimum of 25 gal/A by ground with a retreatment interval of 7- to 10-days.
Foliar Ground or aerial	4 lb/gal EC [TX910016]	1.0 lb/A	4	4.0 lb/A	14	Use limited to TX. Applications may be made alone or as a tank mix with a pyrethroid. Applications may be made in a minimum of 25 gal/A by ground or 5 gal/A by air with a retreatment interval of 7- to 10-days.
	4 lb/gal EC [FL800046] [FL890007] [LA910016] [TX910012]	1.0 lb/A	4	4.0 lb/A	7	Use limited to FL, LA, and TX. Applications may be made in a minimum of 25 gal/A by ground or 3 gal/A by air with a retreatment interval of 7- to 10-days.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, (Days)	Use Directions and Limitations
	4 lb/gal EC [AR970004] [CA780163] [CA790096] [DE910002] [DE920002] [LA910008] [MD910009] [NC890007] [NJ900006] [NJ960010] [TN890007] [TN930003] [TN960006] [VA910005] [VA930002]	1.0 lb/A	4	4.0 lb/A	7	Use limited to AR, CA, DE, LA, MD, NC, NJ, TN, and VA. Applications may be made in a minimum of 25 gal/A by ground or 5 gal/A by air with a retreatment interval of 7- to 10-days.
Foliar Ground or aerial	4 lb/gal EC [CA780163]	1.0 lb/A	4	4.0 lb/A	14	Use limited to CA for processing tomatoes. Applications may be made in a minimum of 25 gal/A by ground or 5 gal/A by air with a retreatment interval of 7- to 10-days.

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Appendix B: Data Supporting Guideline Requirements for the Reregistration of Methamidophos

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1550	**61-1**	**Product Identity and Composition**	A, B	00014037, 43661001, Data Gap
830.1620	**61-2A**	**Start. Mat. & Mnfg. Process**	A, B	00014024, 43661001, Data Gap
830.1670	**61-2B**	**Formation of Impurities**	A, B	00014024, 43661001, Data Gap
830.1700	**62-1**	**Preliminary Analysis**	A, B	00014024, 43661002, Data Gap
830.1750	**62-2**	**Certification of limits**	A, B	00014024, 43661002, Data Gap
830.1800	**62-3**	**Analytical Method**	A, B	00014023, 00014025-00014030, 00014032, 00014033, 43661001, Data Gap
830.6302	**63-2**	**Color**	A, B	00014021, 43661001, 43661003, Data Gap
830.6303	**63-3**	**Physical State**	A, B	00014021, 43661001, 43661003, Data Gap
830.6304	**63-4**	**Odor**	A, B	00014021, 43661001, 43661003, Data Gap
830.6313	**63-13**	**Stability**	A, B	00014021, Data Gap
830.6314	**63-14**	**Oxidizing/Reducing Action**	A, B	Data gap
830.6315	**63-15**	**Flammability**	A, B	Data gap
830.6316	**63-16**	**Explodability**	A, B	Data gap

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REQUIREMENT			USE PATTERN	CITATION(S)
830.6317	**63-17**	**Storage Stability**	A, B	Data gap
830.6319	**63-19**	**Miscibility**	A, B	Data gap
830.6320	**63-20**	**Corrosion characteristics**	A, B	00014021, Data gap
830.7000	**63-12**	**pH**	A, B	Data gap
830.7050	**None**	**UV/Visible Absorption**	A, B	Data gap
830.7100	**63-18**	**Viscosity**	A, B	Data gap
830.7200	**63-5**	**Melting Point**	A, B	43661001, 43661003, Data Gap
830.7220	**63-6**	**Boiling Point**	A, B	43661001, 43661003
830.7300	**63-7**	**Density**	A, B	00014021, 43661001, 43661003, Data Gap
830.7370	**63-10**	**Dissociation Constant**	A, B	43661003, Data Gap
830.7550	**63-11**	**Octanol/Water Partition Coefficient**	A, B	43661003, Data Gap
830.7840	**63-8**	**Solubility**	A, B	00014021, 43661001, 43661003
830.7860				
830.7950	**63-9**	**Vapor Pressure**	A, B	00014021, 4361001, 43661003
ECOLOGICAL EFFECTS				
850.1010	**72-2A**	**Invertebrate Toxicity**	A, B	00041311, 00014110, 00014305
850.1075	**72-1A**	**Fish Toxicity Bluegill**	A, B	00041312, 00144432, 44484402, 00014063

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REQUIREMENT			USE PATTERN	CITATION(S)
850.1075	**72-1C**	**Fish Toxicity Rainbow Trout**	A, B	00041312, 00144429, 00144432, 00014063
850.2100	**71-1**	**Avian Acute Oral Toxicity**	A, B	00014094, 00014095, 00041313, 00093914, 00109717, 00109718, 00144428
850.2200	**71-2A**	**Avian Dietary Toxicity - Quail**	A, B	00093904, 00014304, 00145655, 00130823, 00014064, 44484404
850.2200	**71-2B**	**Avian Dietary Toxicity - Duck**	A, B	00041658, 00130823, 00014304, 00145655, 44484403
850.2300	**71-4A**	**Avian Reproduction - Quail**	A, B	00014114
850.2300	**71-4B**	**Avian Reproduction - Duck**	A, B	00014113
None	**72-3A**	**Estuarine/Marine Toxicity - Fish**	A, B	00144431
850.1025	**72-3B**	**Estuarine/Marine Toxicity - Mollusk**	A, B	40088601
850.1035	**72-3C**	**Estuarine/Marine Toxicity - Shrimp**	A, B	00144430
850.1300	**72-4A**	**Daphnid Chronic Toxicity**	A, B	Data gap
850.1350	**72-4B**	**Estuarine/Marine Invertebrate Life Cycle**	A, B	Data gap
850.4100	**122-1**	**Terrestrial Plant Toxicity (Seedling Emergence)**	A, B	Data gap

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REQUIREMENT			USE PATTERN	CITATION(S)
850.4150	**122-1**	**Terrestrial Plant Toxicity (Vegetative Vigor)**	A, B	Data gap
850.3020	**141-1**	**Honey Bee Acute Contact**	A, B	00036935
TOXICOLOGY				
870.1100	**81-1**	**Acute Oral Toxicity-Rat**	A, B	00014044
870.1200	**81-2**	**Acute Dermal Toxicity-Rabbit/Rat**	A, B	00014049
870.1300	**81-3**	**Acute Inhalation Toxicity-Rat**	A, B	00148449
870.2400	**81-4**	**Primary Eye Irritation-Rabbit**	A, B	00014221
870.2500	**81-5**	**Primary Skin Irritation**	A, B	00014220
870.2600	**81-6**	**Dermal Sensitization**	A, B	00147929
870.3100	**82-1A**	**90-Day Feeding - Rodent**	A, B	00014155
870.3150	**82-1B**	**90-Day Feeding - Non-rodent**	A, B	00014153
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	A, B	44525301
870.3700	**83-3A**	**Developmental Toxicity - Rat**	A, B	00148454, 43906901
870.3700	**83-3B**	**Developmental Toxicity - Rabbit**	A, B	00041315, 44040601
870.3800	**83-4**	**2-Generation Reproduction - Rat**	A, B	00148455, 41234301, 44466001, 44815401, 44815402
870.3465	**82-4**	**90-Day Inhalation-Rat**	A, B	41402401

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REQUIREMENT			USE PATTERN	CITATION(S)
870.4100	**83-1B**	**Chronic Feeding Toxicity - Non-Rodent**	A, B	00147938, 41234304
870.4300	**83-1A/ 83-2A**	**Combined Chronic Toxicit/ Carcinogenicity - Rodent**	A, B	00148952, 43248102
870.4200	**83-2B**	**Oncogenicity - Mouse**	A, B	00145579, 00147937, 43248101
870.6100	**81-7**	**Acute Delayed Neurotoxicity - Hen**	A, B	00041317
870.6200	**81-8**	**Acute Neurotoxicity Screen**	A, B	43025001, 43345801
None	**82-1SS**	**8-Week Subchronic Oral Toxicity Cholinesterase Study - Rodent**	A, B	41867201
None	**82-5A**	**90-Day Delayed Neurotoxicity - Hens**	A, B	40985202
None	**82-5B**	**90-Day Neurotoxicity - Rat**	A, B	43197901
870.5140	**84-2**	**Gene Mutation (Ames Test)**	A, B	00098457
870.5375	**84-2**	**Structural Chromosomal Aberration**	A, B	41234306, 41461401
870.5300	**84-2**	**Gene Mutation - Mammalian Cells**	A, B	42854701
870.5900	**84-2**	**Other Mutagenic Mechanisms - *in vitro***	A, B	41234305

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REQUIREMENT			USE PATTERN	CITATION(S)
870.6200	**82-7**	**Subchronic Neurotoxicity Screening Study - Rodent**	A, B	43197901
870.6200	**82-7**	**Subchronic Oral Delayed Neurotoxicity - Hen**	A, B	40985202
870.7485	**85-1**	**General Metabolism**	A, B	00015224
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	**132-1A**	**Foliar Residue Dissipation**	A, B	40985203, 44685501, 44685502, 44685503
875.2200	**132-1B**	**Soil Residue Dissipation**	A, B	Waived
875.2400	**133-3**	**Dermal Passive Dosimetry Exposure**	A, B	Data Gap
875.2500	**133-4**	**Inhalation Passive Dosimetry Exposure**	A, B	Waived
875.1100	**231**	**Estimation of Dermal Exposure at Outdoor Sites**	A, B	Data gap
875.1300	**232**	**Estimation of Inhalation Exposure at Outdoor Sites**	A, B	Waived
ENVIRONMENTAL FATE				
835.1240	**163-1**	**Leaching/Adsorption/Desorption**	A, B	40504811
835.1850	**165-1**	**Confined Rotational Crop**	A, B	42758701, Data Gap

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REQUIREMENT			USE PATTERN	CITATION(S)
835.2120	**161-1**	**Hydrolysis**	A, B	00150609
835.2240	**161-2**	**Photodegradation - Water**	A, B	00150610
835.2410	**161-3**	**Photodegradation - Soil**	A, B	00150611, Data gap
835.4100	**162-1**	**Aerobic Soil Metabolism**	A, B	41372201
835.4200	**162-2**	**Anaerobic Soil Metabolism**	A, B	43541202
835.4300	**162-4**	**Aerobic Aquatic Metabolism**	A, B	Data gap (can be fulfilled by 835.4400)
835.4400	**162-3**	**Anaerobic Aquatic Metabolism**	A, B	43541202, Data gap
	163-2	**Volatility**	A, B	40985206
835.6100	**164-1**	**Terrestrial Field Dissipation**	A, B	40985206, 43541201, Data gap
None	**165-4**	**Bioaccumulation in Fish**	A, B	00014015
None	**167-1-SS**	**Drinking Water Monitoring**	A, B	Data Gap
RESIDUE CHEMISTRY				
860.1300	**171-4A**	**Nature of Residue - Plants**	A, B	00014077, 00014081, 44209701, 44209702
860.1300	**171-4B**	**Nature of Residue - Livestock**	A, B	00014555, 00014995, 00015222, 4429703, 44209704
860.1340	**171-4C**	**Residue Analytical Method - Plants**	A, B	00014085, 44209705, 44209706
860.1340	**171-4D**	**Residue Analytical Method - Animals**	A, B	44209707, 44209708

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REQUIREMENT			USE PATTERN	CITATION(S)
860.1380	**171-4E**	**Storage Stability**	A, B	44514302
860.1480	**171-4J**	**Magnitude of Residues - Meat/Milk/Poultry /Egg (Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep)**	A, B	00015183, 00015225
860.1500	**171-4K**	**Crop Field Trials-Root and Tuber Vegetables Group (Beets, sugar, roots)**	A, B	00013677, 00014266, 00014269
860.1500	**171-4K**	**Crop Field Trials-Root and Tuber Vegetables Group (Potatoes)**	A, B	00014075, 40747301, 44512201
860.1500	**171-4K**	**Crop Field Trials-Leaves of Root and Tuber Vegetables Group (Beets, sugar, tops)**	A, B	00013677, 00014266, 00014269
860.1500	**171-4K**	**Crop Field Trials-Leafy Vegetables (except Brassica) Vegetables Group (Lettuce)**	A, B	00014073
860.1500	**171-4K**	**Crop Field Trials-Brassica (Cole) Vegetables Group (Broccoli)**	A, B	00014069

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REQUIREMENT			USE PATTERN	CITATION(S)
860.1500	**171-4K**	**Crop Field Trials-Brassica (Cole) Vegetables Group (Brussels sprouts)**	A, B	00014070
860.1500	**171-4K**	**Crop Field Trials-Brassica (Cole) Vegetables Group (Cabbage)**	A, B	00014071
860.1500	**171-4K**	**Crop Field Trials-Brassica (Cole) Vegetables Group (Cauliflower)**	A, B	00014072
860.1500	**171-4K**	**Crop Field Trials-Fruiting Vegetables (Except Cucurbits) Group (Eggplant)**	A, B	00014119, 00014120, 00014130, 00014131
860.1500	**171-4K**	**Crop Field Trials-Fruiting Vegetables (Except Cucurbits) Group (Pepper)**	A, B	00014121, 00014122, 00014123, 00014140
860.1500	**171-4K**	**Crop Field Trials-Fruiting Vegetables (Except Cucurbits) Group (Tomato)**	A, B	00014124-00014129, 40007401, 44514301
860.1500	**171-4K**	**Crop Field Trials-Cucurbits Vegetables Group (Cucumber)**	A, B	00014132, 00014133, 00014138, 00014139
860.1500	**171-4K**	**Crop Field Trials-Cucurbits Vegetables Group (Melon)**	A, B	00014134, 00014135

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REQUIREMENT			USE PATTERN	CITATION(S)
860.1500	**171-4K**	**Miscellaneous Commodities-Cotton, Seed and Gin Byproducts**	A, B	00014074, 44558801
860.1520	**171-4L**	**Processed Food/Feed (Cotton, seed)**	A, B	41966302
860.1520	**171-4L**	**Processed Food/Feed (Potato)**	A, B	44815406
860.1520	**171-4L**	**Processed Food/Feed (Tomato)**	A, B	40007401

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Appendix C: Technical Support Documents

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

The docket initially contained 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 3, 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

These documents include:

- Methamidophos: Revision of EFED Risk Assessment for the Reregistration Eligibility Decision (RED) Document to Include Registrant's Comments.
- EFED Response to Comments Submitted to the Methamidophos Docket During the 60-day Comment Period on the EFED Methamidophos RED Chapter.
- Methamidophos: HED Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document. List A Reregistration Case 0043. Chemcal No. 101201. DP Barcode: D250644. October 30, 1998
- Human Health Risk Assessment: Methamidophos. February 3, 2000
- Methamidophos Summary. December 2, 1999
- Overview of the Revised Methamidophos Risk Assessment. January 13, 2000
- Acephate and Methamidophos: Technical Briefing. February 3, 2000
- Methamidophos: Revised Toxicology Chapter for RED. February 3, 2000
- Final Usage Analysis for Methamidophos RED.
- Methamidophos. List A Case No. 0043. Chemical No. 101201. Revised Dietary

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Exposure and Risk Analyses for the HED Revised Human Health Risk Assessment and HED Review of the Bayer Corporation Probabilistic (Monte Carlo) Acute Dietary Exposure Assessment. DP Barcodes D256039, D256042. MRID No. 448154-10. October 4, 1999

- Methamidophos: Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document. PC Code 101201; DP Barcode: D258447. August 9, 1999

- Review of Methamidophos Incident Reports. DP Barcode D258608, Chemical # 101201. October 5, 1999

- Methamidophos List B Reregistration Case No. 0043/Chemical ID No. 101201. Response to Comments to the Draft Methamidophos Reregistration Eligibility Decision (RED) Document. DP Barcode D254708. August 18, 1999

- Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate Methamidophos. February 16, 2000

- Methamidophos: Review of 21-day Dermal Toxicity in Rats (MRID No. 44525301 and Addendum to MRID No. 44525301)/Short- and Intermediate- Term Dermal Risk assessments. May 18, 1999

- Methamidophos: Review of Two Generation Reproduction Toxicity Study in Rats (MRID No. 4466001 and Addenda MRID No. 44815402)/Impact on Dietary and Non-dietary Risk Assessments. June 16, 1999

- Methamidophos: Review of Potato Processing Study; Chemical ID No. 101201; Reregistration Case No. 0043; MRID No. 44815406; DP Barcode D256034. August 11, 1999

- Methamidophos. Chemical ID No. 101201. Sensitivity Analysis. November 29, 1999

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Appendix D: Bibliography

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a

document title. Any such editorial insertions are contained between square brackets.

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

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

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

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

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

MRID	Citation
00013677	**Morse Laboratories, Incorporated (1976) Chemagro Agricultural Division--Mobay Chemical Corporation Residue Experiment: 462-5746-75D: Report No. 49920. (Unpublished study including report nos. 49921, 50844 and 50845, received Aug 24, 1978 under 3125-280; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:097318-H)**
00014015	**Baychem Corporation (1972) Chemagro, Division of Baychem Corporation, Residue Experiment: Report No. 31933. (Unpublished study received on unknown date under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-G)**
00014021	**Chevron Chemical Company (1970) Monitor Insecticide Residue Tolerance Petition: Physical and Chemical Properties. (Unpublished study received Mar 5, 1970 under 0F0956; CDL:093266-M)**
00014023	**Hayman, E.L. (1969) Monitor by Gas Chromatography. Method dated Oct 16, 1969. (Unpublished study received Mar 5, 1970 under**

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0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-Q)

00014024 **Chevron Chemical Company (19??) Monitor Insecticide Residue Tolerance Petition: Manufacturing Process. (Unpublished study received Mar 5, 1970 under 0F0956; CDL:093266-R)**

00014025 **Leary, J.B. (1969) Determination of Monitor Insecticide and the Thiono Isomer Impurity in Technical Monitor Insecticide. Method dated Apr 23, 1969. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-S)**

00014026 **Leary, J.B. (1968) Determination of N,O,S-Trimethyl phosphoramidothioate in Monitor Insecticide. Method dated Jun 13, 1968. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 093266-T)**

00014027 **Leary, J.B. (1968) Determination of N,O,O-Trimethyl phosphoramidothioate in Monitor Insecticide. Method dated Jun 13, 1968. (Unpublished study received Mar 5, 1970 under 0F0956;1 submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-U)**

00014028 **Leary, J.B. (1969) Determination of O,~S-Dimethyl phosphorothioate in Monitor Insecticide. Method dated Dec 12, 1969. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-V)**

00014029 **Leary, J.B. (1968) Determination of Dimethyl sulfate in Monitor Insecticide. Method dated Jun 13, 1968. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-W)**

00014030 **Leary, J.B. (1970) Determination of Methyl sulfuric acid in Monitor Insecticide. Method dated Jan 21, 1970. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-X)**

00014032 **Leary, J.B. (1968) Determination of N, N, O, S -Tetramethyl phosphoramidothioate in Monitor Insecticide. Method dated Jun 13, 1968. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093266-Z)**

00014033 **Leary, J.B. (1968) Determination of N, N, O, O-Tetramethyl phosphoramidothioate in Monitor Insecticide. Method dated Jun 13, 1968. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron**

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Chemical Co., Richmond, Calif.; CDL:093266-AA)

00014037 **Chevron Chemical Company (19??) Monitor Insecticide Residue Tolerance Petition: Name and Chemical Identity. (Unpublished study received Mar 5, 1970 under 0F0956; CDL:093266-AF)**

00014044 **Cavalli, R.D.; Hallesy, D.W. (1968) Acute Oral Toxicity of RE 9006 (95%) in Rats: SOCO 14/I:87. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093265-B)**

00014049 **Cavalli, R.D.; Hallesy, D.W. (1968) Acute Dermal Toxicity of Monitor Technical: SOCO 30/I:121-8. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093265-G)**

00014063 **Schoenig, G. (1968) Report to Chevron Chemical Company, Ortho Division: Four-Day Fish Toxicity Study on Monitor (RE-9006) 75% Technical SX-171: IBT No. A6482. (Unpublished study received Mar 5, 1970 under 0F0956; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093265-W)**

00014064 **Jackson, G.L. (1968) Report to Chevron Chemical Company, Ortho Division: Quail Toxicity of Monitor (RE 9006): IBT No. J6483. (Unpublished study received Mar 5, 1970 under 0F0956; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093265-X)**

00014069 **Mayberry, T.W.; Sakamoto, S.S.; Leary, J.B.; et al. (1969) Residue Data Sheet: Broccoli. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-B)**

00014070 **Cinereski, J.E.; Leary, J.B.; Sakamoto, S.S.; et al. (1969) Residue Data Sheet: Brussels Sprouts. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-I)**

00014071 **Cinereski, J.E.; Leary, J.B.; Mayberry, T.W.; et al. (1969) Residue Data Sheet: Cabbage. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-L)**

00014072 **Mayberry, T.W.; Sakamoto, S.S.; Leary, J.B.; et al. (1970) Residue Data Sheet: Cauliflower. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-R)**

00014073 **Sakamoto, S.S.; Leary, J.B.; Klaich, M.; et al. (1969) Residue Data Sheet:**

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Lettuce. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-W)

00014074 **Sakamoto, S.S.; Kalens, K.J.; Witherspoon, B. (1969) Residue Data Sheet: Cotton. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-AC)**

00014075 **Gerber, C.E.; Leary, J.B.; Sakamoto, S.S. (1970) Residue Data Sheet: Potatoes. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-AG)**

00014077 **Chevron Chemical Company (1968) Metabolism of Monitor Insecticide by Plants. (Unpublished study received Mar 5, 1970 under 0F0956; CDL:093264-AO)**

00014081 **Tutass, H.O. (1968) Uptake and Translocation of Monitor Insecticide by Tomato, Cabbage and Bean Plants. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093264-AU)**

00014085 **Chevron Chemical Company (1968) Monitor Residue Analysis by Thermionic Gas Chromatography. Method RM-10 dated May 31, 1968. (Unpublished study including letter dated Oct 17, 1969 from D.E. Pack to Kenneth J. Kalens, received Mar 5, 1970 under 0F0956;CDL:093264-AY)**

00014094 **Fletcher, D. (1971) Report to Chevron Chemical Company, Ortho Division: Acute Oral Toxicity Study with Monitor Technical in Bobwhite Quail: IBT No. J261. (Unpublished study received Mar 22, 1972 under 0F0956; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 092118-C)**

00014095 **Fletcher, D. (1971) Report to Chevron Chemical Company, Ortho Division: Acute Oral Toxicity Study with Monitor Technical in Mallard Ducks: IBT No. J262. (Unpublished study received Mar 22, 1972 under 0F0956; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 092118-D)**

00014110 **Wheeler, R.E. (1978) 48 Hour Acute Static Toxicity of Monitor (SX887) to 1st Stage Nymph Water Fleas (Daphnia magna Straus). (Unpublished study received Sep 15, 1978 under 239-2404; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:235153-A)**

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00014113 **Fink, R. (1977) Final Report: One-Generation Reproduction Study– Mallard Duck: Project No. 149-104; Report No. 54030. (Unpublished study received Apr 9, 1979 under 239-2404; prepared by Wildlife International, Ltd. in cooperation with Glencoe Mills, Inc. and Washington College for Mobay Chemical Corp., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:238015-B)**

00014114 **Beavers, J.B.; Fink, R. (1978) One-Generation Reproduction Study– Bobwhite Quail--Technical Monitor: Final Reports: Report No. 66155. (Unpublished study received Apr 9, 1979 under 239- 2404; prepared by Wildlife International, Ltd. in cooperation with Glencoe Mills, Inc. and Washington College for Mobay Chemical Corp., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:238015-C)**

00014119 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 2: Report No. 37305. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-D)**

00014120 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37306. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-E)**

00014121 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37307. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-F)**

00014122 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37308. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-G)**

00014123 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37309. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-H)**

00014124 **Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37310. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-I)**

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Appendix E: Generic Data Call In

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Appendix F: Product Specific Data Call In

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Appendix G: EPA'S Batching of *Methamidophos* Products for Meeting Acute Toxicity Data Requirements for Reregistration

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an Existing Study (Option). 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.

Five products were found which contain ***Methamidophos*** as the active ingredient. These products have been placed into ***one*** batch and a ***No Batch*** in accordance with the active and inert ingredients and type of formulation.

Batch 1	EPA Reg. No.	Percent active ingredient	Formulation Type
	3125-280	40.58	Solid
	59639-56	40.58	Solid

No Batch	EPA Reg. No.	Percent active ingredient	Formulation Type
	3125-341	74.6	Solid
	3125-348	60.0	Liquid
	59639-68	72.0	Solid

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Appendix H: List of Registrants Sent DCIs

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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.

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

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

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

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   C. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' website.

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients,

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uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: http://npic.orst.edu..

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

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

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

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

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.

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