US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Oxydemeton-methyl (ODM)

When EPA concluded the organophosphate (OP) cumulative risk assessment in July 2006, all tolerance reassessment and reregistration eligibility decisions for individual OP pesticides were considered complete. OP Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs. OP tolerance reassessment decisions (TREDs) also are considered completed.

Combined PDF document consists of the following:

- 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 (July 31, 2006)

- Amendment to the 2002 Oxydemeton-methyl IRED and the initial IRED

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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

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

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

Attachment A:

Organophosphates included in the OP Cumulative Assessment

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

Amendment to the 2002 Oxydemeton-methyl IRED and the Interim Reregistration Eligibility Decision for Oxydemeton-methyl (ODM)

This document contains both the Amendment to the 2002 Oxydemeton-methyl IRED and the initial IRED.

Docket ID EPA-HQ-OPP-2005-0281
Amendment to the 2002 Oxydemeton-methyl IRED: EPA-HQ-OPP-2005-0281-0003
IRED Oxydemeton-methyl (ODM): EPA-HQ-OPP-2005-0281-0002

Amendment to the 2002 Oxydemeton-methyl IRED

September 23, 2005

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 23, 2005

CERTIFIED MAIL

Dear Registrant:

Subject: Amendment to the 2002 Oxydemeton-methyl IRED

The purpose of this letter is to advise you of an amendment to the Interim Reregistration Eligibility Decision (IRED) document for oxydemeton-methyl (ODM). This amendment pertains only to the restricted-entry interval (REI) for head lettuce.

Background

The ODM IRED was signed in August of 2002. At that time, the calculated REI for lettuce was 14 days, based conservatively on potato dislodgable foliar residue (DFR) and default transfer coefficients. The registrants, Gowan Company, felt that a 14 day REI would not be workable for lettuce growers, based on their need to reenter lettuce fields for irrigation activities, specifically to move irrigation pipe. They proposed instead to maintain the 3 day REI on the label while they developed lettuce-specific DFR data, on an expedited basis, to refine the exposure estimate. EPA agreed to this proposal, and required the registrant to submit lettuce DFR data by October 31, 2003, as noted in a Memorandum of Agreement (MOA) dated January 10, 2003.

The lettuce DFR data have been submitted and reviewed. EPA has also received and reviewed new transfer coefficient (TC) data provided by the Agriculture Reentry Task Force (ARTF), of which the ODM registrant is a member. The new transfer coefficient for low exposure activities in lettuce is estimated to be 100 cm^2 per hour. Considering both the DFR data and new TC, the margin of exposure (MOE) for low exposure activities (irrigating, scouting, thinning, and weeding immature plants) is 91 with a 6 day REI. Irrigation of mature plants is the only medium to high exposure activity other than harvesting expected to occur in lettuce. Irrigation workers will be protected by the personal protective equipment (PPE) required in the exception to the REI, as noted in the amended label language below. Harvesting would not occur until 14-28 days after application.

EPA's alternatives assessment indicates there are no efficacious alternatives to ODM for control of the lettuce aphid. Thus, EPA has worked closely with lettuce growers and state enforcement officials to craft an exception to the REI that allows workers with the appropriate PPE to reenter ODM treated fields to move irrigation pipe, an activity that must take place less than 6 days after ODM application. EPA uses such exceptions only sparingly in situations where re-entry is critical to crop production, exposure can be mitigated with PPE, and the longer REI is protective of all other re-entry activities. Both growers and California state enforcement officials participated in the development of the revised provisions outlined below.

The ARTF data discussed above related to crop-specific transfer coefficients will be peer reviewed by a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). At that time, if the Agency adopts a TC other than the 100 cm^2 per hour assumed in the current ODM calculations, EPA will reconsider the REI for lettuce.

The revisions listed below must be included in labeling submitted in response to the product-specific DCI.

Amended Mitigation Measure

New label language for lettuce:

"Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application.

Minimum of 7 days between applications.

Restricted entry interval (REI) = 6 days. Do not enter or allow workers to enter during the restricted-entry interval of 6 days. Exception: This exception for early entry activities for irrigators in lettuce supercedes the early entry exceptions under 170.112 (e)(7)(ii) of the Worker Protection Standard (exception to perform irrigation tasks). Workers may enter treated areas to perform irrigation tasks after 2 days following application, as long as workers wear long pants, long-sleeved shirt, chemical resistant gloves, and chemical-resistant boots. Notify workers of the early entry exception including each task named in the exception.

Preharvest Interval (PHI) = 21 days for all of US, except Arizona and California:
28 days for Arizona only
28 days for California fall and winter lettuce
14 days for California spring and summer head lettuce if only 1 application
21 days for California spring and summer head lettuce if 2 applications."

All of the supporting documentation used in the development of the IRED and supporting this amendment can be found in the EPA docket system under docket # OPP-34167. The supporting documents may also be accessed electronically at *http://www.epa.gov/oppsrrd1/op/odm.htm.*

If you have questions on the ODM IRED, the amendments listed in this document, or

questions about the Generic DCI, please contact the Chemical Review Manager, Katie Hall at (703) 308-0166. For questions about product reregistration and/or the Product Specific DCI, please contact Moana Appleyard at (703) 308-8175.

Sincerely,

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

Interim Reregistration Eligibility Decision for Oxydemeton-methyl (ODM)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 Oxydemeton-methyl (commonly known as ODM or Metasystox-R®). 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 December 8, 1999. Additionally, the Agency held a Technical Briefing in Sacramento, CA, on December 8, 1999, 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 December 8, 1999, and closed on February 8, 2000.

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

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

The IRED is based on the updated technical information found in the ODM 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 ODM (revised as of December 8, 1999), 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 also includes comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For ODM, a proposal was submitted by Gowan Company, 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 process.

Please note that the ODM 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 ODM alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of ODM. 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 of 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 that have already been attributed to current uses of ODM. The Agency will issue the final tolerance reassessment decision for ODM and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophosphates are considered.

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

In this IRED, the Agency has determined that ODM 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 ODM may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation

measures identified in this IRED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section IV of this IRED describes labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by ODM. 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, Véronique LaCapra at (703) 605-1525. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Moana Appleyard at (703) 308-8175.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Interim Reregistration Eligibility Decision
for
Oxydemeton-methyl
(ODM)

Case No. 0285

TABLE OF CONTENTS

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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
ARI	Aggregate Risk Index
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
ODM	Oxydemeton-Methyl
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline

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

WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for ODM. The decisions outlined in this document do not include the final tolerance reassessment decision for ODM; however, some tolerance actions, such as revocation of unsupported tolerances and modifications to standardize the nomenclature may be undertaken prior to completion of the final tolerance reassessment. 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 ODM once the 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 ODM. After considering the revised risks, as well as mitigation proposed by Gowan Company, the technical registrant of ODM, and comments and mitigation suggestions from other interested parties including the Natural Resources Defense Council, California Rural Legal Assistance Foundation, and the Northwest Alfalfa Seed Growers Association, EPA developed its risk management decision for uses of ODM that pose risks of concern. This decision is discussed fully in this document.

ODM is a restricted use pesticide. It is a broad spectrum, systemic organophosphate insecticide/acaricide registered for foliar and bark treatment uses to control many insects, primarily aphids, mites, and thrips. Registered use sites include terrestrial food crops (vegetable, field, tree fruit and nut crops) and terrestrial non-food crops (ornamental uses). Approximately 150,000 lbs of ODM active ingredient are used annually in the US. At this time, products containing ODM are intended solely for use in agricultural and non-agricultural settings by certified applicators. The only currently registered uses likely to involve applications to public access areas or residential sites are soil injection and tree injection by certified applicators to shade trees and ornamentals.

Regulatory History

A Special Review of ODM was initiated in 1987 based on concerns for reproductive effects in workers. One outcome of the Special Review was a Settlement Agreement in 1994, in which Gowan agreed not to market ODM for use on citrus, field corn, popcorn, onions, pears, safflower, snap beans, sorghum, and turnips. An exception to this agreement was allowed which permits use of ODM on citrus grown in Florida under Special Local Need (SLN No. FL960006). Also in accordance with the agreement, established tolerances were to be retained in the event that these uses could be reinstated after EPA's “favorable review” of the required data and completion of the dietary and worker risk assessments as part of reregistration. The Special Review will be closed out based on the assessment and the risk mitigation outlined in this document. Of the nine off-labeled uses, field corn, popcorn, pears, snap beans, and turnips are being voluntarily cancelled. Citrus, onions, safflower, and sorghum will be reinstated.

Overall Risk Summary

EPA's human health risk assessment for ODM indicates some risk concerns. Dietary (food) risks, both acute and chronic, are well below the Agency's level of concern. Similarly, drinking water risk estimates based on screening models, from both ground and surface water for acute and chronic exposures, are not of concern for all population subgroups. There are, however, risk concerns for workers who mix, load, apply, flag or are exposed to residues when re-entering treated areas. Also, EPA has identified acute and chronic risks of concern to birds and mammals, and ODM is highly toxic to honey bees.

To mitigate risks of concern posed by the uses of ODM, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the occupational and ecological risk concerns. Results of the risk assessments, and the necessary label amendments to mitigate those risks, are presented in this interim RED.

Dietary Risk

Acute and chronic dietary risk for food and drinking water do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to ODM.

Occupational Risk

Occupational exposure to ODM is of concern to the Agency, and a number of risk mitigation measures are needed. Several mixer/loader/applicator risk scenarios for ODM currently exceed the Agency's level of concern, i.e., ARIs are less than 1. (The aggregate risk index, ARI, is a mathematical formula used to combine dermal and inhalation exposures with different safety factors.) Considering the benefits of ODM use, EPA believes these risks can be mitigated to an acceptable level with measures including reductions in application rates, restrictions on application methods, and the addition of personal protective equipment and/or the use of closed systems. The use of ODM on certain crops (field corn, pears, popcorn, snap beans, and turnips) will be cancelled. For all remaining uses, the current Restricted Entry Intervals (REIs) of 48 to 72 hours (2-3 days) will have to be lengthened to intervals ranging from 3 to 30 days in order to address risks to post-application workers who enter treated fields.

Residential & Other Non-Occupational Risk

ODM is not currently registered for residential use, and therefore a residential risk assessment was not conducted for ODM. Soil injection uses on ornamentals located in interior plantscapes, ornamental gardens, parks, golf courses, and non-residential lawns and grounds is being voluntarily cancelled. Tree injection in residential areas is not expected to result in exposure to ODM, due to the contained nature of the application method (injected into trunk).

Ecological Risk

Ecological risks are also of concern to the Agency. Of particular concern is the potential for acute and chronic avian and mammalian effects, as well as the toxicity to non-target insects, particularly honeybees. To address these risks, the registrants have agreed to reduce application rates and frequencies, establish buffer zones around areas managed for wildlife or as wildlife habitat, and include additional precautionary labeling.

Benefits

ODM has a minor, but essential niche in vegetable production. Currently there are no equally efficacious alternatives available for many vegetable crops. Further, many commenters have indicated, and EPA concurs, that ODM fits well with current integrated pest management (IPM) programs for these minor-use crops and for certain ornamentals.

For the remaining uses of ODM the Agency has determined that, with the adoption of all of the label amendments noted in this document, these uses may continue. These decisions will not, however become final until the cumulative risks of all of the organophosphates have been considered.

The Agency is issuing this Interim Reregistration Eligibility Document (IRED) for ODM, 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 ODM. As part of the process discussed by the Tolerance Reassessment Advisory Committee (TRAC), which sought to open up the process to interested parties, the Agency's risk assessments for ODM have already been subject to numerous public comment periods, and a further comment period for ODM 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, depending on the content of the risk management decision. Neither the tolerance reassessment nor the reregistration eligibility decision for ODM can be considered final, however, until the cumulative risk for all organophosphate pesticides is considered. The cumulative assessment may result in further risk mitigation measures for ODM.

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 mode of action or mechanism of toxicity. ODM 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 ODM. It is intended to be only the first phase in the reregistration process for ODM. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for ODM.

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 TRAC, which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

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

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

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

In addition to the policy issues that resulted from the TRAC process, the Agency issued on September 29, 2000, a Pesticide Registration notice (PR 2000-9) that presents EPA's approach for managing risks to occupational handlers and workers who may be exposed to organophosphate pesticides. 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 that PR notice.

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

II. Chemical Overview

A. Regulatory History

ODM was first registered in the United States in 1961 for manufacturing use, and then in 1962 for use on ornamentals. In 1964 ODM was registered for pest control in food crops.

A Special Review of ODM was initiated in 1987 due to concerns that ODM had the potential to adversely affect reproduction and thus, that exposure to ODM may pose risk concerns for agricultural workers. A Position Document 1 (PD 1) was published in the Federal Register (52FR192) of October 5, 1987, to announce the initiation of this Special Review. In 1992, the EPA's Peer Review Committee for Developmental and Reproductive Toxicity evaluated the weight-of-evidence for ODM with reference to its potential for reproductive and developmental toxicity and concluded, based on the evidence available at that time, that ODM produced effects on the reproductive system of rats.

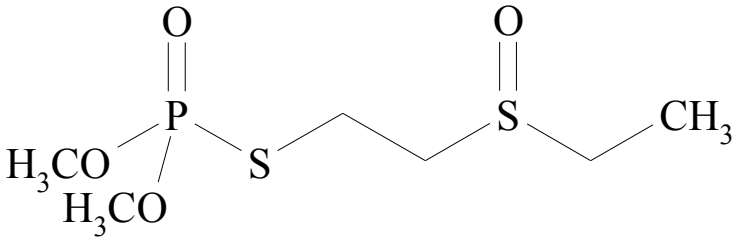
At the time the Special Review was initiated, Miles Inc. was the basic producer of ODM. In 1994, based on Miles' request, the Agency published a notice (59FR11601) proposing voluntary cancellation of all remaining ODM products. During the comment period, the registration was supported by another registrant, Gowan Company. Therefore, a final cancellation notice was not issued at that time and ODM remained in Special Review. Gowan Company reached a Settlement Agreement with the Agency in September, 1994. At the time that Miles requested voluntary cancellation of its products, the due dates for data to support reregistration of ODM were approaching and subsequently lapsed. Therefore, the Agency required risk mitigation measures from Gowan to allow ODM products to remain on the market while the required data were being generated. In addition to committing to generate data to better characterize the risk to workers, Gowan agreed not to market ODM on citrus, field corn, popcorn, onions, pears, safflower, snap beans, sorghum, and turnips. An exception to this agreement was allowed which permits use of ODM on citrus grown in Florida under a Special Local Need registration (SLN No. FL960006).

In the course of reregistration, new data that further characterizes the mutagenic and reproductive effects of ODM were submitted to EPA. In October 2000, an Ad Hoc Committee of EPA toxicologists met to review the Agency's initial 1992 conclusions and to assess the impact of the new data submissions on these conclusions. The Ad Hoc Committee determined, among other things, that the occupational/residential exposure endpoints should be based on cholinesterase inhibition (ChEI) and not on reproductive effects. The Committee concluded that risk assessments based on ChEI would be protective of any reproductive effects that might occur at higher doses.

Based on the reregistration assessments discussed in this IRED and the supporting documentation, the Special Review of ODM will be concluded and a notice closing out the Special Review will be issued in the near future.

B. Chemical Identification

ODM:



- **ODM:** (S-[2-(ethylsulfinyl)-ethyl] O,O-dimethyl phosphorothioate)
- **Chemical family:** Organophosphate
- **Case number:** 0285
- **CAS registry number:** 301-12-2
- **OPP chemical code:** 058702
- **Empirical formula:** $C_{14}H_{24}NO_4PS_3$
- **Molecular weight:** 246.3
- **Vapor Pressure:** 5.1×10^{-5} mbar at 25°C
- **Trade and other names:** Metasystox-R
- **Basic manufacturer:** Gowan Company (technical registrant)

ODM is a colorless to amber-colored liquid with a boiling point of 106°C. It is miscible with water; readily soluble (10-100 g/100 mL) in dichloromethane, 2-propanol, and toluene; and practically insoluble (<1 g/100 mL) in n-hexane. Because ODM pure active ingredient (PAI) and technical grade of the active ingredient (TGAI) are not stable, ODM is diluted with solvent to form a 50% ai formulation intermediate (FI) which is used to produce end-use product formulations. Preliminary analysis of the FI indicates that there are no impurities present or formed that would be of known toxicological concern.

C. Use Profile

The following information is based on the currently registered uses of ODM.

Type of Pesticide: Insecticide.

Summary of Current Use Sites:

Food: Field Crops (cotton, field corn, peppermint, popcorn, spearmint, and sugar beets); Seed Field Crops (alfalfa, clover, safflower, sorghum); Fruit (grapefruit, lemons, oranges, pears); Non-Bearing Fruits (apples, apricots, cherries, crab apples, grapes, nectarines, peaches, plums, prunes, quinces); Berries (strawberries, pre-bloom and post-harvest only), Vegetables (beans-lima, broccoli, Brussels sprouts, cabbage, cauliflower, cucumber, eggplant, head lettuce, onions, peppers, pumpkin, snap beans, squash, turnips); Melons (muskmelon, watermelon); and Nuts (filberts, walnuts).

Residential: Ornamentals (soil injection and tree injection) located in interior plantscapes, ornamental gardens, parks, golf courses, lawns and grounds.

Public Health: None.

Other Nonfood: Christmas tree plantations, seed orchard trees, ornamental flowering plants, ornamental bulbs, woody shrubs, and various ornamental and shade trees.

Target Pests: aphids, mites, leafhoppers, thrips, corn rootworm beetles and lygus bugs

Formulation Types Registered: In addition to the 50% formulation intermediate, ODM is formulated as an emulsifiable concentrate (EC) formulation (25% ai), and as a liquid ready-to-use formulation (50% ai) for tree injection.

Method and Rates of Application:

Equipment - aerially (fixed wing or helicopter), airblast sprayers, groundboom sprayers, chemigation, bark treatment (e.g., brush-on), low pressure handwand, high pressure handwand, backpack sprayer, tree injection and soil injection.

Method and Rate - foliar applications for most agricultural uses; agricultural use rate is typically 0.375 - 1.125 lbs ai/acre.

Timing - may be applied up to 3 times per year depending on the crop.

Use Classification: ODM is a restricted use pesticide (RUP).

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of ODM, based on available pesticide usage information for 1987 through 1997. A full listing of all uses of ODM, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Approximately, 145,000 to 186,000 pounds active ingredient (a.i.) are used to treat 213,000 to 283,000 acres annually. Most of the acreage is treated with 1 pound a.i. or less per application. In terms of percent crop treated, the major sites for ODM are broccoli, with an average of 62% crop treated, cauliflower with 46%, and Brussels sprouts with 75%. The remaining usage of ODM is primarily on a variety of fruits, vegetables, and field crops. Although lettuce is not a major site according to the table below, there is a new pest in lettuce, the lettuce aphid, which makes ODM increasingly important for that crop.

Table 1. ODM Estimated Usage for Representative Sites

Site	Acres Grown (000)	% of Crop Treated		Lbs AI Applied (000) Wtd Avg	States of Most Usage
		Wtd [1] Avg	Est [2] Max		
Strawberries	50	<0.5%	<0.5%	2	OR WA
Citrus	851	<0.5%	<0.5%	<0.5	AZ CA FL TX
Peaches	272	<0.5%	<0.5%	<0.5	
Pears	71	<0.5%	<0.5%	<0.5	
Filberts (Hazelnuts)	28	3%	4%	<0.5	CA OR
Walnuts	205	<0.5%	1%	<0.5	CA
Eggplant	3	4%	7%	<0.5	CA
Peppers, Hot	34	<0.5%	<0.5%	<0.5	CA
Peppers, Sweet	67	<0.5%	<0.5%	1	CA
Mint	167	12%	28%	16	IN ID
Lettuce	265	5%	9%	7	CA

Site	Acres Grown (000)	% of Crop Treated		Lbs AI Applied (000) Wtd Avg	States of Most Usage
		Wtd [1] Avg	Est [2] Max		
Broccoli	107	62%	68%	46	CA
Brussels Sprouts	4	75%	83%	3	CA
Cabbage	84	7%	8%	7	CA
Cantaloupes	110	5%	7%	1	CA
Cauliflower	57	46%	65%	22	CA
Cucumbers	151	2%	8%	2	CA
Pumpkins	41	<0.5%	<0.5%	1	CA
Squash	58	<0.5%	<0.5%	1	MI CA
Watermelons	239	<0.5%	<0.5%	1	CA TX OK
Beets	7	2%	3%	<0.5	CA
Potatoes	1,373	<0.5%	<0.5%	9	WA
Sweet Corn	731	<0.5%	<0.5%	1	CA WI
Beans, Dry	1,809	<0.5%	<0.5%	<0.5	
Onions	152	2%	8%	3	OR
Safflower	323	<0.5%	<0.5%	<0.5	
Snap Beans	274	<0.5%	<0.5%	<0.5	
Corn	74,921	<0.5%	<0.5%	1	UT
Alfalfa(seed)	200	11%	18%	8	NV OR ID
Cotton	13,009	<0.5%	1%	12	LA CA MS TX GA
Sorghum	11,394	<0.5%	<0.5%	5	NM
Sugar Beets	1,425	<0.5%	1%	2	CA OR
Turnips		<0.5%	<0.5%	<0.5	
Total				152	

[1] Weighted Average is based on data for 1987-1997; the most recent years and more reliable data are weighted more heavily. Average application rates are calculated from the weighted average.

[2] Est Max = Estimated maximum, which is estimated from available data.

III. Summary of ODM Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide ODM, as fully presented in the documents, "Human Health Risk Assessment; ODM" dated December 8, 1999 (and subsequent addenda), and "Current EFED RED Chapter for ODM," dated September 10, 1999 (and subsequent addenda). 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.

These risk assessments for ODM were presented at a December 8, 1999, Technical Briefing in Sacramento, California, 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 ODM only; the Agency must consider the cumulative risks of all the organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for ODM in December, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. The revisions were done as a result of comments received during Phase 3 and also because of internal EPA policy changes. Major revisions to the human health risk assessment are listed below:

- based on recently submitted data demonstrating the absence of adverse genetic effects, the FQPA Safety Factor was reduced from a 10X to a 1X,
- worker exposure estimates were revised to allow for a wider range of possible application rates used in mixer/loader/applicator risk calculations, and the most recent Agricultural Reentry Task Force (ARTF) data were used in revising the calculated REIs,
- a probabilistic assessment of acute dietary exposure and risk was used,
- a new assessment of chronic dietary risk was conducted using an endpoint for cholinesterase inhibition in laboratory animals rather than human volunteers, and
- drinking water risks were revised to reflect the most recent refinements in water modeling.

1. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is essentially complete, and that it supports an interim reregistration eligibility determination. Further details on the toxicity of ODM can be found in the December 8, 1999 Human Health Risk Assessment and subsequent addenda.

a. Reproductive Toxicity and Heritable Effects

A Special Review of ODM was initiated in 1987 due to concerns that ODM has the potential to adversely affect reproduction and thus, that exposure to ODM may pose risks to applicators and mixers/loaders who use products containing ODM and workers who re-enter treated fields. The Position Document 1 (PD 1) that initiated the Special Review, also expressed the need for data pertaining to the reversibility of effects on the male reproductive system, and noted that there may be a relationship between mutagenicity and the observed reproductive effects.

The Agency's concerns regarding reproductive effects were based primarily on the results of a two-generation rat reproduction study (MRID 00155396) and interim progress reports from an ongoing male rat reproductive toxicity study (MRID 40463001). Observed reproductive effects were decreased parental body weight, parental testes weight and fertility index, vacuolation of the corpus epididymus, decreased litter size, decreased pup weight and increased pup mortality. In addition to these reproductive effects, positive results for mutagenic effects were observed in two *in vitro* mutagenicity tests. Results of two other *in vitro* mutagenicity tests were inconclusive. The PD 1 cites several Data Call-In (DCI) Notices, including requests for mutagenicity and dermal penetration data (DCI April 1986) and male reproduction studies for acute and chronic exposure to ODM (DCI June 1987).

In 1992, the Agency's Peer Review Committee (PRC) for Developmental and Reproductive Toxicity met to evaluate the weight-of-evidence for ODM with reference to its potential for reproductive and developmental toxicity (Memorandum dated September 30, 1992). Two developmental toxicity studies, five reproductive toxicity studies, and several *in vitro* and *in vivo* mutagenicity tests were evaluated. Based on its evaluation, the PRC concluded that there was clear evidence of reproductive toxicity in the rat in the form of decreased litter size and viability, decreased fertility, and decreased weight of the testes and ovaries. Although of uncertain biological significance, epididymal vacuolation was assumed to be of concern and possibly to be associated with decreased fertility. Subsequent studies (MRID 4249001 and 42500101) demonstrated that epididymal vacuolation probably has no effect on fertility.

In general, the PRC found that the effect of ODM observed at the lowest dose was cholinesterase depression in the brain and erythrocytes, with plasma cholinesterase being depressed at higher dose levels. Nevertheless, the critical effects of concern at that time were considered to be the observed reproductive effects rather than the depression of cholinesterase observed at lower doses. Based on their weight-of-evidence evaluation, the PRC upheld the 1987 decision that ODM is a reproductive toxicant and that the short-term endpoint should be based on reproductive effects.

Since 1992, several toxicology data submissions which further characterize the mutagenic and reproductive effects of ODM have been reviewed by the Agency. In light of existing and recently submitted toxicity data, in 1999 the Hazard Identification Assessment Review Committee (HIARC) conducted a weight-of-evidence evaluation to select toxicological endpoints for acute and chronic dietary as well as occupational (dermal and inhalation) risk assessments. As specified by the Food Quality Protection Act (FQPA) of 1996, the HIARC also evaluated the ODM available studies to determine if the data indicated the potential for increased sensitivity of infants and children.

The HIARC decisions used for the revised ODM risk assessments are described in a committee report dated July 21, 1999. The HIARC chose ChEI endpoints for risk assessment purposes, reasoning that because cholinesterase inhibition generally occurs at doses lower than other effects, these ChEI endpoints would be protective.

Furthermore, previous concerns for heritable effects based on an inconclusive *in vivo* rat alkaline elution assay (MRID 43776102) had led the HIARC to retain a 10x FQPA safety factor for ODM (Combined Report of the HIARC and Safety Factor Committee and its Recommendation for the Organophosphates, dated August 6, 1998). This was based on a concern that the test substance in the alkaline elution assay may not have reached the target organ (the testes). However, the subsequent reevaluation of data from a rat toxicokenetic study (MRID 00152388) showed rapid distribution of ODM to the target organ (the testes). Based on the toxicokenetic data indicating that the alkaline elution test design did allow sufficient time for the test substance to reach the target organ, the alkaline elution assay, which showed negative results for DNA single strand breaks was upgraded to acceptable. The requirement for additional testing to evaluate adverse effects on germinal cells was revoked, and the toxicology database was considered to be complete. The Agency has concluded that previous concerns for adverse heritable effects resulting from exposure to ODM have been addressed (see section III.A.1.c. for a full discussion of the FQPA safety factor assessment).

In 2000, an Ad Hoc Committee of HED toxicologists (see report dated December 19, 2000) met to reevaluate and summarize all the new data and how the Agency's position had evolved since 1992. The Committee determined that in addition to ChEI, the results of special reproductive toxicity studies in the rat showed decreased male and female fertility of unknown origin. Specifically, absolute ovarian and testicular weights decreased, and a high incidence of epidymal vacuolation was observed in males. Although ODM was found to produce reproductive toxicity, based on its consideration of the weight of evidence in the complete ODM toxicity database, Ad Hoc Committee concurred with the conclusions of the HIARC, which based occupational exposure endpoints on ChEI and not on reproductive effects.

The ODM toxicity database contains a two-litter, two-generation reproductive toxicity study in rats (MRID 41461901) that was conducted to better characterize the dose response relationship toxicity of ODM and to assess both reproductive effects and cholinesterase inhibition under the same study conditions. The results, summarized in the table below show ChEI at levels lower than the levels at which reproductive effects are seen, under the conditions

of this study. It must be noted that a previous study (MRIDs 00260513, 00256926) in a different strain of rat showed epididymal vacuolation at a LOAEL of 0.5 mg/kg/day in one out of ten male rats tested; however, ChEI was not assessed in that study. ChEI was also seen at levels lower than systemic toxicity in a developmental toxicity study in rats (MRID 00146812 and 00158342).

Table 2. Comparison of ChEI and Reproductive Effects (MRID 41461901)

Generation	Effects	LOAEL (mg/kg/day)	NOAEL (mg/kg/day)
Parents:	reproductive effects	2.1	0.38
	ChEI	0.043	(not established)
Offspring:	reproductive effects	2.1	0.38
	ChEI	0.38	0.13

Further, the Ad Hoc Committee concurred that risk assessments based on ChEI would be protective of any reproductive or developmental effects which may occur at higher doses, and that concern regarding mutagenic effects resulting from exposure to ODM had been addressed.

It should be noted that although the HIARC decided not to require a developmental neurotoxicity study for ODM in 1999, the Agency subsequently issued a Data Call-In notice (FR42945, August 6, 1999) requiring all registrants of organophosphorus pesticides, including ODM, with the potential for exposure to children, to conduct acute, subchronic, and developmental neurotoxicity studies and submit the results to the Agency.

b. Carcinogenicity

Oxydemeton-methyl has been classified as "Not Likely" to be carcinogenic in humans via relevant routes of exposure because no compound-induced carcinogenic response was observed in mice or rats.

c. FQPA Safety Factor

The FQPA Safety Factor Committee's earlier recommendation to retain the 10x safety factor, reported in the preliminary risk assessment for ODM, was based on: concern for heritable effects as demonstrated in an *in vivo* mouse spot test which was positive for the induction of somatic cell mutations following intrauterine exposure of embryos; and evidence of DNA strand breaks in rat testes cells in an *in vitro* alkaline elution assay (not confirmed *in vivo*). A mouse specific locus test was required.

In its 60-day response to the preliminary risk assessment for ODM, Gowan Company

disagreed with EPA's rationale for the imposition of the FQPA 10x safety factor and provided extensive technical comments in conjunction with a rebuttal submission to support their arguments against further mutagenicity testing in a rat alkaline *in vivo* germ cell assay. The Agency addressed the registrant's objections to retaining the 10x FQPA safety factor and informed Gowan that it was unable to reconsider the weight-of-evidence evaluation for potential heritable effects until such time as definitive data were available that demonstrate that gonadal tissue was exposed to an adequate dose of ODM in the alkaline elution study or in another appropriate germinal cell assay. In response, Gowan provided a non-guideline, toxicokinetic study which was reviewed and found acceptable. The study data provided evidence that ODM could indeed reach the target organ in a relatively short time and thus the existing *in vivo* alkaline elution assay of rat testes, which was negative for DNA strand breaks, should be reclassified as acceptable.

The acceptability of the alkaline elution assay, in conjunction with the negative results of that assay as well as the negative findings of the dominant lethal assays, lowered the concern for heritable effects from exposure to ODM and prompted the HIARC to re-evaluate the results of the mouse spot test. The primary function of the mouse spot test is as a carcinogenesis screening tool. Although ODM was positive in this test system, it was negative in other *in vivo* assays with somatic cells. In addition, ODM was shown to be non-carcinogenic in long-term studies in both mice and rats.

This new evidence was considered by the HIARC on July 8, 1999, and the FQPA Safety Factor Committee on July 12, 1999. The FQPA Safety Factor Committee concluded that a safety factor is not required for the following reasons:

- Based on the recently submitted toxicokinetic data and a weight-of-evidence re-evaluation of the genetic concerns for ODM, the HIARC revoked the requirement for the mouse specific locus test (which was previously identified as a data gap) and concluded that the genetic concerns resulting from exposure to ODM have been addressed.
- The toxicity data base for ODM is now complete.

Additional reasons for not retaining a safety factor for infants and children which were considered in previous Safety Factor Committee conclusions are as follows:

- There was no evidence of developmental effects being produced in fetuses at lower doses as compared to maternal animals nor was there evidence of an increase in severity of effects at or below maternally toxic doses following *in utero* exposure in the prenatal developmental toxicity studies in rats and rabbits;
- In the pre/postnatal two-generation reproduction study in rats, there was no evidence of enhanced susceptibility in pups when compared to parental animals (i.e., effects noted in offspring occurred at maternally toxic doses or higher);
- There was no evidence of abnormalities in the development of the fetal nervous system in the pre/postnatal studies submitted to the Agency; and

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

2. Dietary Risk from Food

a. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of ODM, the FQPA safety factor is 1; therefore, the acute or chronic RfD is the same as the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not present a risk of concern for the Agency. A summary of the toxicological endpoints and factors used for the dietary risk assessment is presented below in Table 3.

Table 3. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of ODM

Assessment	Dose (mg/kg/day)	Endpoint	Study	UF[a]	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary	No NOAEL LOAEL 2.5	Decreased RBC and brain ChE activity in males after a single dose.	Acute Neurotoxicity in the rat (MRID 43929901)	300[b]	1	0.008
Chronic Dietary	NOAEL 0.013 LOAEL 0.13	Decreased erythrocyte and brain ChE	Chronic dog (MRIDs 00151805, 41082201, 41980801, 43454201)	100[c]	1	0.00013

[a] Uncertainty Factor

[b] Uncertainty factors of 10x for intra-species variability, 10x for inter-species extrapolation, and 3x for lack of a NOAEL.

[c] Uncertainty factors of 10x for intra-species variability and 10x for inter-species extrapolation.

b. Exposure Assumptions

Revised acute and chronic dietary risk analyses for ODM were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92. The Tier 3 acute analysis also included use of weighted average percent crop treated data and

anticipated residues developed using residue data from available crop field trials and livestock feeding studies, and USDA/PDP and FDA monitoring data. The Tier 3 chronic dietary analysis included use of weighted average percent crop treated data, anticipated residues developed using residue data from available crop field trials and livestock feeding studies, PDP data from USDA, and FDA monitoring data. Where percent crop treated estimates indicated little or no ODM use (including but not limited to the 9 crops removed from Gowan's marketing label in 1994), EPA applied a default minimum assumption of 1% crop treated.

c. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose (aPAD, cPAD) does not exceed the Agency's risk concerns. The ODM acute dietary risk from food is well below the Agency's level of concern. For example, for the most exposed subgroup, females over the age of 13 and nursing (13-50 years), 7.1% of the aPAD is occupied at the 99.9th percentile of exposure. For the general U.S. population exposure estimates occupied 3.5% of the aPAD (Table 4).

Table 4. Summary of Acute Dietary Exposure and Risk Estimates for ODM

Population Subgroup	99.9th Percentile % aPAD
General US Population	3.5
Females (13-50 years)	7.1
All Infants <1yr	3.5
Children (1-6 years)	6.4

Similarly, the chronic dietary risk from food alone is below the Agency's level of concern. For the most exposed subgroups, non-nursing infants (<1 year), 5.3% of the cPAD is occupied. General U.S. population exposure estimates consumed 2.0% of the cPAD (Table 5).

Table 5. Summary Chronic Dietary Exposure and Risk Estimates for ODM.

Population Subgroup	% cPAD
U.S. Population	2.0
All Infants (<1 year)	4.0
Nursing Infants (<1 year)	1.0
Non-nursing Infants (<1 year)	5.3
Children (1-6 years)	4.5

3. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface water and ground 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. To estimate exposure in drinking water, EPA first determines if the monitoring data are adequate. Then, modeling may be used as an estimate if the monitoring data are not adequate. Modeling provides a conservative, upper-bound estimate of exposure. The monitoring data for ODM was very limited for both surface water and ground water. Therefore, EPA used modeling to determine estimates of exposure through drinking water.

The Tier II models PRZM and EXAMS were used to estimate surface water concentrations, and the Tier I model SCI-GROW was used to estimate groundwater concentrations. While both PRZM-EXAMS and SCI-GROW are screening models designed to provide conservative estimates of a potential pesticide concentration in water, PRZM-EXAMS is more refined than SCI-GROW.

Limited surface and ground water monitoring data indicated that ODM was detected at levels lower than those determined by modeling. As a result, EPA believes that the models are not likely to underestimate the potential for ODM residues to be present in drinking water.

ODM sulfone (ODMS), the only metabolite included in the tolerance expression, does not appear to be persistent and was not formed in significant quantities in laboratory studies. In addition, the metabolites desmethyl ODM sulfone, and desmethyl ODM did not form in significant quantities in laboratory studies, and do not appear to be persistent. Therefore, the use of parent ODM as a surrogate for the non-persistent metabolites is reasonable.

a. Surface Water

EPA used PRZM-EXAMS to estimate the upper-bound potential ODM concentrations in drinking water derived from surface water. This Tier II model incorporates crop, weather, and soil conditions in use areas, in addition to chemical-specific characteristics. Based on its environmental fate characteristics, ODM is not expected to persist or accumulate in surface waters. However, ODM is likely to be transported in surface runoff if rainfall occurs soon after application. PRZM-EXAMS predicted maximum (acute) and 36-year mean (chronic) concentrations of 12.4 and 0.9 ppb, respectively, in surface water that could be used for drinking water (see the surface water resource assessment summary in chapter 3 section B.2.a. for a full explanation of these estimated concentrations).

b. Ground Water

The SCI-GROW model is a screening model used to estimate concentrations of pesticide in shallow ground water under permeable soils. Based on environmental fate characteristics and supporting ground water modeling, ODM is not expected to leach to ground water at greater than 0.006 ug/L (ppb) (see the ground water resource assessment summary in chapter 3 section B.2.b.

for a full explanation of this estimated concentration).

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 calculates a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels could exceed this level. The DWLOC represents the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency's drinking water analysis are summarized here. Details of this analysis are found in the HED Human Health Risk Assessment, dated December 8, 1999 and the "Current EFED RED chapter for Oxydemeton methyl" dated September 10, 1999.

For acute risk, the potential drinking water exposure derived from either ground or surface water is not of concern for all populations. That is, the estimated environmental concentrations (EECs) are well below the DWLOCs. Table 6 below presents the results of the acute drinking water assessment.

Table 6. Summary of EECs and DWLOCs for Acute Risk.

Population Subgroup	Surface Water Maximum EECs (ppb)	Ground Water EECs (ppb)	DWLOC acute (ppb)
Adult Male	12.4	0.006	273
Adult Female	12.4	0.006	223
Infants <1 yr	12.4	0.006	77
Children 1-6	12.4	0.006	75

As shown above, the drinking water estimated concentrations in ground water (0.006 ppb) and surface water (12.4 ppb) are well below the acute DWLOCs for ODM. Residues in drinking water are below the Agency's level of concern on an acute basis for all population subgroups.

Table 7. Summary of EECs and DWLOCs for Chronic Risk.

Population Subgroup	Surface Water 36-Year Mean EECs (ppb)	Ground Water EECs (ppb)	DWLOC chronic (ppb)
Adult Male	0.9	0.006	4
Adult Female	0.9	0.006	4
Infants <1 yr	0.9	0.006	1
Children 1-6	0.9	0.006	2

The estimated mean concentration in surface water (0.9) is only slightly less than the DWLOC of 1 for infants less than 1 year in age. The value of 0.9 ppb was calculated based on 3 applications of 0.5 lbs a.i./A to sweet corn in Georgia. However, the registrant has agreed to limit the use on sweet corn to 2 applications of 0.5 lbs a.i./A and to restrict this use to west of the Rocky Mountains. The next highest estimated mean concentration in surface water was 0.7 ppb, based on 3 applications of 0.5 lbs a.i. to sorghum in Kansas. This value is below the DWLOC of 1 for infants. Estimated concentrations of ODM in surface water (0.9 ppb) and in ground water (0.006 ppb) are below the chronic DWLOCs for all other population subgroups. Residues in drinking water are below the Agency's level of concern on a chronic basis for all population subgroups.

4. Aggregate Risk

The aggregate assessment for ODM only considers the combined risk from food and drinking water exposures because none of the uses supported for registration are likely to result in non-occupational, residential-type exposures. ODM is a restricted use pesticide that that only can be applied by certified applicators or those under their direct supervision. Currently registered uses that could result in non-occupational exposures include ornamentals located in interior plantscapes, ornamental gardens, parks, golf courses, and lawns and grounds. ODM is currently registered for application by soil injection on these use sites; however, these uses are not being supported and will be removed from all product labels. Two currently registered tree injection products can be applied to ornamentals in residential areas (such as ornamentals located around apartments or condomiums) by certified applicators. This tree injection use is being supported for registration but is expected to result in negligible post-application exposure.

Aggregate exposure risk assessments for ODM were conducted for acute and chronic exposure. Results of the aggregate risk assessment are summarized in the previous section, and are discussed extensively in the December 8, 1999 Human Health Risk Assessment. Risk estimates indicate that acute and chronic aggregate exposures to ODM from food and drinking water are not of concern.

5. Occupational Risk

ODM is a restricted use pesticide that is only applied by certified applicators or those under their direct supervision. None of the uses supported for reregistration are likely to involve applications to public access areas or at residential sites other than tree injection by certified applicators to shade trees and ornamentals. Occupational workers can be exposed to ODM through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the estimated occupational exposure comes to a No Observed Adverse Effect Level (NOAEL).

Although a common toxicological endpoint was used to assess both the dermal and

inhalation routes, the uncertainty factors for dermal exposure and inhalation exposure are different (i.e., 100 for the dermal route, and 300 for the inhalation route). As a result, the MOEs for these two routes of exposure were combined using an aggregate risk index (ARI) method. ARIs, which are the ratios of the MOEs to the uncertainty factors adjusted to a common denominator of 1, are calculated using the following formula:

$$ARI = 1 / \{[1 / (Dermal\ MOE / Dermal\ UF)] + [1 / (Inhalation\ MOE / Inhalation\ UF)]\}$$

The calculated ARI is then compared to a target of 1; generally, ARIs greater than 1 are not of concern.

It should be noted that estimated inhalation risk for all exposure time frames is a relatively minor component of the combined dermal and inhalation risk estimates. Inhalation MOEs generally ranged from about 1,000 to 60,000, well above the target MOE of 300 for this route. Except for applying liquids as a tree bark treatment using a paintbrush, inhalation MOEs alone were not of concern. For this single scenario, the inhalation MOE alone was 210.

a. Toxicity

The toxicity of ODM is integral to assessing the occupational risk. All risk calculations are based on the current toxicity information available for ODM. The toxicological endpoints, and other factors used in the occupational risk assessments for ODM are listed below in Table 8.

Table 8. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessments for ODM.

Assessment	Dose (mg/kg/day)	Endpoint	Study	UF	Comment
Short-term (1-7 days) Dermal	NOAEL 5 LOAEL 10	Plasma, RBC, Brain ChE inhibition	7-day dermal toxicity (rat) (no MRID)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Intermediate-term (7-90 days) Dermal	NOAEL 0.3 LOAEL 1.0 in males	Brain ChE inhibition	14-day dermal toxicity (rat) (MRID 40499304)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Inhalation	No NOAEL LOAEL 17	Clinical signs (tremors)	Acute inhalation study (rat) (MRIDs 40779805C, 40779805	300	Route-specific study; MOE based on UF for inter-species (10x) extrapolation, intra-species variability(10x), and lack of NOEL (3x)

No dermal absorption factor is needed since the occupational endpoints have been

derived from dermal toxicity studies. Because the more typical 28-day dermal toxicity study is not available for ODM, EPA has selected occupational endpoints from the 7 and 14-day dermal studies. Use of the 14-day dermal endpoint (LOAEL = 0.3 mg/kg/day) is supported by the sub-chronic rat neurotoxicity study with a LOAEL of 0.62 mg/kg/day (1.2 mg/kg/day equivalent dermal dose) and is considered to be protective of longer exposures, i.e., up to 90 days. Because of the relatively minor use of ODM, continuous exposures of greater than 90 days are not expected.

Acute toxicity studies provide information on the potential for health hazards that may arise as a result of a single (≤ 1-day) exposure. These data provide a basis for precautionary labeling and protective clothing requirements. Acute toxicity data for ODM technical are summarized below in Table 9.

Table 9. Acute Toxicity Profile for ODM

Route of Exposure	Results	Tox Category	MRID
Acute oral	female rat LD50 = 48 mg/kg	I	40779801
Acute dermal	female rat LD50 = 112 mg/kg	I	00143350
Eye irritation	rabbit–slightly irritating	III	00151801
Dermal irritation	rabbit-non-irritating	IV	00151801
Dermal sensitization	guinea pig–not a skin sensitizer	n/a	40779802
Acute inhalation	female rat LC50 = 0.427 mg/L	II	40779805

b. Exposure

Chemical-specific exposure data were not available for ODM, so risks to pesticide handlers were assessed using data from the *Pesticide Handlers Exposure Database (PHED)*, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. to calculate risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from ODM labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that are used by the Agency, 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 data, but all are the best available data. The quality of the data used for each scenario assessed is discussed in the "Human Health Risk Assessment; Oxydemeton-methyl," which is available in the public docket.

Anticipated use patterns, application methods, and range of application rates were derived from current labeling. Application rates specified on ODM labels range from 0.375 - 1.125 lbs active ingredient per acre in agricultural settings. The Agency typically uses acres

treated per day values that are thought to represent 8 hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency in a step-wise fashion, considering increasing levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures to obtain an appropriate ARI (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., ARIs that are less than 1), increasing levels of personal protective equipment (PPE) and engineering controls (EC). The current label requirements for ODM are listed below along with the levels of protection that formed the basis for calculations of exposure from ODM activities:

- Current Label: Long-sleeved shirt and long pants; Coveralls; Chemical-resistant gloves; Chemical resistant footwear plus socks; Protective eyewear; Chemical-resistant headgear for overhead exposure; Chemical resistant apron when cleaning equipment or mixing or loading; a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides, or a canister approved for pesticides.
- Baseline: Long-sleeved shirt, long pants, shoes and socks.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, and a respirator for some scenarios.
- Engineering controls: Closed mixing system; water-soluble bags (gel packs); enclosed cockpit; enclosed cab; enclosed truck (all include single layer clothing, and either chemical resistant gloves or no gloves, as noted in Table 9).

For handlers, both short-term and intermediate-term assessments were conducted for ODM, to reflect exposures of either 1-7 days or 7-90 days, respectively. Separate dermal and inhalation MOEs, as well as ARIs, for all short and intermediate-term scenarios may be found in the December 1, 1999 Human Health Assessment for ODM.

Exposure to workers through entry into agricultural fields that have been treated with ODM were also considered. These exposures were considered to be intermediate term exposures.

c. Occupational Risk Summary

In the revised assessment, risks for handlers were assessed for both dermal and inhalation exposures. The resulting risks (MOE values) were then combined in order to obtain an overall risk. Because the Uncertainty Factors for the dermal and inhalation assessments are different, an ARI is used to express combined risks. Dermal and inhalation risks are also examined separately to determine the appropriate protective equipment. Different types of protective equipment may be appropriate in different exposure scenarios, eg., adding a pair of gloves and not a respirator,

and vice versa. All of the risk calculations for handlers are included in the Human Health Risk Assessment.

Thirteen different exposure scenarios were assessed. Within each of the scenarios, further analyses were conducted to determine the level of risk at typical and maximum application rates for various crops. The reader is referred to the complete Human Health Risk Assessment document in the public docket for more information on this comprehensive assessment.

The table in the next section summarizes the risk concerns after all assessments were revised using the most current data and assumptions for occupational handlers, based on combined dermal and inhalation exposures. The table presented in this document outlines the risks that remain of concern at baseline (i.e., those scenarios that have ARIs < 1), and provides the risk estimates for each of these scenarios with PPE, and with engineering controls, to show the level to which these risks can be mitigated.

(1) Agricultural Handler Risk

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers from the usual use-patterns associated with ODM. The scenario numbers listed below correspond to scenario numbers detailed and discussed in the Human Health Risk Assessment. For ODM, combinations of differing rates, acreages, and application methods for short-term and intermediate-term exposures were assessed. Based on the use patterns, 13 major exposure scenarios were identified for ODM:

(1a) mixing/loading liquid formulations for aerial/chemigation application;
(1b) mixing/loading liquid formulations for groundboom application;
(1c) mixing/loading liquid formulations for airblast sprayer application;
(1d) mixing/loading liquid formulations for high-pressure handwand application;
(2a) mixing/loading water-soluble bags (gel packs) for aerial application/chemigation;
(2b) mixing/loading water-soluble bags (gel packs) for groundboom application
(2c) mixing/loading water-soluble bags (gel packs) for airblast sprayer application;
(2d) mixing/loading water-soluble bags (gel packs) for high-pressure handwand application;
(3)* applying sprays with fixed-wing aircraft;
(4)* applying sprays with helicopter aircraft;
(5) applying using a groundboom sprayer;
(6) applying using an airblast sprayer;
(7) applying using a high-pressure handwand;
(8) applying concentrated or dilute liquid to tree bark using a paintbrush;
(9) tree injection using a ready-to-use liquid;
(10) mixing/loading/applying liquid using soil injection;
(11) mixing/loading/applying sprays using a backpack sprayer;
(12) mixing/loading/applying sprays using a low pressure handwand;
(13) flagging during aerial application (sprays).

*Because little information is available to assess applications by helicopter, EPA currently uses data on fixed wing aerial applications to assess both fixed wing and helicopter.

The exposure scenarios with risks of concern for short-term exposures are reported here:

(7) applying using a high-pressure handwand;
(8) applying concentrated or dilute liquid to tree bark using a paintbrush;
(11) mixing/loading/applying sprays using a backpack sprayer;
(12) mixing/loading/applying sprays using a low pressure handwand.

It should be noted that intermediate-term dermal exposures (in this case, exposure greater than 7 days) are the main risk drivers for all scenarios. For intermediate term exposure, all scenarios have remaining risk concerns at baseline. The following scenarios have remaining risk concerns for intermediate-term exposures with maximum feasible PPE or engineering controls:

(1a) mixing/loading liquid formulations for aerial/chemigation application;
(1b) mixing/loading liquid formulations for groundboom application;
(2a) mixing/loading water-soluble bags (gel packs) for aerial application/chemigation;
(2b) mixing/loading water-soluble bags (gel packs) for groundboom application
(2c) mixing/loading water-soluble bags (gel packs) for airblast sprayer application (for application rates of 0.75 lbs/ai/Acre or more);
(2d) mixing/loading water-soluble bags (gel packs) for high-pressure handwand application;
(3) applying sprays with fixed-wing aircraft;
(4) applying sprays with helicopter aircraft;
(5) applying using a groundboom sprayer (for application rates of 0.75 lbs ai/acre or more);
(6) applying using an airblast sprayer;
(7) applying using a high-pressure handwand (engineering controls not feasible);
(8) applying concentrated or dilute liquid to tree bark using a paintbrush (engineering controls not feasible);
(11) mixing/loading/applying sprays using a backpack sprayer (engineering controls not feasible);
(12) mixing/loading/applying sprays using a low pressure handwand (engineering controls not feasible);

Some mixer/loader/applicators or handlers, particularly growers who treat only their own small fields, are more likely to have short-term exposures – that is, exposures of seven days or less. Other handlers, especially custom applicators who apply ODM professionally to multiple fields, are more likely to apply ODM over the course of 1 week to several weeks. Those who mix/load or apply ODM to multiple fields may have intermediate-term exposure.

Dermal and inhalation risks could not be quantitatively assessed for two exposure scenarios because there are no appropriate chemical-specific or PHED data sets available. Also, reliable information for area treated or amount handled is unavailable. These scenarios are:

(9) tree injection using a ready-to-use liquid, and
(10) mixing/loading/applying liquid using soil injection.

Applications for tree injection involve placing a sealed capsule containing ODM into a pressurized injector unit which is installed in holes pre-drilled into the base of trees at the root flare. Handler exposure during product mixing/loading is not expected and applicator exposure is believed to be minimal.

Soil injection uses (shade, nursery trees and shrubs) potentially involve mixer, loader, and applicator exposures. ODM is mixed and loaded, using an open pour system, into an injection device and injected 6 inches below the soil surface at the drip line. Based on screening-level estimates using limited information on this scenario, there are significant exposure and potential risk concerns for the soil injection use, primarily associated with mixing/loading activities. The data necessary to assess these risks would include exposure data, the typical number of trees treated daily, and the typical trunk diameter of the treated trees. However, the registrant is no longer supporting soil injection uses and these uses will be removed from product labels.

All ARIs in the table below are based on combined dermal and inhalation risks. Calculations for aerial and chemigation applicators, and the mixer/loaders that support them, assume that 350 acres are treated per day; groundboom calculations assume 80 acres; calculations for airblast applications to grapes assume 40 acres; and calculations for airblast application to tree crops assume 20 acres.

Table 10. Agricultural Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)
Note: Target ARI is 1 or greater

Exposure Scenario (Scenario #)	Application Rate lbs/Ai/Acre (crop)	ARI at Baseline [a]		ARI with PPE [b]		ARI with Engineering Controls [c]	
		Short-term	Intermediate-term	Short-term	Intermediate-term	Short-term	Intermediate-term
Mixer Loader Exposures							
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	(safflower) 1.0	0.0034	0.00021	0.55	0.035	1.2	0.07
	(corn & mint) 0.75	0.0046	0.00028	0.73	0.047	1.6	0.093
	(cole crops) 0.5	0.0069	0.00041	1.1	0.071	2.3	0.14
	(walnuts) 0.375	0.0092	0.00055	1.5	0.094	3.1	0.19
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	(safflower) 1.0	0.015	0.00091	2.4	0.15	5.1	0.31
	(corn & mint) 0.75	0.02	0.0012	3.2	0.21	6.7	0.41
	(cole crops) 0.5	0.03	0.0018	4.8	0.31	9.9	0.61
	(walnuts) 0.375	0.04	0.0024	6.5	0.41	14	0.81
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)	(tree crops) 1.125	0.054	0.0032	8.7	0.55	18	1.1
	(grapes) 0.375	0.080	0.0048	13	0.82	27	1.6
Mixing/Loading Liquid Formulations for High-Pressure Handwand (1d)	(tree crops) 1.125	0.054	0.0032	8.7	0.55	18	1.1
Mixing/Loading Water-soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	(corn & mint) 0.75	See Engineering Controls				1.4	0.082
	(cole crops) 0.5	See Engineering Controls				2.0	0.12
	(walnuts) 0.375	See Engineering Controls				2.6	0.16

Exposure Scenario (Scenario #)	Application Rate lbs/Ai/Acre (crop)		ARI at Baseline [a]		ARI with PPE [b]		ARI with Engineering Controls [c]	
			Short-term	Intermediate-term	Short-term	Intermediate-term	Short-term	Intermediate-term
Mixing/Loading Water-soluble Bags (Gel Packs) for Groundboom Application (2b)	(corn & mint) 0.75		See Engineering Controls				5.9	0.36
	(cole crops) 0.5		See Engineering Controls				8.7	0.54
	(walnuts) 0.375		See Engineering Controls				12	0.71
Mixing/Loading Water-soluble Bags (Gel Packs) for Airblast Sprayer (2c)	(tree crops) 1.125		See Engineering Controls				16	0.95
	(grapes) 0.375		See Engineering Controls				23	1.4
Mixing/Loading Water-soluble Bags (Gel Packs) for High-Pressure Handwand (2d)	(tree crops) 1.125		See Engineering Controls				16	0.95
Applicator Exposures								
Applying Sprays with Fixed-wing Aircraft (3)	0.75		See Engineering Controls				2.7	0.16
	0.5						4.0	0.24
Applying Sprays with Helicopter Aircraft (4)	0.75		See Engineering Controls				2.7	0.16
	0.5						4.0	0.24
Applying Sprays with a Groundboom (5)	0.75		4.0	0.25	5.0	0.32	12	0.70
	0.5		6.0	0.38	7.5	0.48	18	1.1
Applying Sprays Using an Airblast (6)	(tree crops) 1.125		0.43	0.026	0.7	0.042	8.0	0.49
	(grapes) 0.375		0.64	0.039	1.1	0.064	12	0.74
Applying Using a High-Pressure Handwand (7)	1.125		0.083	0.0052	0.36	0.026	Not Feasible	
Applying Liquids as a Tree Bark Treatment Using a Paintbrush (8)	2 lb ai/gal [d]	10 gal [e]	0.00097	0.000058	0.0079	0.00048	Not Feasible	
		5 gal [e]	0.0019	0.00012	0.016	0.00095	Not Feasible	

Exposure Scenario (Scenario #)	Application Rate lbs/Ai/Acre (crop)	ARI at Baseline [a]		ARI with PPE [b]		ARI with Engineering Controls [c]	
		Short-term	Intermediate-term	Short-term	Intermediate-term	Short-term	Intermediate-term
Tree Injection (Ready-to-Use Liquid) (9)	No Data						
Mixer/Loader/Applicator Exposures							
Soil Injection (10)	No Data						
Backpack Sprayer/Knapsack (11)	0.75 lb ai/gal	0.046	0.0028	0.072	0.0044	Not Feasible	
Low Pressure Handwand -liquid (12)	0.75 lb ai/gal	0.0012	0.000070	0.3	0.019	Not Feasible	
Flagger Exposures							
Flagging Aerial (Sprays) (13)	0.75	1.2	0.073	1.3	0.08	59	3.6
	0.5	1.8	0.11	1.9	0.12	89	5.5

[a] Baseline represents long pants, long sleeve shirt, shoes and socks.

[b] PPE represents (by scenario):

1a, 1b, 1c, 1d, 5, 6, 7, 11, 12: double layer clothing with chemical resistant gloves.
8: double layer clothing, chemical resistant gloves, and dust mist respirator.
13: double layer clothing

[c] Engineering Controls represents (by scenario):

1a, 1b, 1c, 1d: closed mixing system, single layer of clothing and chemical resistant gloves
2a, 2b, 2c, 2d: water-soluble bags (gel packs), single layer clothing, chemical resistant gloves
3, 4: enclosed cockpit, single layer clothing, and no gloves
5: enclosed cab, single layer clothing, and no gloves
6: enclosed cab, single layer clothing and chemical resistant gloves
13: enclosed truck, single layer clothing, and no gloves

[d] Maximum application rate for paintbrush application applies to application of undiluted liquid.

[e] For paintbrush application of ODM to tree bark, a range of 5-10 gallons per day of undiluted liquid represents an estimate of the volume of liquid applied in a single day (From EPA HED estimates).

(2) Post-application Occupational Risk

The post-application occupational risk assessment considers exposures to workers entering treated sites. All of the post-application risk calculations are described in an addendum to the Human Health Risk Assessment, dated August 17, 2000, which is available in the public docket. This addendum includes recent data developed by the registrant and from the Agricultural Reentry Task Force.

Post-application scenarios were classified as intermediate-term (7 days to several months); thus the NOAEL of 0.3 mg/kg/day was used to estimate post application worker risk. Workers are expected to be involved in post-application activities such as harvesting, scouting, irrigating, etc. in various fields where exposure to ODM-treated crops is likely to occur daily for 1 week to several months. This frequency of exposure is most likely to occur during post-application activities for cole crops (cauliflower, broccoli, Brussels sprouts) where 51-100% of the crop is treated with ODM. Only post-application dermal exposure was assessed because post-application inhalation exposure is expected to be negligible.

The scenarios identified are as follows:

- harvesting;
- scouting, weeding, hoeing, and other non-harvesting activities;
- pruning, thinning and other activities such as mechanical harvesting.

Current labels require a restricted-entry interval (REI) of 48 hours, or 72 hours for regions where average rainfall is less than 25 inches per year. These REIs apply to all use sites.

The exposure component of post-application risk assessment is based on a dislodgeable foliar residue study, in which residues from cotton, bell peppers, cauliflower, and sugarbeets were analyzed. Applications were made at the maximum registered use rate. Dislodgeable foliar residue (DFR) samples were collected from each crop at intervals from 1 hour to 35 days post-application and analyzed for residues of ODM and its sulfone metabolite. Climatological information indicated no rainfall occurred during the sampling period, which is not atypical for California where much ODM is used.

EPA notes that the sugar beet and bell pepper DFR data were strikingly different from the cauliflower and cotton DFR data. The cotton and cauliflower residues dissipated to a level resulting in MOEs > 100 after 7 and 8 days respectively, while the sugar beet and bell pepper residues dissipated to a level resulting in MOEs > 100 only after 64 and 33 days respectively.

Where possible, the results for each crop were extrapolated to crops in the corresponding Agency-defined crop group. Thus, cauliflower data were considered representative of other cole crops, bell pepper data were considered representative of eggplants, and cotton and sugar beet data were assumed to represent those crops only. Restricted entry intervals (REIs) for crops that could not be represented by the crops mentioned above were estimated using the average of the initial DFR values and the average dissipation rate.

Post-application margin of exposure (MOE) estimates for ODM have been revised since the December 8, 1999 risk assessment based on EPA's revised agricultural transfer coefficient policy (Science Advisory Council for Exposure Policy 003.1, Agricultural Transfer Coefficients, Revised 8/7/2000) which includes data collected by the Agricultural Reentry Task Force (ARTF). In general, the revised policy employs methodology which clusters crops, crop growth stages, and post-application activities into groups that are expected to result in comparable exposure. This has resulted in a total of 18 crop groups; twelve of which are applicable to ODM. Transfer coefficients (TCs) derived from studies conducted by the ARTF, specific registrants, and found in published scientific literature have been applied to the activities in the defined crop groups. The table below presents the calculated REIs for the ODM use sites that are being supported by the registrant. The REIs for currently labeled use sites that are not being supported are not shown. Pre-harvest Intervals (PHIs) are shown in parentheses following each crop name. The application rates shown in the table are those that are being supported, not those on current labels. The target MOE is 100 for all crops and activities.

Table 11. Summary of Post-application Exposure and Risk Estimates.

Crop *(PHI)*	lbs ai/A per app. (# apps/ season)	Activity	TC ($\mu g/cm^2$)	Day[1] MOE=100
Alfalfa, lima beans, and clover *(21)*, safflower *(7)*	0.5 (2)	irrigation, scouting, thinning, weeding (immature)	100	4
		irrigation, scouting, weeding (mature)	1,500	15
		hand harvesting (beans only)	2,500	17
Sugar beets *(30)*	0.5 (1)	irrigation, scouting, thinning, weeding (immature)	100	23
		irrigation, scouting, weeding (mature)	1,500	59
Broccoli, broccoli raab, and cauliflower *(7)*, Brussels sprouts *(10)*	0.5 (2-3)	irrigation, scouting, thinning, weeding (immature)	2,000	5
		scouting (mature)	4,000	7
		harvesting, irrigation, pruning, topping, tying (mature)	5,000	8
Cabbage *(7)*	0.75 (3)	irrigation, scouting, thinning, weeding (immature)	2,000	6
		scouting (mature)	4,000	8
		harvesting, irrigation, pruning, topping, tying (mature)	5,000	9

Crop *(PHI)*	lbs ai/A per app. (# apps/ season)	Activity	TC ($\mu g/cm^2$)	Day[1] MOE=100
Citrus: grapefruit, lemon, and orange trees *(7)* *MOEs based on foliar application*	0.375(2)	irrigation, scouting, weeding	1,000	11
		pruning, harvesting	3,000	16
Corn (sweet) *(7 for 1 app., 21 for 2 apps.)* and sorghum *(45 for grain, 21 for grazing or cutting for forage)*	0.5(2)	scouting, weeding (immature)	100	4
		scouting, weeding (mature)	400	10
		irrigation, scouting, weeding (mature/full foliage)	1,000	14
		hand harvesting, detasseling	17,000	26
Cotton *(14)*	0.5(1)	irrigation, scouting, weeding (immature)	100	0
		irrigation, scouting, weeding, (mature)	1,500	6
		hand harvesting	2,500	7
Cucumbers and summer squash *(3)*, pumpkins, winter squash and melons *(14)*, watermelons *(7)*	0.5(1)	irrigation, scouting, thinning, weeding (immature)	500	11
		irrigation, scouting, weeding (mature)	1,500	15
		harvesting, pruning, pulling, leaf thinning, turning	2,500	17
Filberts *(116)* (mechanical shaking and windrowing not addressed)	0.5(1)	irrigation, scouting, weeding	500	11
		harvesting/ poling, pruning	2,500	17
Non-bearing fruit trees: apple, apricot, cherry, nectarine, peach, plum/prune, and quince	0.375(2)	propping	100	1
		irrigation, scouting, weeding	1,000	11
		pruning, training, tying	3,000	16
Grapes (non-bearing)	0.375(2)	hedging, irrigation, scouting, weeding	500	8
		scouting	1,000	11
		leaf pulling, pruning, training/tying	5,000	18

Crop *(PHI)*	lbs ai/A per app. (# apps/ season)	Activity	TC ($\mu g/cm^2$)	Day[1] MOE=100
		girdling, cane turning	10,000	21
Lettuce, head (*PHI is 21, except in AZ (all crops) and CA (fall and winter crops), where the PHI is 28 days, and in CA (spring and summer crops) where the PHI is 14, 21, and 28 days after 1, 2, and 3 applications, respectively)*	0.5(3)	irrigation, scouting, thinning, weeding (immature)	500	11
		irrigation, scouting, weeding (mature)	1,500	15
		hand harvesting	2,500	17
Mint *(14)*	0.75(2)	irrigation, scouting, thinning, weeding (immature)	100	7
		irrigation, scouting, weeding (mature)	1,500	19
Onions *(30)*	0.5(2)	irrigation, scouting, weeding, thinning (immature)	300	8
		hand harvesting, thinning (mature)	2,500	17
Strawberries (pre-bloom and post harvest)	0.5 (2)	irrigation, scouting, weeding, pruning, mulching	400	10
		hand pruning, training	1,500	15
Walnuts *(30)* (mechanical shaking and windrowing not addressed)	0.375(1)	irrigation, scouting, weeding	500	8
		harvesting/ poling, pruning	2,500	15
Flowers, cut and dried	0.375(2)	irrigation, scouting, thinning, weeding (immature)	2,500	15
		irrigation, scouting, weeding (mature)	4,000	17
		harvesting, pruning, thinning, pinching	7,000	19
Nursery stock, field grown	0.5(2)	hand pruning containerized ornamentals	100	4
		harvesting ball/burlapped/containerized ornamentals	400	10

Crop *(PHI)*	lbs ai/A per app. (# apps/ season)	Activity	TC ($\mu g/cm^2$)	Day[1] MOE=100
Bulbs, ornamental field grown	0.5(2)	irrigation, scouting, thinning, weeding (immature)	2,500	17
		irrigation, scouting, weeding (mature)	4,000	19
Christmas trees	0.5(2)	irrigation, scouting, weeding, thinning	1,000	14
		pruning, harvesting, staking, topping, training	3,000	18

[1] Number of days after application when the MOE reaches 100.

6. Incident Data

In an effort to further characterize the actual risk to workers from ODM use, EPA has consulted the available data bases on exposure and poisoning incidents. These include the OPP Incident Data System (IDS), Poison Control Center data, California Department of Pesticide Regulation data, and information from the National Pesticide Information Center (formerly know as the National Pesticide Communications Network (NPTN)). For a more complete discussion of human poisoning incidents, see the memo entitled, "Review of Oxydemeton Methyl Incident Reports" dated September 26, 1997, available in the public docket and on the Internet.

The IDS had 6 incidents between 1991 and 1996. All involved groups of workers who were exposed through drift or by accidental early re-entry to treated fields. Symptoms included those typical of OP poisoning, nausea, dizziness, vomiting, and headaches. Of the six, four involved ODM in combination with other pesticides. ODM was not among the top 200 chemicals for which NPTN received calls for the period 1984-1991.

ODM was among the 28 chemicals for which Poison Control Center data were required. EPA's analysis of these 28 involved rankings on 3 separate measures: number and percent requiring hospitalization, treatment, or displaying life-threatening symptoms; California data comparing the number of incidents to reported applications; and ratios of poisonings and hospitalizations to estimated pounds used in agriculture. There were a total of 505 incidents in the PCC data base, however only 34 cases were attributable to occupational exposure. Exposure to ODM is less likely to require medical care or result in symptoms than exposure to other ChE inhibiting compounds. Likelihood of symptoms in occupational cases is difficult to judge due to the relatively low number of exposures. In California, where most ODM is used, poisoning incidents involving ODM as the primary cause of poisoning are relatively infrequent–one to two per year. The ratios of poisonings per 1,000 applications for both handlers and field workers is only about 1/4 of the median for the reported insecticides in California. Of the 20 exposure cases reported in California between 1982-1994, 13 reported systemic illnesses such as headache, nausea, blurred vision, etc. Exposures resulted from a variety of activities including applying,

mixing, loading and off-target drift.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the "Current EFED RED Chapter for ODM," dated September 10, 1999, available in the public docket. Several revisions have been made since the preliminary risk assessment was completed. These revisions are summarized in two documents, "Addendum to ODM Re-registration Eligibility Document Chapter," dated June 8, 2001, and "Response to Ecological Risk (EcoR) Committee Concerning ODM Interim Re-registration Elgibility Document Chapter," dated March 21, 2002.

1. Environmental Fate and Transport

The environmental fate database for parent ODM is essentially complete for the uses on current end-use products, which are minor crops in dry areas. However, some additional uses are being reinstated (citrus, onions, safflower and sorghum) that could expand the geographic extent of ODM use. In addition, uncertainty remains with respect to the persistence under aerobic aquatic conditions of two toxic metabolites of ODM, ODM sulfone and ODM sulfide.

The routes of dissipation of parent ODM include microbially-mediated metabolism in both aerobic and anaerobic environments, and hydrolysis at high pH values. This is supported by the short half-lives observed in the aerobic soil metabolism, anaerobic aquatic metabolism, and hydrolysis studies ($t_{1/2}$ = 3.2 , $t_{1/2}$ = 3.5, and $t_{1/2}$ = 2.5 days at pH 9, respectively). Volatility is not a significant route of dissipation, based on the Henry's Law Constant of 1.5 x 10^{-11} Atm m^3/Mol measured in volatility studies. Similarly, photodegradation in water or on soil is not an important route of dissipation, with calculated half-lives of 137 days in water and 63 days in soil.

ODM quickly degrades to form two types of metabolites in laboratory studies: toxic and non-toxic. Of these, some are persistent, and others are non-persistent. The metabolites of potential concern for ecological risk are those which are both toxic and persistent.

Under laboratory conditions, ODM forms five non-toxic metabolites. Through aerobic soil metabolism, parent ODM degrades to four non-toxic degradates: ODM thiol (2-(ethylsulfinyl) ethane sulfonic acid), 2-(ethylsulfonyl) ethane sulfonic acid, desmethyl ODM, and desmethyl ODM sulfone. The first two metabolites are believed to be persistent and the latter two are not persistent. Through anaerobic aquatic metabolism, parent ODM degrades to one non-toxic, persistant degradate: EMSME (1-(ethylsulfinyl)-2-(methylsulfinyl)ethane).

In addition to these non-toxic degradates, ODM forms two toxic degradates: ODM sulfone and ODM sulfide (MSI). Both toxic degradates are cholinesterase inhibitors. ODM sulfone is a product of aerobic soil metabolism, and it is uncertain whether this persistent metabolite will also form and persist in water. ODM sulfide is a metabolite of anaerobic aquatic metabolism. Although ODM sulfide was previously reported as unstable ($t_{½}$ = 9 days) based on

first order kinetics, EFED believes that a more realistic estimate of the chemical's persistence should be based on second order (biphasic) kinetics and that ODM sulfide should be considered persistent in water, at least under anaerobic conditions.

2. Water resource assessment

ODM and its non-persistent metabolites are not likely to be found in ground or surface water because of their relatively short half lives. Because of limited environmental fate data for the metabolites, parent ODM was used as a surrogate for modeling the non-persistent metabolites. This is a reasonable approach since the non-persistent metabolites exhibit similar fate and transport properties as parent ODM. However, modeling estimates are not representative of the five persistent metabolites of ODM, ODM-thiol, 2-(ethylsulfonyl) ethane sulfonic acid, EMSME, ODM sulfone and ODM sulfide. These persistent metabolites are believed to be mobile and could reach both ground and surface water. Since the first three persistent degradates are non-toxic, their potential presence in water is not of concern. The Agency is requiring data on the persistence under aerobic aquatic conditions of both toxic metabolites, ODM sulfone and ODM sulfide. If these metabolites are found to persist in water, the drinking water and aquatic ecological assessments may need to be revised.

a. Surface Water

Monitoring data for ODM are available but limited. The STORET database contains data from 1984-1997 from wells and surface water in California (2 samples) and in New Mexico (94 samples). All samples were either below detection limits or between the detection limits and quantitation limit, with a detection limit range of 0.090-0.5 ppb. It was not possible to determine if the samples were all from agricultural areas where ODM is used. There are no USGS NAWQA data available for ODM residues in surface water. A search of the California Department of Pesticide Regulation surface water database found no additional information for ODM in California.

Because of the lack of adequate surface water monitoring data, PRZM 3.12 and EXAMS 2.975 models were used to estimate surface water concentrations. Modeled EECs in surface water for ODM were used in both the ecological risk assessment and the human health assessment. The 1 in 10 year peak surface water EECs ranged from 2.1 (based on 2 applications of 0.5 lbs ai/A to alfalfa, in OR) to 12.4 ug/L (based on 3 applications of 0.5 lb ai/A to sweet corn, in GA) and the chronic EECs ranged from 0.2 (alfalfa in OR or 3 applications of 0.5 lbs ai/A to cotton in CA) to 0.9 ug/L (sweet corn, in GA). The registrant has agreed to limit the use on sweet corn to 2 applications of 0.5 lbs a.i./A and to restrict this use to west of the Rocky Mountains. The next highest EECs in surface water were 11 ug/L (acute) and 0.7 ug/L (chronic), based on 3 applications of 0.5 lbs a.i. to sorghum in Kansas.

b. Ground Water

Monitoring of ODM in ground water is available but limited. In all ground water

samples taken, there were no detections of ODM residues. No monitoring data are currently available from the USGS for ODM in ground water. Since the ground water monitoring data for ODM are limited, a ground water screening model was used to estimate the potential concentrations of ODM and its non-persistent metabolites.

The SCI-GROW model was used to estimate the potential leaching of ODM and its non-persistent metabolites into ground water. SCI-GROW predicted that an upper bound concentration of 0.006 ppb of parent ODM would reach shallow ground water. A 2.25 lbs ai/A/yr (3 applications of 0.75 lbs ai/A) application to cabbage was modeled. Other model inputs include a 3.2 day aerobic soil half-life and a K_{oc} of 122 ml/g.

3. Toxicity (Hazard) Assessment

a. Toxicity to Terrestrial Organisms (Birds and Mammals)

ODM is generally highly toxic to avian species on an acute oral exposure basis, with LD_{50} values ranging from 7 mg/kg (very highly toxic) to 60 mg/kg (moderately toxic). Results for the two required subacute (5 day) dietary exposure studies in birds were very different from one another, with one study resulting in an LC_{50} of 217 ppb (highly toxic) for the bobwhite quail, and the other resulting in an LC_{50} of >2500 (slightly toxic to practically non-toxic) for the mallard duck. Ducks are more selective feeders than are quail, and the apparent lack of sensitivity of ducks to ODM-treated feed may have resulted from their avoidance of treated feed, rather than a lack of toxicity.

Table 12. Acute Oral Toxicity to Birds: Single Dose by Gavage

Species	LD_{50} (mg/kg)	Toxicity Category
Northern bobwhite quail *(Colinus virginianus)* (MRID 00060636)	17	Highly toxic
Mallard duck *(Anas platyrhynchos)* (MRID 00160000)	27	Highly toxic
Japanese quail (MRID 00160000)	42	Highly toxic
California quail (MRID 00160000)	24	Highly toxic
Pheasant (MRID 00160000)	21	Highly toxic
Chukar (MRID 00160000)	60	Moderately toxic
Rock Dove (MRID 00160000)	7	Very Highly toxic
House sparrow (MRID 00160000)	35	Highly toxic

Table 13. Subacute Oral Toxicity to Birds[1]: Five Days of Treated Feed

Species	LC_{50} (mg/kg)	Toxicity Category
Northern bobwhite quail *(Colinus virginianus)* (MRID 00022923)	217	Highly toxic
Mallard duck *(Anas platyrhynchos)* (MRID 00022923)	>2500	Slightly toxic to practically nontoxic
[1] Test organisms observed an additional three days while eating untreated feed.		

Chronic effects to birds measured in avian reproduction studies included a reduction in the weight of bobwhite quail offspring (14 day survivors). This effect was observed at and above a LOAEC of 7 ppm. At the higher dose of 17 ppm, effects included a reduction in the number of viable embryos and live 3-week embryos per hen. In a similar mallard duck study, no treatment-related reproductive effects were observed. At the chronic LOAEC of 54 ppm, reduced food consumption was observed.

Table 14. Chronic Oral Toxicity to Birds

Species/ Study Duration	NOAEC (ppm a.i.)	LOAEC (ppm a.i.)	LOAEC Endpoints
Northern bobwhite (Colinus virginianus) (MRID 40747202)	1.8	6.9	Reduced 14-day survivor weight. At 17 ppm, effects included a reduction in the number of viable embryos and live 3-week embryos per hen
Mallard duck (Anas platyrhynchos) (MRID 40747201)	17	54	Reduced food consumption

Wild mammal testing is not required for ODM. Rat toxicity values obtained from the Health Effects Assessment are used to estimate toxicity to wild mammals. In an acute oral toxicity study in the rat (MRID 40779801), the LD_{50} values were 48 mg/kg for females and 61 mg/kg for males. Based on this study, ODM is moderately to highly toxic to mammals on an acute basis. In a 2-generation rat reproduction study (MRID 41461901), ODM produced decreases in male and female fertility and parental systemic toxicity at a LOEC of 50 ppm (parental NOEC = 9 ppm).

ODM is moderately to highly toxic to honeybees based on the results of two honeybee acute contact studies (MRID 00036935 and MRID 05001991). Honeybee larvae are also susceptible (MRID 00074486). Toxicity to adult honeybees from contact with foliar residues of ODM appears to be short lived, with low toxicity observed 3 hours after application (MRID 00060628).

b. Toxicity to Aquatic Organisms

Technical ODM ranges from moderately to highly toxic to freshwater fish on an acute basis, with 96-hour LC50s of 0.7 and 1.2 ppm. The formulated product (25-50% a.i.) is slightly to moderately toxic to freshwater fish, with 96-hour LC50s ranging from 1.9 to 26 ppm.

Table 15. Acute (96-hour) Oral Toxicity to Freshwater Fish

Species	Test material (%a.i.)	96-hour LC_{50} (ppm)	Toxicity Category
Rainbow trout *(Oncorhynchus mykiss)* (MRID STOOXY01)	98	0.7	Highly toxic
Bluegill sunfish *(Lepomis macrochirus*) (MRID STOOXY02)	98	1.2	Moderately toxic
Rainbow trout *(Oncorhynchus mykiss)* (MRID 00074349)	25	23	Slightly toxic
Rainbow trout *(Oncorhynchus mykiss)* (MRID 00003503)	50	6.4	Moderately toxic
Bluegill sunfish *(Lepomis macrochirus)* (MRID 00003503)	50	13	Slightly toxic
Bluegill sunfish *(Lepomis macrochirus)* (MIRID 00060639)	50	1.9	Moderately toxic
Bluegill sunfish *(Lepomis macrochirus)* (MRID 00074349)	25	26	Slightly toxic

Chronic effects in freshwater fish (rainbow trout, MRID 41054501) were observed at 4.9 ppm and included reduced fry survival and growth. The acute LC_{50} for rainbow trout (0.7 ppm) was lower than the chronic NOAEC (2.6 ppm) from this study, probably due to a difference in the size or age of individuals tested in the acute and chronic studies.

On an acute basis, technical ODM is highly to very highly toxic to freshwater invertebrates (48-hour LC_{50}s ranged from 0.2 to 1.1 ppm), and the formulation intermediate (50% a.i.) is very highly toxic to freshwater invertebrates (48-hour LC_{50}s of 0.003 and 0.2 ppm). Chronic effects in *Daphnia magna* following 21 days of exposure to technical ODM (MRID 40986601) included reduced adult mean length, reduced adult survival, and reduced numbers of young per adult per day at a LOAEC of 0.046 ppm.

No data are currently available to assess the acute or chronic toxicity of ODM to estuarine and marine fish. Similarly, no data are available to assess the toxicity of the active ingredient to estuarine and marine invertebrates. Data are available on the toxicity of the formulated product (25% a.i.), which show that the formulated product is moderately toxic to estuarine/marine shrimp and fiddler crabs on an acute basis, with 96-hour LC_{50}s of 1.2 ppm (shrimp) and 8.6 ppm (fiddler crabs).

Table 16. Acute (96-hour) Oral Toxicity to Estuarine/Marine Invertebrates

Species	Test material (%a.i.)	96-hour LC_{50} (ppm)	Toxicity Category
Pink shrimp (*Penaeus duorarum*) (MRID 00074348)	25	1.2	Moderately toxic
Fiddler crab (MRID 00074348)	25	8.6	Moderately toxic

c. Toxicity to Plants

Data on toxicity to terrestrial and aquatic plants are not required for ODM because it is not a herbicide and there is no evidence suggesting that it is phytotoxic.

4. Exposure and Risk Calculations

a. Levels of Concern

In assessing risk to non-target organisms, EPA compares the results of ecotoxicity and exposure data to evaluate the potential for adverse ecological effects. The Agency calculates risk quotients (RQs) by dividing exposure estimates by acute and chronic ecotoxicity values, where exposure is calculated as the estimated environmental concentration or EEC:

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider mitigation. An RQ that is greater than the LOC indicates that a pesticide used as directed has the potential to cause adverse effects to non-target organisms. Risk presumptions, along with the corresponding LOCs, are presented in the table below:

Table 17. Levels of Concern for Terrestrial and Aquatic Animals

Risk Presumption	LOC terrestrial animals	LOC aquatic animals
Acute High Risk: there is potential for acute risk	0.5	0.5
Acute Restricted Use: there is potential for acute risk, but this risk may be mitigated through restricted use classification	0.2	0.1
Acute Endangered Species: endangered species may be adversely affected	0.1	0.05
Chronic Risk: there is potential for chronic risk	1	1

b. Exposure and Risk to Non-target Terrestrial Organisms

(1) Avian Risk

Avian EECs, both acute and chronic, are estimated using the L-fate model based on Hoerger and Kenaga, 1972, as modified by Fletcher *et al*., 1994. Acute avian RQs are calculated by dividing the maximum Estimated Environmental Concentration (EEC) by the subacute bobwhite quail LC_{50} of 217 ppm:

$$\text{Acute RQ} = \frac{\text{Max. EEC (ppm)}}{LC_{50}\ (217\ \text{mg/kg diet})}$$

The acute risk (0.5), restricted use (0.2), and endangered species (0.1) LOCs are slightly exceeded for most application rates and feed items other than seeds (Table 18). Acute RQ values range from 0.03 (1 aerial application of 0.5 lbs ai/A to cotton, for residues on seeds) to 2.0 (3 aerial applications of 0.75 lbs ai/A to cotton or cabbage, for residues on shortgrass).

Table 18. Avian Acute Risk Quotients

Site/App. Method	App. Rate (No. of Apps.)/ Appl interval	Food Items	Max. EEC (ppm)	Acute RQ (EEC/LC_{50})
Cabbage and cotton/ aerial	0.75 lbs ai/A (3)/7 days	Shortgrass	473	2.2
		Tallgrass	217	1.0
		Broadleaf plants/ Insects	266	1.2
		Seeds	30	0.1
Corn and sorghum/ aerial	0.5 lbs ai/A (3)/7 days	Shortgrass	224	1.0
		Tallgrass	103	0.5
		Broadleaf plants/ Insects	126	0.6
		Seeds	14	0.06
Alfalfa/aerial	0.5 lbs ai/A (2)/14 days	Shortgrass	211	1.0
		Tallgrass	97	0.5
		Broadleaf plants/ Insects	119	0.6
		Seeds	13	0.06

Site/App. Method	App. Rate (No. of Apps.)/ Appl interval	Food Items	Max. EEC (ppm)	Acute RQ (EEC/LC_{50})
Citrus/air blast	0.375 lbs ai/A (2)/14 days	Shortgrass	158	0.7
		Tallgrass	73	0.3
		Broadleaf plants/ Insects	89	0.4
		Seeds	10	0.05
Cotton/aerial	0.5 lbs ai/A (1)	Shortgrass	120	0.6
		Tallgrass	55	0.3
		Broadleaf plants/ Insects	68	0.3
		Seeds	8	0.03

Chronic avian RQs are calculated by dividing the 56-day average EEC by the bobwhite quail chronic NOEC of 1.8 mg/kg:

$$\text{Chronic RQ} = \frac{\text{56-day average EEC}}{\text{NOEC (1.8 mg/kg diet)}}$$

The avian chronic LOC of 1 is exceeded for all feed items (Table 19). Chronic RQ values range from 3 (1 aerial application of 0.5 lbs ai/A to cotton, for residues on seeds) to 168 (3 aerial applications of 0.75 lbs ai/A to cotton or cabbage, for residues on shortgrass).

Table 19. Avian Chronic Risk Quotients

Site/ App. Method	App. Rate in lbs ai/A (No. of Apps.)/ App. interval	Food Items	56-day EEC (ppm)	Chronic RQ (EEC/NOEC)
Cabbage and cotton/ aerial	0.75 (3)/7 days	Short grass	304	168
		Tall grass	140	78
		Broadleaf plants/ Insects	172	96
		Seeds	19	11
Corn and sorghum/ aerial	0.5 (3)/7 days	Short grass	141	78
		Tall grass	65	36

Site/ App. Method	App. Rate in lbs ai/A (No. of Apps.)/ App. interval	Food Items	56-day EEC (ppm)	Chronic RQ (EEC/NOEC)
		Broadleaf plants/ Insects	79	44
		Seeds	9	5
Alfalfa/ aerial	0.5 (2)/14 days	Short grass	135	75
		Tall grass	62	34
		Broadleaf plants/ Insects	75	42
		Seeds	8	4
Citrus/ air blast	0.375 (2)/14 days	Short grass	101	56
		Tall grass	46	26
		Broadleaf plants/ Insects	57	32
		Seeds	6	3
Cotton/aerial	0.5 (1)	Short grass	73	41
		Tall grass	34	19
		Broadleaf plants/ Insects	41	23
		Seeds	5	3

(2) Mammalian Risk

Mammalian EECs, both acute and chronic, are estimated using the L-fate model based on Hoerger and Kenaga, 1972, as modified by Fletcher *et al*., 1994. The concentration of ODM in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the rat acute LD_{50} value (48 mg/kg) by the % body weight of food consumed:

$$LC_{50} = \frac{LD_{50}\ (48\ mg/kg)}{\%\ body\ weight\ consumed}$$

LC_{50}s are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, broadleaf plants and small insects, large insects, and seeds). The % body weight consumed is assumed to be 95% for 15-g animals feeding on short grass, broadleaf plants, and insects, 66% for 35-gram animals feeding on short

grass, broadleaf plants, and insects, and 15% for 1,000-g mammals feeding on short grass, broadleaf plants, and insects. All seed-eating mammals are assumed to consume 3% of their body weight.

Acute RQ values are calculated by dividing the maximum EECs by the derived LC_{50} value. Only the results for the most sensitive weight class, the 15-gram mammal, are shown in Table 20. The acute high risk (0.5), restricted use (0.2), and endangered species (0.1) LOCs are exceeded for most mammalian feed items other than seeds. The greatest exceedences are for 15g mammals feeding on short grass. Acute RQ values range from 0.03 (1 aerial application of 0.5 lbs ai/A to cotton, for residues on seeds) to 9.4 (3 aerial applications of 0.75 lbs ai/A to cotton or cabbage, for residues on shortgrass).

Table 20. Mammalian Acute Risk Quotients

Site/ App. method	App. Rate in lbs ai/A (No. of Apps.)/ App. interval	Food Items	Max. EEC (ppm)	Acute RQ (15 g)
Cabbage and cotton/aerial	0.75 (3) / 7 days	Short grass	473	9.4
		Broadleaf plants and small insects	266	4.3
		Large insects	30	5.3
		Seeds	30	0.1
Corn and sorghum /aerial	0.5 (2) / 7 days	Short grass	224	4.4
		Broadleaf plants and small insects	126	2.0
		Large insects	14	2.5
		Seeds	14	0.06
Alfalfa/aerial	0.5 (2) / 14 days	Short grass	211	4.2
		Broadleaf plants and small insects	119	1.9
		Large insects	13	2.4
		Seeds	13	0.06
Citrus/airblast	0.375 (2) / 14 days	Short grass	158	3.1
		Broadleaf plants and small insects	89	1.4
		Large insects	10	1.8
		Seeds	10	0.04
Cotton/aerial	0.5 (1)	Short grass	120	2.4
		Broadleaf plants and small insects	68	1.1
		Large insects	8	1.3
		Seeds	8	0.03

Chronic mammalian RQs are calculated by dividing the 56-day EECs by the chronic rat NOEC of 9 mg/kg from the 2-generation rat study (MRID 41461901). As for acute risk, the chronic RQs are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (short grass, tall grass, broadleaf plants

and small insects, and seeds). Only the results for the most sensitive weight class, the 15-gram mammal, are shown in Table 21. The chronic LOC of 1 is exceeded for most application rates and food items other than low-end application rates on seeds. Chronic RQs range from 0.6 (1 aerial application of 0.5 lbs ai/A to cotton, for residues on seeds) to 34 (3 aerial applications of 0.75 lbs ai/A to cotton or cabbage, for residues on shortgrass).

Table 21. Mammalian Chronic Risk Quotients

Site/ App. Method	App. Rate in lbs ai/A (No. of Apps.)/ App. interval	Food Items	56-day EEC (ppm)	Chronic RQ (15 g)
Cabbage and cotton/aerial	0.75 (3)/7 days	Short grass	304	34
		Tall grass	140	16
		Broadleaf plants/ Insects	172	19
		Seeds	19	2.1
Corn and sorghum/ aerial	0.5 (3)/7 days	Short grass	141	16
		Tall grass	65	7.2
		Broadleaf plants/ Insects	79	8.8
		Seeds	9	1.0
Alfalfa/ aerial	0.5 (2)/14 days	Short grass	135	15
		Tall grass	62	6.9
		Broadleaf plants/ Insects	75	8.3
		Seeds	8	0.9
Citrus/ air blast	0.375 (2)/14 days	Short grass	101	11
		Tall grass	46	5.1
		Broadleaf plants/ Insects	57	6.3
		Seeds	6	0.7
Cotton/aerial	0.5 (1)	Short grass	73	8.1
		Tall grass	34	3.8
		Broadleaf plants/ Insects	41	4.6
		Seeds	5	0.6

(3) Risk to Non-target Insects

Currently, the Agency does not conduct quantitative risk assessments for non-target insects. Because ODM is highly toxic to bees, risk to non-target insects is presumed. However, the toxicity to bees from foliar residues of ODM appears to be short-lived, with risks decreasing substantially a few hours after application.

c. Exposure and Risk to Non-target Aquatic Organisms

Freshwater EECs are presented in section III.B.2.a. of this document. To calculate acute risk to fish and invertebrates, the maximum 1 in 10 year peak surface water EEC of 11 ppb was used (based on modeling surface water concentrations following 3 applications of 0.5 lb ai/A to grain sorghum, in Kansas). To calculate chronic risk, the 60-day (fish) and 21-day (invertebrates) EECs were used. Aquatic RQ values are calculated by dividing the appropriate EEC by the species-specific LC_{50} value (for acute risk) or the species-specific NOAEC (for chronic risk).

For freshwater fish and invertebrates, no acute or chronic concern levels are exceeded based on toxicity studies using technical ODM or (where toxicity studies are available) the formulated end-use products. The one exception is for a study using the formulation intermediate (50% a.i.), in which the EC_{50} for water fleas (*Daphnia magna*) was 0.0033 mg/L. Using this most sensitive endpoint, calculated acute RQs for freshwater invertebrates would range from 0.6 to 2, exceeding the LOCs for acute high risk (0.5), acute restricted use (0.1), and acute endangered species (0.05).

There are no data available to assess the toxicity and exposure of marine/estuarine fish and invertebrates from technical ODM and its metabolites.

d. Exposure and Risk to Nontarget Plants

A risk assessment was not conducted for non-target plants because ODM is an insecticide and there is no indication that it is phytotoxic. Risk to non-target plants is assumed to be minimal.

5. Endocrine Disruption

Exposure to ODM results in reproductive effects in nontarget animals. In mammalian studies, dietary exposure of rats to ODM reduced the ratio of the number of pregnant females to the number of females mated (fertility index), reduced the ratio of the number of pups alive after 5 days to the number of pups born (viability index), reduced ovarian and testicular weights, and increased the length of estrous cycles. Histological changes in reproductive organs included increased incidence of epididymal vacuolation in corpus epididymis of males and decreased number of corpora lutea in the ovaries of females. Additionally, in avian reproduction studies,

dietary exposure to technical grade ODM resulted in increased numbers of eggs laid per hen and reduced 14-day survivor weight. In chronic studies of freshwater invertebrates, technical grade ODM had a significant effect on the number of young produced per adult.

Although there is insufficient evidence from mammalian studies to support classifying ODM as an endocrine disruptor in humans, the endocrine disrupting potential of ODM in other species is uncertain. To assess endocrine disrupting potential in humans, the Agency relies on a weight-of-evidence approach. To assess endocrine disrupting potential in wildlife, the Agency relies on specific effects as triggers. Following exposure to ODM, observed effects included reduced number of young in mammals, birds and aquatic animals, reduced testicular and ovarian weights in mammals, and increased length of estrous cycles. Although it is not known whether the reproductive effects observed in ODM-treated animals result from changes in endocrine-mediated pathways, these reproductive effects raise the concern that ODM may disrupt endocrine function in wildlife.

6. Ecological Incidents

A single 6(a)2 ecological incident has been reported for ODM. In 1997 the California Department of Fish and Game reported that four California quail were found dead in a farm yard adjacent to a broccoli field; broccoli leaves were found in the croup of the affected birds and ODM (Metasystox R) and methamidophos (Monitor) residues were detected on the leaves. It is unclear whether the birds died from the combined effect of the two organophosphate pesticides; however, methamidophos has a subacute dietary LC_{50} (range: 42 - 47 ppm) for quail and while ODM has a subacute dietary LC_{50} (range: 434 - 1309 ppm) that is roughly a order of magnitude less toxic to quail.

7. Endangered Species

Endangered species LOCs for ODM are exceeded for acute risks to birds and mammals for all application rates and feed items except for expected residues on seeds from rates less than 0.75 lbs ai/A. The LOCs for chronic risks to endangered birds for all feed items are exceeded for all rates, and those for chronic risks to mammals are exceeded for all items other than seeds at rates applied more than twice per season. Since ODM is an insecticide, it is assumed that endangered terrestrial invertebrates, including insects, are potentially at risk. No data are available to assess risks to marine/estuarine fish from exposure to technical ODM and its metabolites.

ODM was included in the reinitiated Biological Opinion of 1989 from the US Fish and Wildlife Service for its use on several field crops and in forestry for use on douglas fir. In this opinion, the Service found jeopardy to one amphibian species, the Wyoming toad, and four species of freshwater fish. Reasonable and Prudent Alternatives were given for each jeopardized species. Reasonable and Prudent Measures were also given for 28 non-jeopardized species to minimize incidental take of these species. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment

procedures and an older approach to consultation which is currently being revised through interagency collaboration.

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

The Agency is currently engaged in a Proactive Conservation Review with USFWS 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 ODM 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 which address ODM, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to ODM at levels of concern.

8. Risk Characterization

Based on available pesticide survey usage information for the years of 1987 through 1997, approximately 145,000 to 186,000 pounds a.i. of ODM is used to treat 213,000 to 283,000 acres each year (U.S. annual average). Most of the acreage is treated with 1 pound a.i. or less per application per year. Based on a weighted 10-year average, the major use sites of ODM in terms of acres treated, lbs used, and percent crop treated (%CT) are broccoli (66,000 acres, 46,000 lbs, 62% CT), cotton (40,000 acres, 12,000 lbs, <1% CT), cauliflower (26,000 acres, 22,000 lbs, 46% CT), mint (20,000 acres, 16,000 lbs, 12% CT), alfalfa grown for seed (22,000 acres, 8,000 lbs, 11% CT), head lettuce (13,000 acres, 7,000 lbs, 5% CT), and sorghum (10,000 acres, 5,000 lbs, <1% CT). Most use is on vegetables and fruit in California. Use on mint is concentrated in Indiana and Idaho, and use on alfalfa in Indiana, Nevada, and Oregon. A summary of the RQ values for ODM is presented in Table 22.

Table 22. Summary of Risk Quotients for ODM

Organism	Acute risk quotients	Chronic risk quotients
Birds	0.03 - 2.0	3 - 168
Mammals (15 g)	0.03 - 9.4	0.6 - 34
Insects	no RQs calculated, but risk is presumed	no RQs calculated, but risk is unlikely
Freshwater fish	<0.05	<1
Freshwater invertebrates	<0.05[1]	<1
Estuarine/marine fish and invertebrates	no data	no data

[1]If calculated using the EC_{50} for *Daphnia magna* from a study using the formulation intermediate (50% a.i.), RQs for freshwater invertebrates would range from 0.6 to 2.1.

Although relative to other organophosphate pesticides, the terrestrial and aquatic RQ values for ODM are low, these RQ values should not be viewed as conservative since they were based on estimated environmental concentrations that do not reflect the contribution of persistent toxic degradates (such as ODM sulfone) to total toxic residues. Furthermore, ODM dose response curves for avian and aquatic species are relatively steep (slopes of 8 to 9), which means that minor increases in exposure can result in marked increases in the percentage of organisms affected. In addition, ODM has been shown to produce reproductive effects in non-target organisms and may disrupt endocrine function in wildlife.

a. Risk to Terrestrial Organisms

Both acute and chronic LOCs are exceeded for birds and mammals exposed to ODM. The highest RQs are associated with chronic exposures. Since no data were available with which to calculate the dissipation rate for total foliar residues in avian and mammalian food items, chronic terrestrial RQs were calculated using a default foliar dissipation rate of 35 days. For the purposes of comparison, chronic terrestrial RQs were also calculated using measured foliar residue data from a limited number of ecologically relevant dietary field residue studies. Maximum detected ODM residues on clover hay 7 and 14 days after application were 25 mg/kg and 10 mg/kg, respectively (MRID 411467-01). Estimates of maximum total foliar residues on alfalfa hay 21-days after application averaged 5.1 mg/kg (MRID 411467-05). Chronic RQ values based on 7, 14 and 21-day measured total foliar residues are 14, 5.5, and 2.8, respectively, for avian species and 2.7, 1.1, and 0.6, respectively, for mammalian species. Although model estimates for 56-day exposure values are considerably higher than measured foliar residues, use of either value (model or measured) results in RQs that exceed chronic levels of concern.

Based on a weighted 10-year average (1987-1997), approximately 12,000 lbs of ODM are use to treat 40,000 acres of cotton in the U.S. each year. Birds and mammals seeking cover and feeding on contaminated food in southwestern cotton fields may be at risk from exposure to ODM. Birds are known to make use of cotton fields for food and cover. Field studies conducted in cotton fields in Arizona (Dicrotophos IRED) concluded that birds were "diverse and had high species richness and abundance" in the test fields. Passarines (songbirds) were the most common type of bird using cotton fields in both studies. Quail and doves were also fairly common in cotton fields in Arizona. More birds are likely attracted to cotton fields in the Southwest because the irrigated fields provide dense vegetative cover that is scarce elsewhere in the desert environment. In addition, cotton fields in the Southwest frequently occur along rivers and their associated riparian habitats are favored by birds.

Overall, songbirds and quail are likely to be the most frequently exposed birds in cotton treated with ODM. The risk assessment indicates that many songbirds are highly vulnerable to acute poisoning by ODM due to their small size and insectivorous feeding habit. The risk assessment indicates that adult quail are somewhat less vulnerable but still at risk of acute poisoning. The vulnerability of young quail, which are mostly insectivorous, is likely to be similar to that of songbirds. The field studies confirm that use of ODM on cotton is likely to result in mortality to both quail and songbirds.

b. Risk to Aquatic Organisms

Although acute and chronic LOCs are not exceeded for freshwater fish and invertebrates, aquatic RQs do not reflect the potential contribution of toxic degradates. Parent ODM is highly mobile, but it degrades rapidly through aerobic soil metabolism ($t_{½}$ = 3.2 days) and is unlikely to reach surface waters. However, two toxic degradates of ODM have been shown to persist in aerobic soil (ODM sulfone) and anaerobic water (ODM sulfide). If these degradates prove to be persistent in aerobic water, then aquatic RQ values should be considered non-conservative and would not accurately reflect potential risks to aquatic organisms. Due to a lack of data, risks to estuarine/marine organisms from ODM or its toxic degradates are unknown.

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 ODM active ingredients.

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

Although the Agency has not yet considered cumulative risk 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 ODM.

Based on its current evaluation of ODM alone, the Agency has determined that ODM 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 ODM.

At the time that a cumulative assessment is cosidered, the Agency will address any outstanding risk concerns. For ODM, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for ODM after considering 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 reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet considered the cumulative risks for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing ODM food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered cumulative risk, ODM tolerances will be reassessed in that light. At that time, the Agency will reassess ODM along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical ODM, 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 other assessments 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.

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. As stated previously, a mitigation proposal was received from Gowan Company; details of this proposal are discussed in the next section. Several other comments on mitigation were also received from: the Northwest Alfalfa Seed Growers Association; California Rural Legal Assistance Foundation; and Natural Resources Defense Council (NRDC). These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Comment. The Northwest Alfalfa Seed Growers Association commented that ODM is a very important tool in controlling the lygus bug and aphids. ODM is used extensively with IPM programs to protect pollinators and beneficial insects. There are no comparable alternatives that are effective against the lygus bug and also are not harmful to leafcutter bees. Although ODM is toxic to insects, it is not hazardous to leafcutter bees and other beneficials, because ODM is applied at night, and degrades rapidly.

Response. This comment provided no specific mitigation suggestions. It did, however, provide valuable use and usage data, some of which had already been used to update the risk assessments.

Comment. The California Rural Legal Assistance Foundation commented that the calculated REIs of 5 - 59 days may not be adequate because they do not account for concurrent exposure to residues of other ChEI organophosphates and n-methyl carbamates. The assumed body weight of 70 kg is too high for women workers, and the assumption of an 8 hour day is also unrealistic due to the long days that are expected of workers during peak periods. REIs must be set to

provide an adequate margin of safety for workers, even if it conflicts with minimizing the inconvenience to the manufacturer and current users. In addition, reentry workers will not wear protective gear if it slows down work and decreases their rate of compensation. The additional safety factor for infants and children should not have been removed.

Response. The "no unreasonable adverse effects on the environment" standard of FIFRA includes consideration of occupational and ecological risks, as well as the economic, social, and environmental costs and benefits of the pesticide's use. REIs have been determined considering both risks and benefits. Regarding protective gear being required for reentry workers, EPA typically does not require PPE for reentry workers to protect them from pesticide residues due to evidence that it is impractical, and the concern that heat-stress may actually increase the risk of injury. Finally, the FQPA Safety Factor was removed because sufficient additional data were available to address concerns relating to genotoxic effects. For a full discussion of the FQPA safety factor evaluation, refer to section III.A.1.c. of this document.

The Natural Resources Defense Council (NRDC) also provided general comments on the organophosphates. The Agency has prepared a formal response to the general comments received from NRDC. Those comments and responses are available in the public docket.

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 is currently evaluating the cumulative risk posed by the entire class of organophosphates.

EPA has determined that risk from exposure to ODM is within its own "risk cup." In other words, if ODM did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for ODM (including those proposed and revised in the following section) meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water (residential risk was not included since none of the uses being supported for registration are expected to result in non-occupational risk). Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to ODM "fit" within the individual risk cup. Therefore, the ODM tolerances remain in effect and

unchanged until the cumulative risk from all organophosphates is considered.

b. Tolerance Summary

Based on the available plant and animal metabolism data, EPA has determined that plant and animal commodity tolerances should be separated because they differ in terms of residues of concern. Tolerances should be recodified for plant commodities from 40 CFR 180.330(a) to (a)(1) and animal commodities from 180.330(a) to (a)(2).

EPA has determined that tolerance expression in 40 CFR 180.330(a)(1) should reflect that only residues of oxydemeton-methyl (ODM) and its metabolite oxydemeton-methyl sulfone (ODMS) are of concern in plants. Therefore, the tolerance expression in 40 CFR (a)(1) will be amended as follows:

> Tolerances are established for the combined residues of the pesticide oxydemeton-methyl (S-[2-(ethylsulfinyl)-ethyl] O,O-dimethyl phosphorothioate) and its metabolite oxydemeton-methyl sulfone in or on the following raw agricultural commodities.

In September 1997, the Agency determined that preliminary *in vitro* cholinesterase data did not indicate cholinesterase inhibition for the ODMS metabolites in rat whole brain preparations. However, that preliminary Agency assessment is contingent on submission of an acceptable full report on the conditions, supporting data on optimization of the incubation times and time course of the determinations, submission of all the experimental data associated with the submission and the acceptability of that report. Therefore, a final assessment as whether to amend the tolerance expression for animal commodity tolerances to reflect residues of oxydemeton-methyl *per se* is not possible at this time. As a result, the tolerance expression in 40 CFR 180.330(a)(2) should continue to reflect residues of ODM and its cholinesterase-inhibiting metabolites; however, it should employ the term "combined residues." Therefore, the tolerance expression in 40 CFR (a)(2) will be revised as follows:

> Tolerances are established for the combined residues of the pesticide oxydemeton-methyl (S-[2-(ethylsulfinyl)-ethyl] O,O-dimethyl phosphorothioate) and its cholinesterase-inhibiting metabolites in or on the following raw agricultural commodities.

Because certain registered uses have product labels which prohibit harvest within one year of application, the Agency considers them to be nonfood uses of ODM. As a result, the tolerances in 40 CFR 180.330 for these nonfood uses are no longer needed and should be revoked for apple; grape; and plum, prune, fresh.

Because bean, lima, forage; clover, seed screenings; and sorghum milled fractions (except flour) are no longer significant animal feed items, the tolerances in 40 CFR 180.330 are no longer needed and should be revoked.

Although existing tolerances can only be considered reassessed upon consideration of the

cumulative risk assessment of all organophosphates, the Agency can commence proceedings to revoke or lower existing tolerances, and to correct commodity definitions. The raising of any tolerances and the establishment of new tolerances will be deferred pending the outcome of the cumulative assessment.

Adequate data are available to reassess the established tolerances for the following commodities: bean, lima; beet, sugar; beet, sugar, tops; broccoli; Brussels sprouts; cabbage; cauliflower; clover, forage; clover, hay, grown for seed; corn, forage; cotton, undelinted seed; cucumber; filbert; grapefruit; lemon; lettuce, head; melon; mint, hay; onion, dry bulb; orange, sweet; pumpkin; safflower, seed; sorghum, forage; sorghum, grain; squash, summer; squash, winter; strawberry; and walnut. Adequate data also are available to reassess the tolerances for milk and for the fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep.

Insufficient field trial data are available to reassess the tolerances for the following commodities: alfalfa, green; alfalfa, hay, grown for seed; corn, stover; and corn, fresh, kernal plus cob with husks removed. Tolerances listed as "to be determined" (TBD) in Table 24 cannot be determined at this time because additional data are required.

The registrant must propose a tolerance of 2 ppm for ODM residues of concern in/on broccoli raab. The tolerance petition should include all available residue data that are pertinent to the registered use. The proposed tolerance is based on the translation of data from broccoli and cabbage treated according to the maximum use pattern.

A tolerance also must be proposed for grain sorghum stover. In addition, as a result of changes in Table 1 (GLN 860.1000), a tolerance is now required for cotton gin byproducts. The appropriate tolerance levels for these commodities will be determined when adequate field trial data have been submitted and evaluated. Tolerances for residues of ODM at the quantification limit of the method (0.01 ppm) in eggs and in poultry fat, meat, and meat byproducts must be established. Proposed tolerance reassessments, proposed new tolerances, and corrected commodity definitions are presented in Table 24.

As a follow up to the voluntary cancellation of the field corn, popcorn, pear, snap bean, and turnip use sites, the Agency will propose revocation of the established tolerances for the unsupported uses of bean, snap, succulent; bean, snap, forage; corn, grain; pear; turnip; and turnip, greens.

The Agency will follow up with an FR of Receipt of Request for Voluntary Use Deletion for eggplant and pepper use sites. Although the registrant has requested use deletion such that no U.S. registrations will exist, the registrant has indicated support for eggplant and pepper tolerances for importation purposes.

Table 24. Tolerance Reassessment Summary for ODM

Commodity	Current Tolerance (ppm)	Interim tolerance decision (ppm)[1]	Comment *[Correct Commodity Definition]*
Tolerances To Be Listed Under 40 CFR §180.330 (a)(1)			
Alfalfa, green	5	TBD[2]	Additional data are required. *[Alfalfa, forage]*
Alfalfa, hay, grown for seed	11	TBD[2]	Additional data are required. *[Alfalfa, hay]*
Apple	1	Revoke	Nonbearing uses have been determined to be non-food use.
Apriot	0.5	Revoke	Nonbearing uses have been determined to be non-food use.
Bean, lima	0.5	0.2	The reassessed tolerance is based on the maximum combined residues of ≤0.15 ppm in/on treated samples of lima beans according to maximum use pattern.
Bean, lima, forage	2	Revoke	No longer a significant feed item.
Bean, snap, succulent	0.5	Revoke	Use to be deleted.
Bean, snap, forage	2	Revoke	Use to be deleted.
Beet, sugar	0.3	0.3	*[Beet, sugar, roots]*
Beet, sugar, tops	0.5	0.5	
Broccoli	1	1	
Broccoli raab	None	2	The proposed tolerance is based on the translation of data from broccoli and cabbage.
Brussels sprouts	1	1	
Cabbage	1	2	The reassessed tolerance is based on the maximum combined residues of 1.22 ppm in/on treated samples of cabbage according to maximum use pattern.
Cauliflower	1	1	
Clover, forage	5	5	
Clover, hay, grown for seed	11	10	The reassessed tolerance is based on the maximum combined residues of 9.84 ppm in/on treated samples according to maximum use pattern. *[Clover, hay]*
Clover, seed screenings	11	Revoke	No longer a significant feed item.

Commodity	Current Tolerance (ppm)	Interim tolerance decision (ppm)[1]	Comment *[Correct Commodity Definition]*
Corn, stover	3	TBD[2]	Additional data are required. *[Corn, sweet, stover]* and *[Corn, field, stover]*
Corn, forage	3	1	The reassessed tolerance is based on the maximum combined residues of 0.9 ppm in/on treated samples according to maximum use pattern. *[Corn, sweet, forage]* and *[Corn, field, forage]*
Corn, fresh, kernal plus cob with husks removed	0.5	TBD[2]	Additional data are required. *[Corn, sweet, kernel plus cob with husks removed]*
Corn, grain	0.5	Revoke	Use to be deleted.
Cotton, gin byproducts	None	TBD[2]	Data for cotton gin byproducts are now required as a result of changes in Table 1 (GLN 860.1000). Field trial data must be submitted.
Cotton, undelinted seed	0.1	0.02	Provided labels are amended such that ODM use on cotton is limited to two applications per season, the reassessed tolerance is based on the maximum combined residues of ≤0.02 ppm in/on treated samples.
Cucumber	1	1	
Eggplant	1	1	
Filbert	0.05	0.05	
Grapefruit	1	1	
Grape	0.1	Revoke	Nonbearing uses have been determined to be non-food use.
Lemon	1	1	
Lettuce, head	2	2	
Melon	0.3	0.2	The reassessed tolerance is based on the maximum combined residues of ≤0.2 ppm in/on treated samples according to maximum use pattern.
Mint, hay	12.5	12.5	*[Peppermint, tops]*
	12.5	12.5	*[Spearmint, tops]*
Onion, dry bulb	0.05	0.05	
Orange, sweet	1	1	*[Orange]*
Pear	0.3	Revoke	Use to be deleted.
Pepper	0.75	0.75	

Commodity	Current Tolerance (ppm)	Interim tolerance decision (ppm)[1]	Comment *[Correct Commodity Definition]*
Plum, prune, fresh	1	Revoke	Nonbearing uses have been determined to be non-food use.
Pumpkin	0.3	0.2	The reassessed tolerance is based on the maximum combined residues of ≤0.1 ppm in/on treated samples according to maximum use pattern.
Safflower, seed	1.0	1.0	
Sorghum, forage	2.0	2.0	*[Sorghum, grain, forage]*
Sorghum, grain	0.75	0.75	*[Sorghum, grain, grain]*
Sorghum, grain, stover	None	TBD[2]	Field trial data must be submitted.
Sorghum milled fractions (except flour)	2.0	Revoke	No longer a significant feed item.
Squash, summer	1	1	
Squash, winter	0.3	0.3	
Strawberry	2	2	
Turnip	0.3	Revoke	Use to be deleted.
Turnip, greens	2.0	Revoke	Use to be deleted.
Walnut	0.3	0.05	
Tolerances to be listed under 40 CFR §180.330(a_2)			
Cattle, fat	0.01	0.01	
Cattle, meat byproducts	0.01	0.01	
Cattle, meat	0.01	0.01	
Egg	None	0.01	Tolerances for residues of ODM at the quantification limit of the method (0.01 ppm) in egg, poultry fat, meat, and meat byproducts must be established.
Goat, fat	0.01	0.01	
Goats, meat byproducts	0.01	0.01	
Goat, meat	0.01	0.01	
Hog, fat	0.01	0.01	

Commodity	Current Tolerance (ppm)	Interim tolerance decision (ppm)[1]	Comment *[Correct Commodity Definition]*
Hog, meat byproducts	0.01	0.01	
Hog, meat	0.01	0.01	
Horse, fat	0.01	0.01	
Horse, meat byproducts	0.01	0.01	
Horse, meat	0.01	0.01	
Poultry, fat	None	0.01	Tolerances for residues of ODM at the quantification limit of the method (0.01 ppm) in egg, poultry fat, meat, and meat byproducts must be established.
Poultry, meat byproducts	None	0.01	
Poultry, meat	None	0.01	
Milk	0.01	0.01	
Sheep, fat	0.01	0.01	
Sheep, meat byproducts	0.01	0.01	
Sheep, meat	0.01	0.01	

[1]Tolerances may be reassessed only upon consideration of the cumulative risk of all organophosphates. The tolerance levels provided here are for this single chemical, if no cumulative assessment were required. The Agency will commence proceedings to lower existing tolerances and to correct commodity definitions. The raising of existing tolerances or establishment of new tolerances will be deferred, pending the outcome of the cumulative assessment.

[2]TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

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 recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA

authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, ODM may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight-of-the-evidence of available data, there are possible endocrine system related effects for ODM.

3. Mitigation Needed for Reregistration

The mitigation measures needed to address the occupational and ecological risks associated with the use of ODM are described below. The regulatory rationale for each of these mitigation measures is discussed in the subsequent sections of the text (Section IV.D.). Mitigation measures are expressed as specific label amendments which are listed in Section V.D. Provided the following mitigation measures are incorporated in their entirety into labels for ODM-containing products, the Agency finds that the remaining currently registered uses of ODM would be eligible for reregistration, pending a cumulative assessment of the organophosphates.

- Eliminate the following use sites: eggplants, field corn, bell peppers, pears, popcorn, snap beans, and turnips;
- Except for tree injection application to ornamentals, eliminate all residential use sites, including ornamentals located in interior plantscapes, ornamental gardens, parks, golf courses, lawns and grounds;
- Require all product to be sold in closed systems, including water soluble bags;
- Require enclosed cabs for application;
- Require enclosed cabs for flaggers, or the use of mechanical flagging or GPS;
- Require mixer/loaders using product in a closed system to wear a chemical resistant apron, chemical resistant gloves, and protective eyewear if the system operates under presure;
- Require applicators using enclosed cabs to wear long-sleeved shirts, long pants, shoes, and socks;
- Require handlers performing tasks for which engineering controls are not feasible, such as cleaning equipment or cleaning up after a spill, to wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical resistant footwear plus socks, and a chemical-resistant apron if exposed to the concentrate;
- Eliminate all hand-held application methods except tree injection;
- For citrus, require the use of trunk-directed microjet sprinklers; (FL SLN only);
- For sweet corn, restrict use to west of the Rockies (including HI) and prohibit hand detassling;
- For cotton, restrict use to AZ and CA;
- For filberts, restrict use to OR and WA;

- For non-bearing fruit trees, filberts, and walnuts, restrict application to airblast sprayer only;
- Reduce application rates to 0.5 lbs a.i./acre for the following crops: sugar beets, cotton, Spanish bulb onions, and safflower;
- Reduce the maximum number of applications to 1 per season for cotton, curcurbits, all melons, and sugar beets;
- Reduce the maximum number of applications to 2 per season for lima beans, broccoli, broccoli raab, cauliflower, sweet corn, non-bearing fruit trees and grapes, Spanish bulb onions, safflower, sorghum, and strawberries (pre-bloom and post-harvest only);
- Increase the REIs for all crops (see section IV. D. 1. b. (3));
- Require mechanical harvesting for alfalfa grown for seed, sugar beets, filberts, peppermint, spearmint, safflower, walnuts, field grown ornamental bulbs, and Christmas trees (note: these crops are already harvested mechanically in most cases);
- Require a no-spray buffer zone of 25 feet (groundboom and chemigation), 50 feet (airblast) or 100 feet (aerial) between the application site and any area managed for wildlife or wildlife habitat.

D. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

(1) Acute Dietary (Food)

Acute dietary risk from food is well below the Agency's level of concern – a Tier 3 DEEM™ analysis yielded acute PAD values that are less than 8% at the 99.9th percentile of exposure for the most sensitive population subgroups (females 13-50 years). Therefore, no mitigation measures are necessary at this time to address acute dietary risk from food.

(2) Chronic Dietary (Food)

Chronic dietary risk from food is also below the Agency's level of concern – chronic PAD values are less than 6% for the most sensitive population subgroups. Therefore, no mitigation measures are necessary at this time to address chronic dietary risk from food.

(3) Drinking Water

The modeled estimates of potential drinking water exposure from both ground and surface water sources (i.e., EECs) do not exceed the acute or chronic DWLOC values, and therefore do not exceed the Agency's level of concern. No mitigation is necessary at this time.

b. Residential Risk Mitigation

Uses that could result in residential exposure are no longer being supported. These include ornamentals located in interior plantscapes, ornamental gardens, parks, golf courses, and lawns and grounds. The tree injection product can be used by a certified applicator in residential areas (such as ornamentals located around apartments or condomiums), but this application method is expected to result in negligible post-application exposure.

c. Occupational Risk Mitigation and Remaining Risks

(1) Occupational Risk Mitigation

The following agricultural crops are being voluntarily cancelled: bell peppers, eggplant, field corn, popcorn, pears, snap beans, and turnips. Bell pepper and eggplant will retain their tolerances for importation purposes. The following list includes the use parameters (e.g., application methods and rates) for the remaining crops, including the mitigation measures to be implemented. The use of full engineering controls (closed systems, enclosed cabs) is required for mixing, loading and applying ODM for all application methods and all use sites. In addition, applicators must not apply ODM within 25 feet (groundboom and chemigation), 50 feet (airblast), or 100 feet (aerial) of any area managed for wildlife or as wildlife habitat.

Use sites

Alfalfa grown for seed

- 2 aps/crop cycle;
- 14 days between applications;
- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- REI of 15 days;
- mechanical harvesting required;
- apply in early morning or evening to avoid exposure to bees;
- chaff from seed may be used for feed or forage, but the cut green crop may not be used for these purposes;
- PHI of 21 days.

Beans, lima

- 2 aps/crop cycle (down from 3);
- 7 days between applications;

- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- do not graze or cut treated vines for feed or forage within 21 days of application;
- REI of 17 days;
- PHI of 21 days.

Beets, sugar

- 1 ap/crop cycle (down from 2);
- 0.5 lbs ai/season (down from 0.75);
- possible app. methods: aerial, chemigation, groundboom;
- mechanical harvesting required;
- do not harvest beets or use beet tops for feed or forage within 30 days of application;
- REI of 30 days (MOE at 30 days = 12 for scouting and weeding mature plants)
- PHI of 30 days.

Broccoli, broccoli raab (CA SLN), cauliflower

- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- REI of 7 days (MOE = 97 for irrigating, pruning, and tying mature plants);
- exception of 3 days for irrigating immature crops (MOE at 3 days = 58);
- PHI of 7 days (MOE = 97 for hand harvesting).

Brussels sprouts

- 3 aps/crop cycle;
- 7 days between applications;
- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- REI of 7 days (MOE = 97 for irrigating, pruning, topping and tying mature plants);
- exception of 3 days for irrigating immature crops (MOE at 3 days = 58);
- PHI of 10 days (MOE>100).

Cabbage

- 3 aps/crop cycle;
- 7 days between applications;
- 0.75 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- REI of 7 days (MOE = 64 for irrigating, pruning, topping and tying mature plants; 81 for scouting mature plants);
- exception of 3 days for irrigating immature crops (MOE at 3 days =39);
- PHI of 7 days (MOE = 64 for hand harvesting).

Carrots grown for seed (ID SLN)

- 2 aps/crop cycle;
- 14 days between applications;
- 0.5 lbs ai/acre;
- possible app. Methods: aerial and groundboom;
- mechanical harvesting is required;
- no portion of the treated field, including, but not limited to, seed, seed screenings, chaff, or root may be used for human or animal consuption;
- producers of carrot seed who use this product, or cause the product to be used in fields they operate, are required to inform, in writing, conditioners receiving seed produced on the fields treated with this product;
- producer is required to provide a copy of the labeling to the conditioner;
- processed seed must be labeled "not for human or animal consumption;"
- processor must dispose of all seed screenings in a such a way that they cannot be distributed or used for food or feed;
- do not apply this product while bees are actively visiting the treatment area;
- REI of 15 days;
- PHI of 21 days.

Christmas trees, field grown or in outdoor nurseries

- 2 aps/crop cycle;
- 7 days between applications;
- 0.5 lbs ai/acre;
- drop all handheld uses except tree injection;
- use of handheld equipment is prohibited for all liquid formulations not packaged as capsules for direct injection into trees;
- use prohibited in CA;
- possible app. methods: aerial, airblast, tree injection;
- require inward nozzle spray on outer rows for airblast;
- require mechanical harvesting;
- use of handheld application equipment is prohibited;
- retail sale of treated plants is prohibited for 18 days after application;
- REI of 18 days

Citrus: oranges, lemons, grapefruit (FL SLN only)

- 2 aps/crop cycle;
- 14 days between applications;
- 0.375 lbs/acre;
- use on citrus is permitted only in Florida;
- application by trunk-directed microjet sprinklers, only;
- all other application methods are prohibited, including groundboom, airblast, and aerial;
- REI of 3 days (MOE based on use of microjet sprinklers not known but is

expected to be low; based on foliar application, MOE at 3 days = 6 for pruning and 17 for irrigating, scouting and weeding);
- PHI = 7 days (based on foliar application, MOE at 7 days = 6 for hand harvesting).

Clover grown for seed
- 2 aps/crop cycle;
- 14 days between applications;
- 0.5 lbs ai/acre;
- possible app. Methods: aerial, chemigation, groundboom;
- mechanical harvesting is required;
- apply in early morning or evening to avoid exposure to bees;
- REI of 15 days;
- PHI of 21 days.

Corn, sweet
- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- use restricted to west of the Rockies (includes HI);
- calc. REI of 13 days;
- do not hand harvest or allow workers to perform hand harvesting tasks for 26 days after application;
- prohibit hand detassling;
- do not harvest corn fodder or use for forage within 26 days of application;
- PHI of 26 days to achieve an MOE>100 for hand harvesting (calc. PHI of 7 days for a single application, 21 days for two applications; at 7 days, the MOE = 2, at 21 days, the MOE = 37).

Cotton
- 1 ap/cycle (down from 3);
- 0.5 lbs ai/acre (down from 0.75 for AZ only);
- use restricted to CA and AZ only;
- prohibit aerial application;
- possible app. methods: groundboom and chemigation;
- do not graze or feed gin trash to dairy or meat animals;
- calc. REI of 7 days;
- PHI of 14 days.

Cucurbits: cucumbers, winter squash, summer squash, pumpkins, muskmelons (canteloupe), watermelons, other melons.
- 1 ap/crop cycle (already the case for squash and pumpkins, down from 2 for others);

- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- REI of 14 days (MOE = 50 for pruning, pulling, leaf thinning, thinning and turning; MOE = 84 for irrigating, scouting, and weeding mature plants);
- PHI of 14 days (MOE = 50 for hand harvesting) for all cucurbits, to match REI (calc. PHI of 3 days for cucumbers and summer squash, 7 days for watermelons, and 14 days for pumpkins, winter squash and melons).

Filberts

- 1 ap/crop cycle;
- 0.5 lbs ai/acre;
- application by airblast sprayer only;
- aerial application and chemigation are prohibited;
- use of handheld application equipment (including paintbrush) is prohibited;
- use restricted to OR and WA;
- mechanical harvesting required;
- require inward nozzle spray on outer rows;
- grazing or feeding cover crops to livestock is prohibited;
- REI of 17 days;
- PHI of 116 days.

Fruit trees, non-bearing: apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces.

- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.375 lbs ai/acre;
- application by airblast sprayer only;
- aerial application and chemigation is prohibited;
- require inward nozzle spray on outer rows;
- retail sale of treated plants is prohibited for 16 days after application;
- REI of 16 days.

Grapes, non-bearing

- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.375 lbs ai/acre;
- application by airblast sprayer only;
- aerial application and chemigation is prohibited;
- require inward nozzle spray on outer rows;
- do not apply to vines that will bear fruit within the next 12 months;
- retail sale of treated plants is prohibited for 18 days after application;
- prohibit leaf pulling, training/tying, girdling, and cane turning (= very high exposure activities requiring a higher REI);
- REI of 18 days.

Lettuce, head

- 3 aps/crop cycle;
- 7 days between applications;
- 0.5 lbs ai/acre;
- possible app. methods: aerial, chemigation, groundboom;
- Registrant has submitted DFR data;
- hand harvesting is prohibited until 14 days following application;
- REI of 3 days (MOE = 7 for irrigating, scouting and weeding mature plants, MOE = 20 for irrigating, scouting, thinning and weeding immature plants)
- PHI of 21 days, except in AZ (all crops) and CA (fall and winter crops), where the PHI is 28 days, and in CA (spring and summer crops) where the PHI is 14 (MOE = 50), 21, and 28 days after 1, 2, and 3 applications, respectively (MOE = 100 at 17 days for hand harvesting).

Mint: peppermint, spearmint

- 2 aps/crop cycle;
- 10 days between applications;
- 0.75 lbs ai/acre;
- possible app. methods: chemigation, groundboom;
- aerial application is prohibited;
- require mechanical harvesting;
- calc. REI of 19 days;
- PHI of 14 days.

Onions, spanish bulb (1 of nine crops)

- 2 aps/crop cycle (down from 3);
- 14 days between applications;
- 0.5 lbs/acre (down from 0.75);
- possible app. methods: aerial, chemigation, groundboom;
- use restricted to west of the Mississippi River;
- use permitted in New York state through a SLN;
- prohibit hand weeding, hand harvesting, and hand thinning;
- REI of 10 days (MOE>100 for irrigating, scouting, and weeding)
- PHI of 30 days.

Ornamentals: flowers grown for cutting (CA SLN), flowers grown for drying (CA SLN)

- 2 aps/crop cycle;
- 7 days between applications;
- 0.375 lbs ai/acre;
- for use only in commercial nurseries;
- outdoor use only, use in greenhouses is prohibited;
- prohibit aerial application;
- possible app. methods: groundboom and airblast

- use of handheld application equipment is prohibited;
- retail sale of treated plants is prohibited for 19 days after application;
- REI of 19 days.

Ornamentals: field grown nursery stock

- 2 aps/crop cycle;
- 7 days between applications;
- 0.5 lbs ai/acre;
- drop all handheld uses except tree injection;
- use of all handheld equipment is prohibited for all liquid formulations not packaged as capsules for direct injection into trees;
- use prohibited in CA;
- for use only on seedling trees and non-bearing fruit trees in commercial nurseries;
- outdoor use only, use in green houses is prohibited;
- possible app. methods: aerial, airblast, groundboom, tree injection;
- require inward nozzle spray on outer rows for airblast;
- retail sale of treated plants is prohibited for 10 days after application;
- calc. REI of 10 days.

Ornamentals: field-grown bulbs (WA SLN)

- 2 aps/crop cycle;
- 7 days between applications;
- 0.5 lbs ai/acre;
- for use only in commercial nurseries;
- outdoor use only, use in greenhouses is prohibited;
- prohibit aerial application;
- possible app. methods: groundboom and airblast;
- mechanical harvesting required;
- use of handheld application equipment is prohibited;
- REI of 19 days (based on scouting mature plants).

Safflower (1 of nine crops)

- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.5 lbs/acre (down from 1.0);
- possible app. methods: aerial, chemigation, groundboom;
- mechanically harvested;
- use restricted to CA and AZ;
- calc. REI of 15 days (based on irrigating, scouting and weeding mature plants);
- PHI of 7 days.

Seed orchard trees (SLN for MT)

- 2 aps/crop cycle;
- 7 days between applications;

- application by tree injection only;

(Note: This SLN has been proposed for revocation).

Sorghum (1 of nine crops)

- 2 aps/crop cycle (down from 3);
- 7 days between applications;
- 0.5 lbs/acre;
- possible app. methods: aerial, chemigation, groundboom;
- mechanically harvested;
- use restricted to CO, KS, OK, and TX only;
- do not use on sweet sorghum;
- do not allow grazing for 21 days;
- REI of 14 days;
- PHI of 45 days for grain, 21 days for grazing or cutting for forage;

Strawberries (pre-bloom and postharvest): not on Sec. 3 label, OR and WA SLNs only

- 2 aps/crop cycle (currently one pre-bloom application and one post-harvest application to plants growing in fields; down from 3, one pre-bloom and 2 post-harvest);
- do not apply to fruit;
- 7 days between applications;
- 0.5 lbs ai/acre;
- application by groundboom only;
- aerial application and chemigation are prohibited;
- calc. REI of 15 days.

Walnuts

- 1 ap/crop cycle;
- 0.375 lbs ai/acre;
- application by airblast sprayer only;
- aerial and chemigation applications are prohibited;
- mechanical harvesting required;
- grazing or feeding cover crops to livestock is prohibited;
- require inward nozzle spray on outer rows;
- grazing or feeding cover crops to livestock is prohibited;
- calc. REI of 17 days;
- PHI of 30 days;

NOTE: There is a separate label for tree injection (that includes non-bearing walnuts and pecans, as well as ornamental/forest trees, and Christmas trees), using a pre-packaged injector unit with 50% liquid concentrate. Labeling for the two existing tree-injection products of ODM will include the following mitigation:

Liquid formulations packaged as capsules for direct injection into trees

- Do not leave capsules unattended while in use;
- remove capsules promptly after treatment;
- do not inject trees that are less than two inches in diameter;
- do not inject trees within two weeks of any other spray or soil chemical treatment;
- do not treat trees that are suffering from stress such as lack of moisture or herbicide damage;
- do not inject this product into trees that will bear edible fruit within one full year following treatment;
- direct injection capsules are limited to use in the following trees: cedar, cottonwood, cypress, douglas fir, elms, juniper, pines (except piñon), redwood, spruce, walnuts and pecans (non-bearing), and willow.

(2) Remaining Worker Risks

Even with the required mitigation for ODM, some potential risks of concern remain mixer/loaders, applicators, and post-application workers. Table 25 below summarizes the calculated ARIs for the mixer- loader scenarios that may still pose risks of concern, even after all feasible mitigation has been taken into account. Table 26 shows ARIs of concern for applicators. In all cases, mixer/loader and applicator short term risks (i.e., exposures of less than 7 days) are not of concern. Because ODM is used on many minor crops with a low percentage of the crop acreage treated, only short term handler exposures would typically be expected for crops such as lima beans, sugar beets, cucumbers, citrus, sweet corn, cotton, cucurbits, non-bearing fruit trees, nuts, and strawberries. Thus risk to mixer/loaders and applicators working in these crops is less likely to be of concern.

Table 25. Remaining ARIs less than the target ARI of 1: intermediate-term exposure to mixer/loaders

Application method	Formulation	0.375 lbs a.i./acre[1]	0.5 lbs a.i./acre[2]	0.75 lbs a.i./acre[3]
Aerial/chemigation	Liquid	NA	0.14	0.093
	Water soluble bags	NA	0.12	0.082
Groundboom	Liquid	0.81	0.61	0.41
	Water soluble bags (WSB)	0.71	0.54	0.36

1. Crops treated by groundboom at 0.375 lbs/ai/acre include: flowers (cut and dried).
2. Crops treated at 0.5 lbs/ai/acre include: alfalfa, clover, lima beans, sugar beets, Brussels sprouts, cauliflower, broccoli, sweet corn, cotton (groundboom only), cucurbits, lettuce, onions, ornamentals, safflower, sorghum, strawberries (groundboom only).
3. Crops treated at 0.75 lbs/ai/acre include: cabbage and mint.

Table 26. Remaining ARIs less than the target ARI of 1: intermediate-term exposure to

applicators

Application method	Formulation	0.375 lbs[1] a.i./acre	0.5 lbs[2] a.i./acre	0.75 lbs[3] a.i./acre
Aerial	Liquid or WSB	NA	0.25	0.16
Groundboom	Liquid or WSB	NA	>1	0.70
Airblast	Liquid or WSB	0.74	0.63	NA

1. Crops treated by airblast at 0.375 lbs/ai/acre include: non-bearing fruit trees, non-bearing grapes, and walnuts.
2. Crops treated at 0.5 lbs/ai/acre include: alfalfa, clover, lima beans, sugar beets, Brussels sprouts, cauliflower, broccoli, sweet corn, cotton (groundboom only), cucurbits, lettuce, onions, ornamentals, safflower, sorghum, strawberries (groundboom only), and filberts (airblast only).
3. Crops treated at 0.75 lbs/ai/acre include: cabbage and mint.

Table 27 presents the remaining risks of concern for post-application workers (MOEs less than the target of 100).

Table 27. Remaining MOEs less than the target MOE of 100: post-application exposure

Use site	REI or early-entry exception	Activity of concern	MOE for activity of concern
Sugar beets	30 days	irrigating and scouting mature plants	12 (at 30 days)
Citrus	3 days	pruning	6 (at 3 days)
		irrigating and scouting	17 (at 3 days)
Cabbage	7 days	hand harvesting and irrigating mature plants	64 (at 7 days)
		scouting mature plants	80 (at 7 days)
	Early entry exception to irrigate immature plants: 3 days	irrigating immature plants	39 (at 3 days)
Cole crops (other than cabbage)	Early entry exception to irrigate immature plants: 3 days	irrigating immature plants	58 (at 3 days)
Cucurbits	14 days	hand harvesting, pruning, leaf thinning, thinning, and turning plants	50 (at 14 days)
		irrigating, weeding, and scouting mature plants	84 (at 14 days)

Use site	REI or early-entry exception	Activity of concern	MOE for activity of concern
Head lettuce	3 days	hand harvesting	50 (at 14 days[1])
		irrigating, scouting, and weeding (by hoe) mature plants	7 (at 3 days)
		irrigating, scouting, thinning and weeding (by hoe) immature plants	20 (at 3 days)

The following sections will characterize the remaining risks to handlers and post-application workers, describe the benefits of ODM use, and explain EPA's regulatory rational for retaining the remaining uses of ODM.

(3) Occupational risk characterization: comparison of ChE and reproductive endpoints

The following discussion compares the cholinesterase endpoint used in the intermediate-term handler and post-application risk assessments to available data on the reproductive risks of ODM, in order to show that the cholinesterase NOAEL used in risk assessment is protective for any reproductive effects (Table 28). Since the remaining risks of concern are all based on intermediate-term exposure, only the intermediate-term endpoint will be discussed.

The NOAEL used for assessment of intermediate-term handler risk (greater than one week of daily exposure) and for assessment of post-application risk was 0.3 mg/kg/day based on ChEI in a 14-day dermal study in rats (MRID 40499304, LOAEL of 1.0 mg/kg/day for ChEI). Two 2-generation reproduction studies were reviewed. In the more recent study (MRID 41461901), systemic, reproductive and offspring toxicities, as well as ChEI measurements in parental animals and pups were evaluated; in the earlier study (MRIDs 00260513 and 00256926) ChEI was not evaluated.

In the more recent reproduction study (MRID 41461901), cholinesterase inhibition was observed at a dose approximately 50-fold lower than reproductive effects in adults (LOAEL of 0.043 mg/kg/day for ChEI, and 2.1 mg/kg/day for reproductive effects). Using this 50-fold factor, it would be possible to estimate that reproductive effects could occur at a dermal dose that is 50 times higher than the dermal ChEI LOAEL of 1.0 mg/kg/day, that is, at a dermal dose of 50 mg/kg/day.

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[1]For spring and summer crops in CA, hand harvesting can only be performed 14 days after a single application of ODM, because the PHI is 14 days. For harvesting that takes place after more than one application of ODM, or in other seasons or locations, the PHI for lettuce is either 21 or 28 days, and the MOE for hand harvesting is greater than 100.

In the earlier reproduction study (MRIDs 00260513 and 00256926), reproductive effects were observed at a LOAEL of 0.5 mg/kg/day. However, the only reproductive effect observed at this dose was epidydimal vacuolation in 1 of 10 males tested. Reproductive effects similar to those observed at 2.1 mg/kg/day in the more recent study (decreased fertility, decreased absolute testicular and ovarian weights, decreased pup weight during lactation) were only observed at the highest dose tested in the earlier study, 5.0 mg/kg/day.

Since ChEI was not measured in the earlier study, it is not possible to compare the LOAELs for ChEI and reproductive effects directly. Converting the reproductive LOAEL from this study to a dermal equivalent dose (using a 50% dermal absorption factor calculated from the dermal absorption study MRID 001638631) results in an equivalent dermal reproductive LOAEL of 1.0. This LOAEL is approximately 3.3-fold higher than the NOAEL of 0.3 mg/kg/day used to assess worker risk. Converting the reproductive LOAEL from the more recent study to a dermal equivalent dose results in an equivalent dermal reproductive LOAEL of 4.2 mg/kg/day. This LOAEL is approximately 14-fold higher than the NOAEL of 0.3 mg/kg/day used to assess worker risk.

Based on the data from these two reproduction studies, the ChEI NOAEL of 0.3 mg/kg/day used to assess intermediate-term handler and post-application risk provides a 3.3-fold to 50-fold protection factor against reproductive effects.

(4) Occupational risk characterization: benefits of ODM use

When calculated worker and ecological risks are of concern, EPA will characterize uncertainties in the risk assessments, assess the potential of additional data to reduce those uncertainties, and consider the benefits, i.e., the cost, availability, and relative risk of alternative pest control methods in making its regulatory decisions. Where benefits are determined to be substantial, uses with associated risks to workers and the environment may be retained.

In assessing available chemical alternatives, EPA would prefer to use direct product performance data to determine the comparative efficacy of a chemical and its alternatives. However, ODM is a relatively old product that has not been tested side-by-side against any of the newer commercial products available for aphid control. In the absence of these data, EPA has compared alternatives by combining existing data using different methodologies, on a variety of vegetable crops, involving several species of aphids. Under the limits of this comparison, EPA found that none of the available alternatives provided adequate control.

Additionally, ODM is an insecticide that fits well with existing integrated pest management (IPM) programs. When used as a foliar application it acts as both a contact and a translaminar insecticide. This means that it is absorbed into the tissue of the plant within 3-5 cell layers and will spread out slightly from the point of droplet origin. Therefore, it is active against damaging insects with piercing-sucking mouthparts such as aphids, thrips and leafhoppers, but not harmful to beneficial insects such as predatory mites, lacewings and lady beetles.

For a more complete discussion of ODM benefits see the Memo dated June 27, 2001, entitled "Oxydemeton-methyl Addendum" in the public docket.

(5) Occupational Risk Characterization: Mixer/Loader/Applicator Risk

In evaluating the intermediate-term handler risks for ODM, EPA compared the assumptions used in the risk assessments to available information on actual use practices. EPA has considered available data for aerial and groundboom mixer/loaders and applicators from California, where the majority of ODM use occurs. For aerial applications, these data indicate that while applications of ODM can occur over a period of greater than 6 months, individual applicators, and the mixer/loaders supporting them, are exposed intermittently and the acres treated in any given day typically range between 10-100, rather than the 350 assumed in EPA's risk assessment. Taking into account the smaller acreage would result in ARI calculations at least 3 times higher than those given in Tables 25 and 26 for aerial scenarios. Groundboom data show a similar pattern with typical daily acreage treated ranging from 10-60 rather than the 80 acre assumption used in the risk assessment, resulting in ARIs at least 1.3 times greater than those in Tables 25 and 26 for groundboom scenarios.

Further, it should be noted that aerial application is only used on a portion of the acres treated with ODM. As part of the mitigation requirements described in section IV.C.3., aerial application will be prohibited on cotton. EPA estimates that aerial application of ODM currently occurs on 18% of broccoli fields, 7% of cauliflower fields, 8% of lettuce fields and 0.4% of watermelon fields. No other cucurbit or cole crops have aerial applications. Generally growers prefer groundboom application and resort to aerial applications only when heavy rains and aphid outbreaks coincide. The exceptions are Kern and Imperial counties in California where close to 100% of applications may be aerial due to large farm sizes and the widespread use of flood and sprinkler irrigation.

Of all crops treated with ODM, only mint and cabbage will be treated at the 0.75 lbs/ai/acre rate. Approximately 7-10% of the 87,000 acres of cabbage grown are treated with ODM; up to 30% of the 170,000 acres of mint are treated. The maximum rate of 0.75 lbs/ai/acre is also typical for these crops and the assumption of 80 acres treated per day by groundboom is realistic. Thus intermediate term exposures for ground applications are likely with ARIs ranging from 0.4 for mixer/loaders to 0.7 for applicators.

The cole crops, broccoli, Brussels sprouts, and cauliflower, typically have 60-80% of the crop treated with ODM and the assumptions of 80 acres treated per day and 0.5 lbs/ai/acre are realistic compared to actual usage data. Thus intermediate term exposures are possible and would result in ARIs for mixer/loaders for ground applications of 0.5-0.6; groundboom applicator ARIs would be > 1.

In light of the benefits of ODM use on mint, cabbage and cole crops, the lack of equally effective alternatives, and the importance of ODM in integrated pest management for these

crops, EPA finds that the risk of ODM use on these crops is not unreasonable.

(6) Occupational Risk Characterization: Post-Application Risk

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 risks to a worker falls below the target MOE, in this case 100. 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 (See Table 11, "Summary of Post-application Exposure and Risk Estimates"). For a specific crop/pesticide combination, the duration required to achieve the target MOE can vary depending on the activity assessed.

In general, EPA prefers to set a simple REI that covers 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 simple 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 ODM, some exceptions were deemed necessary.

In weighing worker risks and benefits, the Agency considered the timing of field activities that are critical to crop production. For many of the ODM uses discussed below, scouting and irrigation are critical activities in crop production, and these activities routinely need to be performed soon after application. In evaluating the restricted entry intervals, the Agency considered the exceptions to the Worker Protection Standard that could inform the decision. EPA's proposed REIs take into account the flexibility already provided by these exceptions. Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the handler personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS (40 CFR 170.204(b)), the individual can determine the appropriate PPE to be used for early entry tasks. 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 (8 hours in 24, mechanically operated) (40 CFR 170.112(b)). This exception also usually applies to mechanical harvesting, tree shaking for nut crops in enclosed cabs, and often applies to mowing. Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field provided early entry PPE is

used (8 hours in 24) (40 CFR 170.112(c)).

For the ODM post-application risk calculations, EPA used the intermediate-term endpoint from a 14-day dermal toxicity study in the rat, with a NOAEL of 0.3 mg/kg/day which assumes consecutive daily exposures over a period of at least 14 days. This situation is most likely to apply to broccoli, Brussels sprouts and cauliflower because these crops have a relatively high (60-80%) percent of the crop treated with ODM. For the remaining minor uses of ODM, post-application exposures are more likely to be sporadic and of a shorter duration. Thus, the calculated MOEs for crops other than broccoli, Brussels sprouts and cauliflower may overestimate post application risk. Each of the crops with MOEs less than 100 are discussed in more detail below:

Sugar beets with an REI of 30 days:

The MOE at 30 days is 12 for irrigating and scouting mature plants. However, very few if any post-application activities are expected to take place in sugar beets. Sugar beets are furrow or drip irrigated, and these irrigation methods do not require workers to routinely enter fields. Certified crop advisors can enter treated fields under WPS to perform scouting activities, but little if any scouting takes place in sugar beet fields. In addition, sugar beets are mechanically harvested. As a result, exposure and risk to post-application workers in sugar beets following an application of ODM is expected to be minimal.

Citrus (oranges, lemons, grapefruit) with an REI of 3 days:

No data were available to calculate MOEs based on the use of trunk-directed microjet sprinklers. Based on a foliar application, the calculated MOE at 3 days is 6 for pruning and 17 for irrigating and scouting. However, the actual exposure and risk to post-application workers following trunk-directed application is expected to be substantially less.

Cole crops (broccoli, broccoli raab, Brussels sprouts, cauliflower) with an REI of 7 days:

For the cole crops with a maximum application rate of 0.5 lbs ai/A, MOEs are $\geq$ 96 at 7 days, depending on the activity. For cabbage (maximum application rate of 0.75 ai/A), the MOE is 64 for hand harvesting, irrigating, pruning, topping, and tying mature plants, 80 for scouting mature plants, and > 100 for irrigating, scouting, thinning and weeding immature plants. Given the lack of equally effective alternatives and the role of ODM in integrated pest management for cole crops, EPA finds that the benefits justify allowing the continued use of ODM with MOEs of $\geq$ 64 for post-application workers.

In most cases, growers are expected to manage their irrigation schedules to avoid entering a posted field during the 7 day REI to move irrigation pipe for sprinkler irrigation. However, water management is critical to the production of vegetable crops and under the hot, dry, and windy conditions typical of California and the southwest, a crop may be lost within 3 days if not irrigated. The need to move pipe to irrigate only applies to immature crops, since once the crop is mature it is no longer possible to walk through the furrows and install pipe without damaging the plants. In addition, furrow irrigation is generally substituted for sprinkler irrigation in mature crops, since wet foliage is more susceptible to mildew. Based on the critical

need to irrigate immature plants, EPA is granting an early entry exception to the REI at 3 days for cole crops, to allow workers to enter posted fields to move irrigation pipe. At 3 days, the MOE is 58 for irrigating immature cole crops other than cabbage; for cabbage, the MOE at 3 days is 39.

Cucurbits (cucumbers, melons, pumpkins, summer squash, winter squash, watermelons) with an REI of 14 days:

At 14 days, the MOE is 50 for hand harvesting, pruning, leaf thinning, thinning, and turning, 84 for irrigating, weeding, and scouting mature plants, and > 100 for irrigating, weeding and scouting immature plants. An REI of 14 days is the maximum REI that growers can tolerate and still use ODM for control of aphids. Since a population explosion of aphids can occur at any time during the crop cycle, and the crops mature in a narrow window of time, harvest cannot be delayed more 14 days following a late season application of ODM. There are no currently registered adequately effective alternatives to ODM for aphid control mid- to late-season in cucurbits.

Head lettuce with an REI of 3 days:

With an REI of 3 days, the MOE for head lettuce is 7 for irrigating, scouting and weeding mature plants, and 20 for irrigating, scouting, thinning and weeding immature plants. The PHI for head lettuce varies by state, season, and number of seasonal applications: 14 days, 21 days, and 28 days. At 14 days, the MOE for hand harvesting lettuce is 50; at 21 and 28 days, the MOE is >100. MOEs were calculated using an average of all available DFR data (studies on cauliflower, cotton, sugar beets, and bell peppers). Of the four crops tested, it would be reasonable to assume that cauliflower would most closely resemble lettuce with respect to residue dissipation, based on general plant shape and leaf characteristics. If the lettuce MOEs were recalculated using only the cauliflower DFR data, then at 3 days the MOE for irrigating, scouting and weeding mature plants would be 77, and the MOE for irrigating, scouting, thinning and weeding immature plants would be >100. At 14 days (the lowest possible PHI), the MOE for hand harvesting would also be >100.

For all estimates (using average DFR values, or cauliflower DFR only), EPA believes that because of the relatively low percent of the lettuce crop (< 10%) that is treated and the sporadic nature of the activities, the exposure would likely be less and the MOEs actually greater. However, it should be noted that the use of ODM on lettuce is expected to increase due to the emergence of the lettuce aphid as a critical pest.

Given the wide range of possible MOE estimates for the critical post-application activities in lettuce, the registrant has agreed to submit DFR data for head lettuce as one of the conditions of reregistration. The REI will remain at 3 days pending the submission and review of these data; however, should the data indicate that MOEs are <100 at 3 days, this REI will be increased and the registrant will be required to revise their labels to reflect the extended REI.

2. Environmental Risk Mitigation

With the reduced application rates presented in section IV.C.3., potential acute and chronic (reproductive) risk to birds and mammals remains from ODM use (the RQs presented in

chapter 3 were calculated taking into account these reduced rates). If the toxic degradates of ODM prove to be persistent in aerobic aquatic environments, potential risk may exist for freshwater fish and invertebrates, as well. The mitigation measures specified above for agricultural workers, i.e., elimination of some use sites, elimination of aerial application to cotton and geographic restriction of use on sorghum will also lessen risk to non-target species, including endangered species.

Measures to reduce drift onto wildlife habitat and exposure to non-target species include increasing the required droplet size for groundboom and aerial applications to at least a "coarse" spray according to the ASAE 572 definition for standard nozzles, or a volume median diameter (VMD) of 385 microns or greater for spinning atomizer nozzles. The boom height for ground applications will be limited to 2 feet above the ground or crop canopy. Airblast application must not be directed above trees and vines, and outward pointing nozzles must be turned of at row ends and when spraying the outer two rows of the orchard or vineyard. For aerial applications, spray must not be released at a height greater than 10 feet above the ground or the crop canopy.

To further reduce drift onto non-target terrestrial species, the Agency is requiring no-spray buffer zones around any area managed for wildlife or wildlife habitat at any time during the year. All applications must be conducted a specified distance from wildlife habitat that is located in the vicinity of the crop to be sprayed. The required distances for each application type are as follows:

- For chemigation and groundboom applications: 25 feet;
- For airblast applications: 50 feet;
- for aerial applications: 100 feet.

E. Other Labeling

In order to remain eligible for reregistration other use and safety information needs to be placed on the labeling of all end-use products containing ODM. 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, was proposed for public comment in a December, 2002 Federal Register Notice.

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of oxydemeton-methyl, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for oxydemeton-methyl products. Label statements implementing these measures are listed in the "spray drift management" section of the label table in Chapter V.D. of this RED document. In the future, oxydemeton-methyl product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV and V, by submitting label amendments and meeting the data requirements described in this section. In addition, for ODM 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 Véronique LaCapra at (703) 605-1525 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

<u>By US mail:</u>
Document Processing Desk (DCI/SRRD)
Véronique LaCapra
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

<u>By express or courier service:</u>
Document Processing Desk (DCI/SRRD)
Véronique LaCapra
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

For end use products containing the active ingredient ODM, 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:

(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 30 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 Moana Appleyard at (703) 308-8175 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)
Moana Appleyard
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

Table 28. Generic Data Requirements

830.7050	UV/Visible Adsorption
840.1000 (200-1)	Background for pesticide aerial drift evaluation
840.1100 (201-1)	Spray droplet size spectrum

840.1200 (202-1)	Spray drift field deposition
860.1380 (171-4e)	Storage stability data: sample storage intervals and conditions for all residue data submitted in support of tolerances must be supplied. In addition, storage stability data are needed for processed commodities and livestock commodities.
860.1500 (171-4k)	Crop field trials: residues of ODM and ODMS in/on sweet corn stover, sweet corn (kernal plus cob with husks removed), sorghum stover, alfalfa forage, alfalfa hay, alfalfa seed, and cotton gin byproducts.
875.2100 (132-1)	Dislodgeable foliar residue dissipation, on head lettuce.
835.4300 (162-4)	Aerobic Aquatic Metabolism: testing the persistence of the metabolites ODM sulfone and ODM sulfide under aerobic aquatic conditions.
850.1075 (72-1)	Acute Freshwater Fish Toxicity using formulated end-product. Additional toxicity testing on the inert ingredients is held in reserve.
850.1075 (72-3a)	Held in reserve: Acute Estuarine/Marine Fish Toxicity. Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.1025 (72-3b)	Held in reserve: Acute Estuarine/Marine Mollusk (Oyster) Toxicity (Shell Deposition). Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.1035 (72-3c)	Held in reserve: Acute Estuarine/Marine Mysid (Shrimp) Toxicity. Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.1300 (72-4a)	Held in reserve: Daphnid Chronic Toxicity. Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.1350 (72-4b)	Held in reserve: Mysid (Shrimp) Chronic Toxicity. Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.1400 (72-4d)	Held in reserve: Early Life-Stage Estuarine Fish Toxicity. Held in reserve pending the results of environmental fate studies establishing the persistence of toxic degradates.
850.5000	When protocols have been defined, toxicity testing of endocrine disrupting potential of ODM is required.

Additional field trial data depicting residues of ODM/ODMS in/on **sweet corn** (stover, and kernal and cob with husks removed) (K+CWHR) are required to provide both adequate geographic representation and a greater number of results by which to judge possible variability.

Sample storage intervals and conditions for all residue data submitted in support of tolerances must be supplied. In addition, **storage stability** data are needed for processed

commodities and livestock commodities.

No field trial data are available for **sorghum stover**. Geographically representative field trial data reflecting the maximum registered application rate must be submitted for sorghum stover before the reregistration requirements for magnitude of the residue in/on sorghum stover can be considered fulfilled.

Additional field trial data depicting residues of ODM and ODMS in/on **alfalfa forage and hay** are required to provide adequate geographic representation. In addition, because there is a registered use for ODM on alfalfa grown for seed, data are required for **alfalfa seed**.

No additional data are required for **cottonseed**. In lieu of conducting additional field trials depicting ODM residues of concern in/on cotton harvested 14 days following the last of three foliar applications at 0.5 lb ai/A, the registrant intends to amend the 2 lb/gal EC (EPA Reg. No. 10163-220) product label to allow only two applications per season at 0.5 lb ai/A. In addition, the registrant must remove the restriction against the grazing or feeding gin trash to dairy or meat animals from the product label; the Agency considers such restrictions to be impractical.

The Agency currently recognizes **cotton gin byproducts** (commonly called gin trash which include the plant residues from ginning cotton consisting of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt) as a RAC (Table 1, OPPTS 860.1000). Data depicting the magnitude of ODM residues of concern in/on cotton gin byproducts following application(s) of a representative formulation according to the maximum registered use patterns are required. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. A minimum of three field trials for each type of harvesting (stripper and mechanical picker) are required, for a total of six field trials. An appropriate tolerance for this RAC should be proposed once acceptable data have been submitted and evaluated.

Due to risks of concern in handling and/or harvesting lettuce, all of the Registrant's ODM end-use products reformulated from the Registrant's ODM end-use products produced after December 31, 2003 shall bear labeling requiring a 14-day restricted entry interval (REI) for use on lettuce if the products are labeled for such unless prior to that date EPA has determined that the 3-day REI may be maintained. The Registrant has agreed to submit to EPA by October 31, 2003 a Dislodgeable Foliar Residue Dissipation study (OPPTS guideline number 875.2100, OPP guideline number 132-1), of its Metasystox-R Spray Concentrate, 25% a.i. emulsifiable concentrate (Reg. No. 10163-220) on lettuce. Provided that the Registrant submits this study by October 31, 2003, EPA agrees to evaluate the data, as well as any other data that the Registrant voluntarily submits by October 31, 2003 to determine whether to maintain, indefinitely or for a definite duration , the 3-day REI for use on lettuce.

The persistent metabolites ODM thiol and 2-(ethyl sulfonyl) ethane sulfonic acid were formed at significant (>10% levels) in the hydrolysis and aerobic soil metabolism studies and did

not appear to degrade. These metabolites may impact water quality and their ecological impact is unknown. These data will be used as inputs into surface water models in order to estimate surface water concentrations and for aquatic ecological risk assessment. Therefore, the Agency requests that the registrant conduct aerobic metabolism studies for each of these metabolites.

Residue analytical method (860.1340 (Guideline 171-4)): the requirement for method validation data in conjunction with proposals for revised tolerances for corn forage, field corn grain, and walnuts at the revised tolerance levels is no longer outstanding. Based on HED's review of available residue field trial data, the existing tolerances for residues of oxydemeton-methyl and its sulfone metabolite in walnuts (0.3 ppm), corn grain (0.5 ppm) , and corn forage/fodder (3 ppm), have been reassessed at lower levels of 0.05 ppm, 0.05 ppm, and 1 ppm, respectively. Although HED has previously required additional method validation data for these commodities showing recovery of residues of concern from samples fortified at the reassessed tolerance levels, Gowan has indicated (letter dated November 27, 1998) it does not wish to generate the additional analytical data necessary to support these lower tolerances.

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. Registrant responses are under review.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. All registrants need to submit applications for amended registration. The MP labeling should conform to the specifications in Table 30 at the end of this section.

B. End-Use Products

1. Additional Product 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.

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 Table 30 at the end of

this section. All registrants need to submit applications for amended registration.

C. Existing Stocks

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

The Agency has determined that the registrant may distribute and sell ODM 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 Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

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

Table 29. Summary of Labeling Changes for Oxydemeton-Methyl

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "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
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations 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 Environmental Protection Agency."	Directions for Use

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"Restricted Use Pesticide." "Due to reproductive effects." "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. Direct supervision for this product is defined as the certified applicator being physically present during mixing, loading, equipment repair and equipment cleaning. Certified applicators must ensure that all persons involved in these activities under their direct supervision are informed of the precautionary statements."	Top front panel
PPE Requirements Established by the IRED[1] for liquid products excluding direct injectables	"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 using engineering controls also must wear: Chemical-resistant gloves, and Chemical-resistant apron See engineering controls for additional requirements. Handlers performing tasks, such as cleaning equipment or spill clean-up, for which engineering controls are not feasible must wear: Coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical-resistant footwear plus socks, Chemical-resistant apron, if exposed to the concentrate"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the IRED for liquid formulations packaged in capsules for direct injection to trees	"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. Applicators and other handlers must wear: Long sleeved shirt and long pants, Shoes plus socks, Chemical-resistant gloves, Chemical-resistant apron, Chemical-resistant footwear, and Protective eyewear.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
Engineering Controls for liquid formulations not packaged in water soluble bags or as capsules for direct injection into trees	"Engineering Controls Mixers and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], and must: -- wear the personal protective equipment required for mixers/loaders using engineering controls, – wear protective eyewear if the system operates under pressure, and -- be provided chemical-resistant footwear and must have it immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown. 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 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 treated area, coveralls, chemical-resistant gloves, and chemical-resistant footwear; -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." 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)]. When entering or leaving an aircraft contaminated with pesticide residues, pilots must wear chemical-resistant gloves and must store used gloves in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Amended Labeling Language	Placement on Label
Engineering Controls for products packaged in water soluble bags	"Engineering Controls Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must : -- wear the personal protective equipment required for mixers/ loaders using engineering controls, and -- be provided chemical-resistant footwear and must have it immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown. 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, ground 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 treated area, coveralls, chemical-resistant gloves, and chemical-resistant footwear, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab. 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)]. When entering or leaving an aircraft contaminated with pesticide residues, pilots must wear chemical-resistant gloves and must store used gloves in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	"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 toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area." Refer to directions for use for required buffer zones around permanent water bodies.	Precautionary Statements immediately following the User Safety Recommendations
Environmental Hazards for liquid formulations packaged in capsules for direct injection to trees	"This pesticide is toxic to fish and wildlife. Do not contaminate water by cleaning of equipment or disposal of wastes."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval (REI) for all liquid formulations not packaged as capsules for direct injection into trees.	"Do not enter or allow entry into treated areas during the restricted entry interval (REI). The REI for each crop is listed in the directions for use associated with each crop."	Directions for Use, Agricultural Use Requirements Box

Description	Amended Labeling Language	Placement on Label
Early Entry Personal Protective Equipment established by the IRED for all liquid formulations not packaged as capsules for direct injection into trees.	"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)"	Directions for Use, Agricultural Use Requirements Box
Notification Requirements for all liquid formulations not packaged as capsules for direct injection into trees.	"ODM is a double notification chemical. Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Near the beginning of the Directions for Use in General Precautions and Restrictions
General Application Restriction for all liquid formulations not packaged as capsules for direct injection into trees	Not for Use in Greenhouses	Near the beginning of the Directions for Use in General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	*Labels must be amended to reflect the following application restrictions which supercede or are in addition to restrictions currently on labels:* **Alfalfa grown for seed** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application. Minimum of 14 days between applications. Permitted application methods: aerial, chemigation, and groundboom Mechanical harvesting is required Apply in early morning or evening to avoid exposure to bees. Chaff from seed crop may be used for feed or forage, but the cut green crop may not be used for these purposes. **Restricted entry interval (REI) = 15 days**. **Preharvest interval (PHI) = 21 days**." **Beans, lima** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application. Minimum of 7 days between applications. Permitted application methods: aerial, chemigation, and groundboom. Do not graze or cut treated vines for feed or forage within 21 days of application. **Restricted entry interval (REI) = 17 days**. **Preharvest interval (PHI) = 21 days**." **Beets, sugar** "Limited to 1 application per crop cycle at 0.5 lbs ai/A per application. Permitted application methods: aerial, chemigation, and groundboom. Mechanical harvesting is required. Do not harvest beets or use beet tops for feed or forage within 30 days of application. **Restricted entry interval (REI) = 30 days**. **Preharvest interval (PHI) = 30 days**."	Directions for Use, Under Application Instructions for Each Cro

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Broccoli, broccoli raab (CA SLN), cauliflower** "Limited to 2 applications per crop cycle at 0.5 lbs/ai/A per application Minimum 7 days between applications Permitted application methods: aerial, chemigation, and groundboom **Restricted-entry interval (REI) = 7 days.** In addition to the early entry exceptions allowed by the Worker Protection Standard, you may enter or allow workers to enter treated areas to irrigate immature plants 3 days following application as long as the worker wears long pants, long sleeved shirt, and shoes plus socks. Notify workers of this exception. **Preharvest interval (PHI) = 7 days**." **Brussels sprouts** "Limited to 3 applications per crop cycle of 0.5 lbs ai/A per application. Minimum of 7 days between applications. Permitted application methods: aerial, chemigation, and groundboom. **Restricted-entry interval (REI) = 7 days**. In addition to the early entry exceptions allowed by the Worker Protection Standard, you may enter or allow workers to enter treated areas to irrigate immature plants 3 days following application as long as the worker wears long pants, long sleeved shirt, and shoes plus socks. Notify workers of this exception. **Preharvest interval (PHI) = 10 days**." **Cabbage (including tight-heading varieties of Chinese cabbage)** "Limited to 3 applications per crop cycle at 0.75 lbs ai/A per application. Minimum of 7 days between applications. Permitted application methods: aerial, chemigation, and groundboom **Restricted-entry interval (REI) = 7 days**. In addition to the early entry exceptions allowed by the Worker Protection Standard, you may enter or allow workers to enter treated areas to irrigate immature plants 3 days following application as long as the worker wears long pants, long sleeved shirt, and shoes plus socks. Notify workers of this exception. **Preharvest interval (PHI) = 7 days**."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Carrots grown for seed (ID SLN)** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application. Minimum of 14 days between applications. Use on carrots grown for seed is permitted only in Idaho (through a 24C registration). Permitted application methods: aerial and groundboom. Mechanical harvesting is required No portion of the treated field, including, but not limited to, seed, seed screenings, chaff, or root may be used for human or animal consumption. Producers of carrot seed who use this product, or cause the product to be used in fields they operate, are required to inform, in writing, conditioners receiving seed produced on the fields treated with this product. The producer is required to provide a copy of the labeling to the conditioner. Processed seed must be labeled "Not for human or animal consumption" at the processing plant. The processor must dispose of all seed screenings in such a way that they cannot be distributed or used for food or feed. This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area. **Restricted entry interval (REI) = 15 days**. **Preharvest interval (PHI) = 21 days**." **Christmas trees (field grown or in outdoor nurseries)** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application. Minimum of 7 days between applications. Use prohibited in California. Permitted application methods: aerial and airblast. Use of handheld application equipment is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Mechanical harvesting is required **Restricted entry interval (REI) = 18 days**. Retail sale of treated plants is prohibited for 18 days after application."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Citrus: oranges, lemons, and grapefruit (FL SLN only)** "Limited to 2 applications per crop cycle at 0.375 lbs ai/A per application. Minimum of 14 days between applications. Use on citrus is permitted only in Florida. Application by trunk-directed microjet sprinklers only. All other application methods are prohibited, including groundboom, airblast, and aerial. **Restricted-entry interval (REI) = 3 days**. **Preharvest interval (PHI) = 7 days**." **Clover grown for seed** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application. Minimum of 14 days between applications. Permitted application methods: aerial, chemigation, and groundboom Mechanical harvesting is required. Apply in early morning or evening to avoid exposure to bees. **Restricted entry interval (REI) = 15 days**. **Preharvest interval (PHI) = 21 days**." **Corn, sweet** "Limited to 2 applications per crop cycle at 0.5 lbs ai/A per application Minimum of 7 days between applications Permitted application methods: aerial, chemigation, and groundboom Use on sweet corn is permitted only in states west of the Rocky Mountains, including Hawaii. **Restricted entry interval (REI) = 13 days.** Prohibition: do not hand harvest or allow workers to perform hand harvesting tasks for 26 days after application. Prohibition: hand detasseling is prohibited. Notify workers of these prohibitions. Do not harvest corn fodder or use for forage within 26 days of application. **Preharvest interval (PHI) = 26 days**."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Cotton** "Limited to 1 application per crop cycle at 0.5 lbs ai/A per application Use on cotton is permitted only in Arizona and California. Permitted application methods: chemigation and groundboom. Aerial application is prohibited. Do not graze or feed gin trash to dairy or meat animals. **Restricted entry interval (REI) = 7 days**. **Preharvest interval (PHI) = 14 days**." **Cucurbits: cucumbers, pumpkins, summer squash, winter squash, watermelons, muskmelons (canteloupes), other melons** "Limited to 1 application per crop cycle at 0.5 lbs ai/A per application Permitted application methods: aerial, chemigation, and groundboom. **Restricted entry interval (REI) is 14 days**. **Preharvest interval (PHI) = 14 days**." **Filberts** "Limited to 1 application per crop cycle at 0.5 lbs ai/acre per application. Use on filberts is permitted only in Oregon and Washington. Permitted application method: airblast. Aerial application and chemigation are prohibited. Use of handheld application equipment (including paintbrush) is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Mechanical harvesting is required. Grazing or feeding of cover crops to livestock is prohibited. **Restricted entry interval (REI) = 17 days**. **Preharvest interval (PHI) = 116 days**."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Fruit trees, non-bearing: apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces** "Limited to 2 applications per crop cycle at 0.375 lbs ai/acre per application. Minimum of 7 days between applications. Permitted application method: airblast. Aerial application and chemigation is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not apply to trees that will bear fruit within the next 12 months. **Restricted entry interval (REI) = 16 days**. Retail sale of treated plants is prohibited for 16 days after application." **Grapes, non-bearing** "Limited to 2 applications per crop cycle at 0.375 lbs ai/acre per application. Minimum of 7 days between applications. Permitted application method: airblast. Aerial application and chemigation is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not apply to vines that will bear fruit within the next 12 months. **Restricted entry interval (REI) = 18 days**. Prohibition: leaf pulling, training, tying, girdling, and cane turning are prohibited. Notify workers of this prohibition. Retail sale of treated plants is prohibited for 18 days after application."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Lettuce, head** "Limited to 3 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 7 days between applications. Permitted application methods: aerial, chemigation, and groundboom. **Restricted entry interval (REI) = 3 days.** Prohibition: hand harvesting is prohibited until 14 days following application. Notify workers of this prohibition. **Preharvest interval (PHI) = 21 days for all of US, except Arizona and California** **= 28 days for Arizona only** **= 28 days for California fall and winter head lettuce** = **14 days for California spring and summer head lettuce if only 1 application** = **21 days for California spring and summer head lettuce if 2 applications,** = **28 days for California spring and summer head lettuce if 3 applications**."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Onions, Spanish (bulb) (Sec. 3)** "Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 14 days between applications. Permitted application methods: aerial,chemigation, and groundboom Use permitted only in states west of the Mississippi River. **Restricted-entry interval (REI) is 10 days**. Prohibition: hand weeding, hand thinning and hand harvesting are prohibited following an application of this product. Notify workers of this prohibition. **Preharvest Interval (PHI) = 30 days**." **Onions, Spanish (bulb) (NY SLN)** "Note: this label permits use in New York State, in spite of the statement on the Master label limiting use to states west of the Mississippi River. Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 14 days between applications. Permitted application methods: aerial, chemigation, and groundboom **Restricted-entry interval (REI) is 10 days**. Prohibition: hand weeding, hand thinning and hand harvesting are prohibited following an application of this product. Notify workers of this prohibition. **Preharvest Interval (PHI) = 30 days**." **Ornamentals: flowers grown for cutting (CA SLN); flowers grown for drying (CA SLN)** "Limited to 2 applications per crop cycle at 0.375 lbs ai/A per application. Minimum of 7 days between applications. For use only in commercial nurseries. Outdoor use only. Use in greenhouses is prohibited. Permitted application methods: groundboom and airblast. Use of handheld application equipment is prohibited. Aerial application is prohibited. **Restricted entry interval (REI) = 19 days**. Retail sale of treated plants is prohibited for 19 days after application."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Ornamentals: field-grown nursery stock** "Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 7 days between applications. Permitted application methods: aerial, airblast, and groundboom**.** Use of handheld application equipment is prohibited. For use only on seedling trees and non-bearing fruit trees in commercial nurseries. Outdoor use only. Use in greenhouses is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Use is prohibited in California. **Restricted entry interval (REI) = 10 days**. Retail sale of treated plants is prohibited for 10 days after application." **Ornamentals: field-grown bulbs (WA SLN)** "Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 7 days between applications. Mechanical harvesting required. For use only in commercial nurseries. Outdoor use only. Use in greenhouses is prohibited. Permitted application methods: airblast and groundboom. Use of handheld application equipment is prohibited. Aerial application prohibited. **Restricted entry interval (REI) = 19 days**. Retail sale of treated bulbs is prohibited for 19 days after application." **Peppermint and spearmint** "Limited to 2 applications per crop cycle at 0.75 lbs ai/acre per application. Minimum of 10 days between applications. Permitted application methods: chemigation and groundboom. Aerial application is prohibited. Mechanical harvesting is required.	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Safflower** "Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 7 days between applications. Permitted application methods: aerial, chemigation, and groundboom. Use on safflower is permitted only in California and Arizona. Mechanical harvesting is required. **Restricted entry interval (REI) = 15 days**. **Preharvest interval (PHI) = 7 days**." **Sorghum** "Limited to 2 applications per crop cycle at 0.5 lbs ai/acre per application. Minimum of 7 days between applications. Use on sorghum is permitted only in Colorado, Kansas, Oklahoma, and Texas. Do not use on sweet sorghum. Permitted application methods: aerial, chemigation, and groundboom. Mechanical harvesting is required. **Restricted entry interval (REI) = 14 days**. **Preharvest interval (PHI) = 45 days for grain and 21 days for cutting for forage.** **Do not allow grazing for 21 days**."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations not packaged as capsules for direct injection into trees	**Strawberries (SLNs for OR and WA)** "Limited to 2 applications per crop cycle: one pre-bloom application at 0.5 lbs ai/acre and one post-harvest application of 0.5 lbs ai/acre to plants growing in fields. Do not apply to fruit. Minimum of 7 days between applications. Application by groundboom only. Aerial application and chemigation are prohibited. **Restricted entry interval (REI) = 15 days**." **Walnuts** "Limited to 1 application per crop cycle at 0.375 lbs ai/acre per application. Permitted application method: airblast. Aerial and chemigation applications are prohibited. Mechanical harvesting is required. Hand harvesting is prohibited. Grazing or feeding cover crops to livestock is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. **Restricted entry interval (REI) = 17 days**. **Preharvest interval (PHI) = 30 days** ."	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations packaged as capsules for direct injection into trees	*Labels must be amended to reflect the following application restrictions which supercede or are in addition to restrictions currently on labels:* "Use Restrictions: > Applicators shall not leave capsules unattended while in use. Remove capsules promptly after treatment. > Do not inject trees that are less than two inches in diameter. > Do not inject trees within two weeks of any other spray or soil chemical treatment. > Do not treat trees that are suffering from stress such as lack of moisture or herbicide damage. > Do not inject this product into trees that will bear edible nuts within one full following treatment. Direct injection capsules are limited to use in the following trees: Cedar, Cottonwood, Cypress, Douglas fir, Elms, Juniper, Pines (except piñon), Redwood, Spruce, Walnuts and Pecans (non-bearing), and Willow." In addition to the restrictions for direct injectables listed in this table, retain all application restrictions on current product labels, unless those restrictions contradict those listed in this table.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Application Restrictions for all liquid formulations packaged as capsules for direct injection into trees	**Note to Registrants:** **If the product is for use on trees being grown for commercial or research use, add** the Agricultural Use Requirements box to the product label as required for products within the scope of the Worker Protection Standard for Agricultural Pesticides (see PR Notice 93-7 for instructions) ***or*** **If the product is NOT intended for use on trees being grown for commercial or research purposes, add the following statement: "**Not for use on trees being grown for sale or other commercial use, or for commercial seed production, or for the production of timber or wood products, or for research purposes."	Near the Beginning of the Directions for Use

Description	Amended Labeling Language	Placement on Label
Spray Drift Restrictions for Outdoor Products Applied as a Liquid	**"SPRAY DRIFT MANAGEMENT"** "Avoiding spray drift is the responsibility of the applicator. The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions." "Do not apply within 150 feet by air or 100 feet by ground of an unprotected person or occupied building." *For ground boom applications:* "For ground boom applications, do not apply within 25 feet of any area managed for wildlife or wildlife habitat." "Apply with nozzle height no more than 2 feet above the ground or crop canopy, and when the wind speed is 10 mph or less at the application site as measured by an anemometer. Use a coarse or coarser spray (ASAE definition 572) for standard nozzles, or a volume median diameter (VMD) of 385 microns or greater for spinning atomizer nozzles." *For overhead chemigation:* "For overhead chemigation, do not apply within 25 feet of any area managed for wildlife or as wildlife habitat." "Apply only when the wind speed is 10 mph or less."	Directions for Use in General Precautions and Restrictions

Spray Drift Restrictions for Outdoor Products Applied as a Liquid	*For airblast applications:* "For orchard and other airblast applications, do not apply within 50 feet of any area managed for wildlife or wildlife habitat." "Do not direct spray above trees and vines, and turn off outward pointing nozzles at row ends and when spraying the outer 2 rows. Apply only when the wind speed is 3-10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side." *For aerial applications:* "For aerial applications, do not apply within 100 feet of any area managed for wildlife or wildlife habitat." "The boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Apply only when the wind speed is 3-10 mph as measured by an anemometer. Use a coarse or coarser spray for standard nozzles (ASAE definition 572), or a volume median diameter (VMD) of 385 microns or greater for spinning atomizer nozzles. If the application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "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 more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Instructions in the Labeling 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 OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4:00 pm.

The docket initially contained preliminary risk assessments and related documents as of September 10, 1998. 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 July 7, 1999. The docket now contains revised risk assessments and related documents and public comments submitted during Phase 5.

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

Appendix A. Table of ODM Use Patterns Eligible for Reregistration

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Crop Uses						
FOOD/FEED USE SITES ELIGIBLE FOR REREGISTRATION						
Alfalfa grown for seed						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220] [NV940005]	0.5 lb/A	2	14	21	Applications may be made in a minimum of 1 gal/A. Chaff from seed crop may be used for feed or forage, but the cut green crop may not be used for these purposes. Mechanical harvesting required. Apply in early morning or evening to avoid exposure to bees.
Beans, lima						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	21	Applications may be made in a minimum of 4 gal/A. Do not graze or cut treated vines for feed or forage within 21 days of application.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Beets, sugar						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	NA	30	Applications may be made in a minimum of 1 gal/A. Mechanical harvesting is required. Do not harvest beets or use beet tops for feed or forage within 30 days of application.
Broccoli						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	7	Applications may be made in a minimum of 1 gal/A.
Broccoli raab						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [CA950002]	0.5 lb/A	2	7	7	Use on broccoli raab is permitted only in California (through a 24C registration). Applications may be made in a minimum of 5 gal/A when applying by aircraft.
Brussels sprouts						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	3	7	10	Applications may be made in a minimum of 1 gal/A.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Cabbage (including tight-heading varieties of Chinese cabbage)						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.75 lb/A	3	7	7	Applications may be made in a minimum of 1 gal/A.
Carrots grown for seed						
Foliar application Aerial Groundboom	2 lb/gal EC [ID-010011]	0.5 lb/A	2	14	21	Use on carrots grown for seed is permitted only in Idaho (through a 24C registration). Applications may be made in a minimum of 1 gal/A. No portion of the treated field, including, but not limited to, seed, seed screenings, chaff, or root may be used for human or animal consumption. Processed seed must be labeled "Not for human or animal consumption." Mechanical harvesting required. Do not apply this product while bees are actively visiting the treatment area.
Cauliflower						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	7	Applications may be made in a minimum of 1 gal/A.
Clover grown for seed						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	14	21	Applications may be made in a minimum of 1 gal/A. Chaff from seed crop may be used for feed or forage, but the cut green crop may not be used for these purposes. Mechanical harvesting required. Apply in early morning or evening to avoid exposure to bees.
Corn, sweet						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	26	Applications may be made in a minimum of 1 gal/A. Use on sweet corn is permitted only in states west of the Rocky Mountains, including Hawaii. Do not harvest corn fodder or use for forage within 26 days of application. Do not hand harvest or allow workers to perform hand harvesting tasks for 26 days after application. Hand detasseling is prohibited.
Cotton						
Foliar application Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Use on cotton is permitted only in Arizona and California. Applications may be made in a minimum of 1 gal/A. Aerial application is prohibited. Do not graze or feed gin trash to dairy or meat animals.
Cucumbers						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
Filberts						
Foliar application Airblast	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	116	Use on filberts is permitted only in Oregon and Washington. Aerial application and chemigation are prohibited. Use of handheld application equipment (including paintbrush) is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Mechanical harvesting is required. Grazing or feeding of cover crops to livestock is prohibited.
Fruit Trees, non-bearing: apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Airblast	2 lb/gal EC [10163-220]	0.375 lb/A	2	7	N/A	Apply specified dosage in 100 gallons of water on non-bearing trees, but do not exceed 300 gallons of finished spray per application. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Aerial application and chemigation is prohibited. Application by airblast sprayer only. Do not apply to vines that will bear fruit within the next 12 months. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows.
Grapefruit						
Trunk-directed microjet sprinklers	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	14	7	Use on grapefruit is permitted only in Florida (through a 24C registration for grapefruit, lemons and oranges). Application by trunk-directed microjet sprinklers only. All other application methods are prohibited, including groundboom, airblast, and aerial.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Grapes, non-bearing						
Foliar application Airblast	2 lb/gal EC [10163-220]	0.375 lb/A	2	7	Not applicable	Aerial application and chemigation is prohibited. Application by airblast sprayer only. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not apply to vines that will bear fruit within the next 12 months. Retail sale of treated plants is prohibited for 18 days after application. Leaf pulling, training/tying, girdling, and cane turning is prohibited after use of this product.
Lemons						
Trunk-directed microjet sprinklers	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	14	7	Use on lemons is permitted only in Florida (through a 24C registration for grapefruit, lemons and oranges). Application by trunk-directed microjet sprinklers only. All other application methods are prohibited, including groundboom, airblast, and aerial.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Lettuce, head						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	3	7	21 (also see "Use Limitations")	Allow only weeding with a hoe. Applications may be made in a minimum of 1 gal/A. A 21-day PHI is in effect, except in AZ (all crops) and CA (fall and winter crops) where a PHI of 28 days has been established. In CA (spring and summer crops), PHIs of 14, 21, and 28 days have been established following 1, 2, or 3 applications, respectively.
Melons [including muskmelons (canteloupes) and other melons]						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
Onions, Spanish (bulb)						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220] [NY030002]	0.5 lb/A	2	14	30	Use on Spanish onions (bulb) is permitted only in states west of the Mississippi River. Use in NY state is permitted through a 24C registration). Prohibition: hand weeding, hand thinning and hand harvesting are prohibited following an application of this product. Notify workers of this prohibition. Apply specified dosage per acre in sufficient water for complete coverage but not less than 10 gallons per acre.
Oranges						
Trunk-directed microjet sprinklers	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	14	7	Use on oranges is permitted only in Florida (through a 24C registration for grapefruit, lemons and oranges). Application by trunk-directed microjet sprinklers only. All other application methods are prohibited, including groundboom, airblast, and aerial.
Peppermint						
Foliar application Groundboom Chemigation	2 lb/gal EC [10163-220]	0.75 lb/A	2	10	14	Two applications may be made in a minimum of 20 gal/A with a 10 day retreatment interval. Mechanical harvesting is required.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Pumpkins						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
Safflower						
Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	7	Mechanical harvesting is required. Use restricted to CA and AZ.
Seed orchard trees						
Tree injection only	0.1 oz/3 ml EC injector [MT960002]	One 3 ml injector unit per 6 inches of tree circumference	2	7	Not applicable	Must use pre-packaged injector unit with 50% liquid concentrate
Sorghum						
Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	45 days for grain 21 days for cutting for forage	Use sorghum is permitted only in Colorado, Kansas, Oklahoma, and Texas. Do not use on sweet sorghum. Mechanical harvesting is required. Do not allow grazing for 21 days.
Spearmint						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Groundboom Chemigation	2 lb/gal EC [10163-220]	0.75 lb/A	2	10	14	See "Peppermint."
Squash, summer						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
Squash, winter						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
Strawberries (pre-bloom and postharvest)						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Groundboom	2 lb/gal EC [OR940053] [WA950004] [WA030002]	0.5 lb/A	2	7	Not applicable	Use limited to OR and WA. Applications may be made in a minimum of 1 gal/A. Application to fruit is prohibited. Two applications may be made each year, one application prebloom and one post-final harvest. The label for SLN No. WA950004 states that Metasystox-R may not be used in accordance with this labeling after 01/25/96. Do not apply to fruit. Aerial application and chemigation are prohibited.
Walnuts						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Airblast	2 lb/gal EC [10163-220]	0.375 lb/100 gal [400 gal of finished spray per acre]	1	Not applicable	30	Applications may be made in 100 gallons of water; but do not exceed 400 gallons of finished spray per acre per application. Low-pressure, low-volume applications are permitted using aerial equipment with increased concentrations of the pesticide in a minimum of 1 gal/A. Aerial applications and chemigation are prohibited. Mechanical harvesting is required. Grazing or feeding cover crops to livestock is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows.
Watermelons						
Foliar application Aerial Chemigation Groundboom	2 lb/gal EC [10163-220]	0.5 lb/A	1	Not applicable	14	Applications may be made in a minimum of 1 gal/A.
NON-FOOD/NON-FEED USE SITES ELIGIBLE FOR REREGISTRATION						
Christmas trees (field grown or in outdoor nurseries)						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Foliar application Aerial Airblast	2 lb/gal EC [10163-220]	0.5 lb/A	2	7	Not applicable	Use prohibited in California. Use of handheld application equipment is prohibited. Mechanical harvesting is required Retail sale of treated plants is prohibited for 18 days after application.
Tree injection	0.1 oz/3 ml EC injector [64014-9] [7946-10]	One 3 ml injector unit per 6 inches of tree circumference	Not stated	Not stated	Not applicable	Do not inject trees less than two inches in diameter. Do not inject trees within two weeks of any other spray or soil chemical treatment. Do not treat trees that are suffering from stress such as lack of moisture or herbicide damage. Applicators shall not leave capsules unattended while in use. Remove capsules promptly after treatment. Do not inject this product into trees that will bear edible nuts within one full year following treatment.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Ornamentals: flowers grown for cutting; flowers grown for drying						
Groundboom Airblast	2 lb/gal EC [CA010003] [CA950005]	0.375 lb/A	2	7	Not applicable	Outdoor use only. Use in greenhouses is prohibited. Use of handheld application equipment is prohibited. Aerial application is prohibited. Retail sale of treated plants is prohibited for 19 days after application.
Ornamentals: field-grown nursery stock						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Aerial Airblast Groundboom	2lb/gal EC [10163-220]	0.5 lb/A	2	7	Not applicable	Use of handheld application equipment is prohibited, other than for tree injection. For use only on seedling trees and non-bearing fruit trees in commercial nurseries. Outdoor use only. Use in greenhouses is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Use is prohibited in California. Retail sale of treated plants is prohibited for 10 days after application.

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Tree injection	0.1 oz/3 ml EC injector [64014-9] [7946-10]	One 3 ml injector unit per 6 inches of tree circumference	Not stated	Not stated	Not applicable	Use of handheld application equipment is prohibited, other than for tree injection. For use only on seedling trees and non-bearing fruit trees in commercial nurseries. Outdoor use only. Use in greenhouses is prohibited. Use is prohibited in California. Retail sale of treated plants is prohibited for 10 days after application. Applicators shall not leave capsules unattended while in use. Remove capsules promptly after treatment. Do not inject this product into trees that will bear edible nuts within one full year following treatment.
Ornamentals: field-grown bulbs						

Application Type Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps. per Crop Cycle	Minimum Retreatment Interval (days)	Pre-harvest Interval (PHI)	Restrictions/Comments
Airblast Groundboom	2 lb/gal EC [WA010005] [WA030001]	0.5 lb/A	2	7	Not applicable	Mechanical harvesting required. For use only in commercial nurseries. Outdoor use only. Use in green houses is prohibited. Use of handheld equipment is prohibited. Aerial application is prohibited. Retail sale of treated bulbs is prohibited for 19 days after application.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

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Data Supporting Guideline Requirements for the Reregistration of Oxydemeton-Methyl

REQUIREMENT			USE PATTERN	MRID CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	Old Guideline Number	Guideline Name		MRID
830.1550	61-1	Product Identity and Composition	All	40620301
830.1600	61-2A	Starting Materials & Manufacturing. Process	All	40620301, 42951201
830.1670	61-2B	Formation of Impurities	All	40620301, 42951201
830.1700	62-1	Preliminary Analysis	All	40202601, 40202602, 40202603,40877101, 42951202
830.1750	62-2	Certification of limits	All	40202601, 40877101
830.1800	62-3	Analytical Method	All	40202601, 40877101, 42951202
830.6302	63-2	Color	All	40784901
830.6303	63-3	Physical State	All	40784901
830.6304	63-4	Odor	All	40784901, 42951203
830.7050	None	UV/Visible Absorption	All	Data gap
830.7200	63-5	Melting Point	All	N/A
830.7220	63-6	Boiling Point		40784901, 42951203
830.7300	63-7	Density	All	40784901, 42951203
830.7840 830.7860	63-8	Solubility	All	40784901, 40784903
830.7950	63-9	Vapor Pressure	All	40784901, 40784902, 42951203
830.7370	63-10	Dissociation Constant	All	40784901, 42951203
830.7550	63-11	Octanol/Water Partition Coefficient	All	40501901, 40784901
830.7000	63-12	pH	All	40784901, 42951203

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
830.6313	63-13	Stability	All	40784901
830.6314	63-14	Oxidizing/Reducing Action	All	40784901, 42951203
830.6315	63-15	Flammability	All	40784901, 42951203
830.6316	63-16	Explodability	All	40784901
830.6317	63-17	Storage Stability	All	40784901, 42951202, 42951203
830.7100	63-18	Viscosity	All	40784901, 42951203
830.6319	63-19	Miscibility	All	40784901
830.6320	63-20	Corrosion characteristics	All	40784901, 42951203
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	A,B	00060636, 00160000
850.2200	71-2A	Avian Dietary Toxicity - Quail	A,B	00022923
850.2200	71-2B	Avian Dietary Toxicity - Duck	A,B	00022923
850.2400	71-3	Wild Mammal Toxicity	A,B	40779801
850.2300	71-4A	Avian Reproduction - Quail	A,B	40747202
850.2300	71-4B	Avian Reproduction - Duck	A,B	40747201
	71-5A	Simulated Terrestrial Field Study	A,B	00060638
850.1075	72-1A	Fish Toxicity Bluegill	A,B	00003503, 00060639, 00074349, Data gap for TEP
850.1075	72-1C	Fish Toxicity Rainbow Trout	A,B	00074349, 00003503
850.1010	72-2A	Invertebrate Toxicity	A,B	40286801, 05017538, 00097842,
850.1010	72-2B	Invertebrate Toxicity - TEP	A,B	00158213, 00074350
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	A,B	Reserved pending fate studies for persistent degradates.
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A,B	Reserved pending fate studies for persistent degradates.
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp	A,B	Reserved pending fate studies for persistent degradates.

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
	72-3E	Estuarine/Marine Toxicity - fiddler crab - TEP	A,B	00074348
	72-3F	Estuarine/Marine Toxicity - Shrimp - TEP	A,B	00074348
850.1300	72-4A	Fish- Early Life Stage	A,B	41054501, Reserved pending fate studies for persistent degradates.
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A,B	40986601, Reserved pending fate studies for persistent degradates.
850.1400	72-4D	Early-life Stage Estuarine Fish	A,B	Reserved pending fate studies for persistent degradates.
850.4025	121-1	Non-target Terrestrial Plant Phytotoxicity	A,B	N/A
850.4400	123-2	Aquatic Plant Growth	A,B	N/A
850.3020	141-1	Honey Bee Acute Contact	A,B	00036935, 00074486, 05001991, 05002083
850.3030	141-2	Honey Bee Toxicity of Residues on Foliage	A,B	00060628
850.5000		Endocrine disrupting potential	A,B	When protocols have been defined, toxicity testing of endocrine disrupting potential of ODM will be required.
	TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity - Rat	A,B	40779801, 40779803
870.1200	81-2	Acute Dermal Toxicity - Rat	A,B	00143350, 40779804
870.1300	81-3	Acute Inhalation Toxicity - Rat	A,B	40779805
870.2400	81-4	Primary Eye Irritation - Rabbit	A,B	00151801, 40779806
870.2500	81-5	Primary Dermal Irritation - Rabbit	A,B	00151801, 40779807
870.2600	81-6	Dermal Sensitization - Guinea pig	A,B	40779802
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A,B	0014615, 4086001
		Subacute (14 Day) Toxicity Studies - Rat	A,B	40499302, 40499303, 40499304
		Subchronic Delayed Neurotoxicity - Hen	A,B	41348201
		90-Day Brain Cholinesterase Study - Rat	A,B	40865203, 44141301
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	A,B	0015186, 40865201, 40865202, 40865203, 44141301

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
870.4100	83-1B	Chronic Feeding Toxicity -Non-Rodent	A,B	00151805, 41082201, 41980801, 43454201
870.4200	83-2A	Oncogenicity - Rat	A,B	00151806, 40865201, 40865202, 40865203, 44141301
870.4200	83-2B	Oncogenicity - Mouse	A,B	42576601
870.3700	83-3A	Developmental Toxicity - Rat	A,B	00146812, 00158342
870.3700	83-3B	Developmental Toxicity - Rabbit	A,B	00146989, 00153606, 42859901
870.3800	83-4	2-Generation Reproduction - Rat	A,B	41461901, 424990101, 42500101, 00260513, 00256926
		Male Fertility Studies	A,B	40463001, 41834003, 42499001, 42500101
870.5140	84-2A	Gene Mutation	A,B	00146091, 00146102, 42136901
870.5375	84-2B	Structural Chromosomal Aberration	A,B	40628201, 40658502, 40534501, 40988001, 41236301, 41667701
870.5915	84-4	Other Mutagenic Mechanisms	A,B	40658501, 40658503, 43776101, 43776102, 43776103
870.6200	81-8A	Acute Neurotoxicity Screening Battery- Rat	A,B	43929901
870.6200	81-8B	Subchronic Neurotoxicity Screening Battery-Rat	A,B	44189501
870.7485	85-1	General Metabolism	A,B	41310201
870.7600	85-2	Dermal Penetration	A,B	001638631
		120-Day Cholinesterase Activity in Humans	A,B	00039839
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	A,B	00158208, 00159209, 00158210, 43821401, 44214001, Data gap
875.2200	132-1B	Soil Residue Dissipation	A,B	43821401, 44214001
875.2400	133-3	Dermal Passive Dosimetry Exposure	A,B	00158006, 41201701
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B	00143057
835.2240	161-2	Photodegradation - Water	A,B	40781501

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
835.2410	161-3	Photodegradation - Soil	A,B	40789701
835.4100	162-1	Aerobic Soil Metabolism	A,B	42830501
835.4400	162-3	Anaerobic Aquatic Metabolism	A,B	42901801
835.4300	162-4	Aerobic Aquatic Metabolism	A,B	Data gap
835.1240	163-1	Leaching/Adsorption/Desorption	A,B	40884201, 40884202
835.1410	163-2	Laboratory Volatilization (from Soil) Study	A,B	40908801
835.1850	165-1	Confined Rotational Crop	A,B	44128101
860.1900	165-2	Field Accumulation in Rotational Crop Study	A,B	44128101
None	165-4	Bioaccumulation in Fish	A,B	Waived
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A,B	00116221, 00120079, 40404901, 40404902, 40404903, 40404904, 44048201, 44048202, 44065201,
860.1300	171-4B	Nature of Residue - Livestock	A,B	00120208, 40404905, 40404906, 44000501, 44016101
860.1340	171-4C	Residue Analytical Method - Plants	A,B	00028722, 00029432, 00037507, 00037509, 00038467, 00038468, 00074357, 00096458, 00107030, 00120078, 00120208, 00120209, 00124231, 00152371, 00156398, 40670001, 41085801, 41085806, 41085809, 41085811, 41085813, 41085815, 41085819, 41146701, 41146705, 41146707, 41247601, 41288901, 41288902, 41319001, 41514501
860.1340	171-4D	Residue Analytical Method - Animals	A,B	00038082, 40404907,
860.1360	171-4M	Multiresidue Methods	A,B	41085822
860.1380	171-4E	Storage Stability	A,B	00037508, 00067459, 00095522, 00152371, 41085821, 44228501, Data gap

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	A,B	00036270, 00036271, 00036272, 00036273, 00038082, 00118252, 00140798, 40404908, 40404909
860.1500	171-4K	Crop Field Trials - Root and Tuber Vegetables Group	A,B	Beets, sugar - 0009522, 00095523, 00120079 Potatoes - 00068261, 00095522, 00117130, 000152371 Turnips - 00107030
860.1500	171-4K	Crop Field Trials - Leaves of Root and Tuber Veg. Group	A,B	Beets, sugar, tops - 00095522, 00095523, 00120079 Turnips, tops - 00107030
860.1500	171-4K	Crop Field Trials - Bulb Vegetables (Allium spp.) Group	A,B	Onion, bulb - PP#3F1391
860.1500	171-4K	Crop Field Trials - Leafy Vegetables (except Brassica) Vegetables Group	A,B	Lettuce (head) - 0038077, 00067474, 00074356, 00120079
860.1500	171-4K	Crop Field Trials - Brassica (Cole) Leafy Vegetables Group	A,B	Broccoli - 0095522, 00120207, 00152371 Broccoli raab - Data on Broccoli and Cabbage will be used. Brussels sprouts - 00070840, 00120207, 00124231 Cabbage - 00095522, 41085802, 44032501 Cauliflower - 00120207
860.1500	171-4K	Crop Field Trials - Legume Vegetables (Succulent or Dried Group)	A,B	Beans, succulent - 00033834, 00038462, 00038463, 00038464, 00152371, 41146701, 41146702 Peas, succulent or dried - 00036270, 00038464, 00152371, 41146703
860.1500	171-4K	Crop Field Trials - Foliage of Legume Vegetables Group	A,B	Beans, vines and hay - 00033834, 00038462, 00038463, 00038464, 00152371, 41146701, 41146702 Peas, vines and hay -00036270, 00038464, 00152371, 41146703
860.1500	171-4K	Crop Field Trials - Fruiting Vegetables (except Cucurbit) Group	A,B	Eggplant - 00075906, 00107031 Peppers - 00075906, 00107031, 41085806, 41514502

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REQUIREMENT			USE PATTERN	MRID CITATION(S)
860.1500	171-4K	Crop Field Trials - Cucurbit Vegetables Group	A,B	Cucumbers - 00107030 Melons - 00095522, 41085808, 41085810 Pumpkins - 00095522, 00152371 Squash, summer - 00095522 Squash, winter - 00095522
860.1500	171-4K	Crop Field Trials - Citrus Fruits (Citrus spp. and Fortunella spp.) Group	A,B	Grapefruit - 00075906, 00107031 Lemon - 00075906, 00107031 Orange - 00075906, 00107031, 41247601
860.1500	171-4K	Crop Field Trials - Pome Fruits Group	A,B	Apples - 00037505, 00075906, 00107031 Pears - 00107030
860.1500	171-4K	Crop Field Trials - Stone Fruits Group	A,B	Apricots - 00103284, 00152371 Plum (fresh prunes) - 00107031, 00120076
860.1500	171-4K	Crop Field Trials - Berries Group	A,B	Blackberries - 00095522 Raspberries - 00095522
860.1500	171-4K	Crop Field Trials - Tree Nuts Group	A,B	Filberts - 00067459, PP#3F1391 Walnuts - 00075902, 00075903, 00115769, 00152371, 41085813
860.1500	171-4K	Crop Field Trials - Cereal Grains Group	A,B	Corn, filed, grain and aspirated grain fractions - 00044956, 00090456, 00107030, 00152371, 41146704 Corn, sweet (K+CWHR) - 00044956, 00090456, 00107030, 00152371, 41085815, 44041101, Data gap Sorghum grain and aspirated grain fractions - 00038079, 00135473, 00152371

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Oxydemeton-Methyl

REQUIREMENT			USE PATTERN	MRID CITATION(S)
860.1500	171-4K	Crop Field Trials - Forage, Fodder, and Straw of Cereal Grains Group	A,B	Corn, field, forage and stover - 00044956, 00090456, 00107030, 00152371, 41146704, Data gap Corn, sweet, forage and stover - 00044956, 00090456, 00107030, 00152371, 41085815 Sorghum (forage and stover) - 00038079, 00135473, 00152371, Data gap
860.1500	171-4K	Crop Field Trials - Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group	A,B	Alfalfa - 00090456, 00120209, 00152371, 41146706, 44032502, Data gap Clover - 0052038, 00120209, 00152371, 41146707
860.1500	171-4K	Crop Field Trials - Miscellaneous Commodities	A,B	Cotton, seed and gin byproducts - 00117130, 41085820, Data gap Grapes - 00038076 Mint (peppermint and spearmint) - 00037506, 00037508, 00037510 Safflower - 0038078, 00038082 Strawberries - 00120078, 00141183, 00152371, 41085811, 41085812
860.1520	171-4L	Processed Food/Feed	A,B	Apples - 0037505 Citrus - 00107031 Corn, field - 41288901 Cottonseed - 41288902 Grapes - 00038076, 00038087 Mint - 00037506, 00037508, 00037510 Safflower - 00038078, 00038082 Sugar beet - 41319001
OTHER				
840.1000	200-1	Background for pesticide aerial drift evaluation	A,B	Data gap
840.1100	201-1	Spray Droplet Size Spectrum	A,B	Data gap
840.1200	202-1	Spray Drift Field Deposition	A,B	Data gap

Appendix C. Technical Support Documents

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, Virginia. 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 December 8, 1999.

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

http://www.epa.gov/oppsrrd1/op/odm.htm

These documents include:

HED Documents:

1. David Soderberg (USEPA/OPPTS/OPP/HED). Acute and Chronic Dietary Exposure Analysis for Oxydemeton-Methyl (ODM). July 20, 1999.

2. Paula Deschamp (USEPA/OPPTS/OPP/HED). Oxydemeton-methyl: Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision (RED) Document. December 2, 1997.

3. Robert F. Fricke (USEPA/OPPTS/OPP/HED). Revised HED Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document. August 24, 1999.

4. Kelly O'Rourke (USEPA/OPPTS/OPP/HED). Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Oxydemeton-methyl. July 8, 1999.

EFED Documents:

1. David Farrar (USEPA/OPPTS/OPP/EFED). Current EFED RED Chapter for Oxydemeton methyl. September 10, 1999.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Interim Reregistration Decision (Bibliography)

Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE INTERIM REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

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

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

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted 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.

Environmental Fate and Effects Assessment References

Austin, 1981. Land Resources Regions and Major Land Resource Areas of the United States. USDA Handbook 296, revised 1981. Washington, D.C.

Austin, M.E. 1972. Land Resource Regions and Major Land Resource Areas of the United States (exclusive of Alaska and Hawaii). U.S. Department of Agriculture, Soil Conservation Service, Agriculture Handbook 296, #0100-163, Washington, DC.

Barrett, M. to Merenda, J. 30 June 1997. Proposal for Method to Determine Screening Concentration Estimates for Drinking Water Derived from Ground Water Sources. USEPA, Office of Pesticide Programs, Washington, D.C.

Caldwell, R.E, and R.W. Johnson. 1981. General Soil Map of Florida. Soil Conservation Service and University of Florida Institute of Food and Agricultural Sciences and Agricultural Experiment Stations, NP.

California, ND. California Department of Food and Agriculture. Computerized results of sampling for pesticide residues in well water. Sacramento, CA

California, 1997. California Department of Pesticide Regulation. E-mail correspondence on the results of database searches for ground and surface water monitoring data for ODM.

Codrea, E. to J. Breithaupt, 21 July 1997. Faxed memo from Gowan, regarding usage data for ODM. USEPA, OPP, Washington, D.C.

Codrea, E. to P. Caulkins, 30 September 1994. Settlement agreement between Gowan and EPA. USEPA, OPP, Washington, D.C.

Davis, D.E., F. Golly. Principles of Mammalogy. Reinhold Corporation, 1963.

Drinking Water Health Advisory: Pesticides, 1989. Lewis Publishers, Chelsea, MI.

Fletcher, J.S., J.E. Nellessen and T.G. Pfleeger. 1994 Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Toxicol. Chem. 13(9):1383-1391

Florida Department of Agriculture and Consumer Services, Bureau of Product Data Evaluation, 1984. Summary of Soil, Hydrogeological and other Environmental Conditions in the State of Florida Related to Pesticides. Tallahassee, Florida.

Gowan, 2 June 1997, Use meeting with EPA/OPP team members and Betsy Codrea.

Hoerger, F. and E.E Kenaga. 1972. Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment. In F.Coulston and F.Korte, eds., Environmental Quality and Safety: Chemistry, Toxicology and Technology. Georg Thieme Publishers, Stuttgart, West Germany, pp 9-28.

Johansen, Carl, A. And D.F. Mayer, N.D. Pollinator Protection, A Bee & Pesticide Handbook, N.P.

Kellogg, R.L., M.S. Maixel, and D.W. Goss, 1992. Agricultural Chemical Use and Ground Water Quality: Where are the Potential Problem Areas? U.S. Dept. Of Agriculture and National Center for Resource Innovation, NP.

Simko, Ben to J. Breithaupt, July 1997. Personal telephone communication. Dr. Simko is an extension agent in Malheur County, Oregon.

USEPA, 1992. "Pesticides in Ground Water Database - A Compilation of Monitoring Studies: 1971-1991." EPA 734-12-92-001, Washington, D.C.

USEPA, 1996. "Drinking Water Regulations and Health Advisories." Office of Water, February, 1996. Washington, D.C.

USEPA, 1997. Environmental Fate One-Liner Database. Office of Pesticide Programs, Washington, D.C.

USEPA, 1997. Oxydemeton-Methyl (Metasystox-R) Hazard Identification Report, CASRN: 301-12-2, PC Code: 058702, Caswell No. 455. Office of Pesticide Programs, Health Effects Division, Washington, D.C.

Wolf, D.C., T.H. Dao, D. Scott, and T.L. Lavy, 1989. Influence of Sterilization Methods on Selected Soil Microbiological, Physical, and Chemical Properties. J. Environ. Qual. 18:39-44.

Occupational and Residential References

Metasystox-R label. EPA Reg. No. 10163-220, dated January 7, 1997.

EPA BEAD memo, 1995. Oxydemeton-Methyl Exposure Parameters for Selected Crops. Received by Versar on 8/2/95.

EPA OREB memo, 1993. Review of Acceptability of Worker Exposure Data Submitted to Support the Reregistration of Oxydemeton-Methyl (Metasystox-R). Dated July 22, 1993.

EPA HED memo, 1998. Oxydemeton-Methyl: Hazard Identification Report. CASRN: 301-12-2, PC Code: 058702, Caswell No. 455.

LUIS Table for Exposure Assessors, 1997. Case 0258 Oxydemeton-Methyl Chemical 058702 Report run on 6/3/97 and 10/28/98.

Metasystox-R label. EPA Reg. No. 10163-220, dated September 18, 1995. (Lists a treatment for lygus bugs on safflower that is not listed in the more recent 1997 label.)

Information provided in Gowan Company's 30-day response (to HED's Risk Assessment) dated November 27, 1998, and two data submissions: MRID #44783101, "Preliminary Evaluation of Handler Exposures to Oxydemeton-methyl"; and MRID #44806801, "Preliminary Evaluation of Oxydemeton-methyl Dislodgeable Foliar Residues and Reentry Intervals: Conventional and Monte Carlo Assessments".

Product and Residue Chemistry MRID References

00028722 Olson, T.J. (1971) Determination of Metasystox-R Residues in Cottonseed and Walnuts by ThermionicEmission Gas Chromatography: Report No. 21590. Method dated Oct 15, 1971. (Unpublished study received Apr 9, 1980 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:242186-C)

00029432 Olson, T.J. (1971) An Interference Study for the Meta-Systox-R Residue Method for Crops: Report No. 30957. Method dated Sep 20, 1971. (Unpublished study

received Feb 26, 1980 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 099269-G)

00033834 Mobay Chemical Corporation (1979) Synopsis of Metasystox-R Residue Chemistry on Beans.
(Unpublished study received Jun 23, 1980 under 3125-111; CDL:099494-A)

00036270 Chemagro Corporation (1972) Recovery of Meta-Systox-R from Milk: Report No. 35409. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-B)

00036271 Chemagro Corporation (1973) Recovery of Meta-Systox-R from Cattle Tissue: Report No. 35410.
(Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-C)

00036272 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: AROMATIC HYDROCARBON-72A-874: Report No. 35556. Rev. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-D)

00036273 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: AROMATIC HYDROCARBON-72A-874: Report No. 35557. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-E)

00037505 Chemagro Corporation (1973) Addition to Synopsis of Analytical Residue, and Flavor Information for Metasystox-R on Various Crops. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093954-A)

00037506 Chemagro Corporation (1972) Synopsis of Analytical and Residue Information for Metasystox-R on Mint. Summary of studies 093952-H through 093952-J, 093954-C, 093954-D and 093954-H through 093954-K. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093954-B)

00037507 Thornton, J.S.; Olson, T.J. (1973) [Determination of Meta-Systox-R in Lettuce, Sugar Beets and Mint by Gas Chromatography]: Report No. 21000. Includes method dated Oct 15, 1971. (Unpublished study including data found in 093952-G and report no. 35862, received Mar 27, 1974 under 4F1485; prepared in

cooperation with Analytical BioChemistry Laboratories, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-D)

00037508 Coahran, D.R.; Jordan, J.C.; Legault, R.R. (1970) Pesticide Residue Analysis: Report No. 27040. (Unpublished study received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., Agricultural Experiment Station, Dept. of Agricultural Chemistry, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-H)

00037509 Thornton, J.S. (1970) A study of the Possible Interferences of Other Pesticides with the Analytical Method for Meta-Systox-R on Crops, I. Test for the Compounds Registered on Mint: Report No. 29063. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL: 093954-I)

00037510 Analytical BioChemistry Laboratories (1973) Chemagro Division of Baychem Corporation Residue Experiment: 862-1230-72D: Report No. 35957. (Unpublished study including report nos. 35958, 35959, 35960..., received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-J)

00038076 Mobay Chemical Corporation (1975) [Metasystox-R Residues in Grapes, Raisins and Wine]. (Unpublished study received Jun 18, 1975 under 5F1643; CDL:094449-B)

00038077 Missouri Analytical Laboratories (1975) Metasystox-R Residues in Lettuce. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 094449-C)

00038078 Missouri Analytical Laboratories (1973) [Metasystox-R Residues in Safflower and Processed Safflower]. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-D)

00038079 Missouri Analytical Laboratories (1975) [Metasystox-R Residues in Sorghum Forage and Grain]. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-E)

00038082 Thornton, J.S.; Yoksh, R.M. (1970) Determination of Meta-Systox-R Residues in

Poultry Tissues and Eggs by Thermionic Emission Flame Gas Chromatography: Report No. 27004. Method dated Mar 17, 1970. (Unpublished study including report nos. 27005, 27444, 35409..., received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-J)

00038087 Morris, R.A.; Simmons, C.E. (1975) The Effect of Processing on Metasystox-R Residues in Grapes: Report No. 43697. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-Q)

00038462 Chemagro Corporation (1971) Metasystox-R Residues in Snap Beans. (Unpublished study received Mar 27, 1974 under 4F1485; CDL: 093952-B)

00038463 Chemagro Corporation (1971) Metasystox-R Residues in Lima Beans in Pod. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093952-C)

00038464 McGill, L.A. (1971) Metasystox-R Residues in Garden Peas. (Unpublished study including report no. 31441, received Mar 27, 1974 under 4F1485; prepared by Oregon State Univ., Dept. of Food Science & Technology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-D)

00038467 Thornton, J.S.; Olson, T.J. (1971) [Residues Study: Meta-Systox-R in Various Crops]: Report No. 21000. Includes method dated Oct 15, 1971. (Unpublished study including report nos. 27674, 30259 and 31443, received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-G)

00038468 Olson, T.J. (1970) A Study of the Possible Interferences of Other Pesticides with the Analytical Method for Metasystox-R on Crops: Report No. 21463. Rev. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-H)

00044956 Nichols, S.S. (1979) Mobay Chemical Corporation--Agricultural Chemicals Division Residue Experiment: 263-1201-78D: [Metasystox-R: Report No. 67491. (Unpublished study received Jul 22, 1980 under KS 80/10; submitted by state of Kansas for Mobay Chemical Corp., Kansas City, Mo.; CDL:242969-A)

00067459 Kiigemagi, U.; Heatherbell, C.J.; Deinzer, M.L. (1979) Residues of Oxydemeton-methyl (Metasystox R) in Filberts: Report No. 67354. (Unpublished study received Jan 9, 1981 under WA 80/77; prepared by Oregon State Univ., Dept. of

Agricultural Chemistry, submitted by Washington, Dept. of Agriculture, Olympia, Wash.; CDL:CDL:244059-A)

00067474 Mobay Chemical Corporation (1979) Addition No. 4 (Lettuce), August 8, 1979, to Brochure Entitled Metasystox-R Residue Chemistry on Various Crops. (Compilation; unpublished study received Feb 21, 1980 under 3125-111; CDL:242028-A)

00068261 U.S. Department of Agriculture (1963) Results of Residue Analyses with Materials Furnished by Chemagro Corporation: Report No. 12819. (Entomology Research Div., Pesticide Chemicals Research Branch, Analytical Investigations; unpublished study; CDL:231848-A)

00070840 Mobay Chemical Corporation (1980) Addition to Synopsis of Metasystox-R Residue Chemistry on Various Fruits, Vegetables, Nuts, Field and Forage Crops. (Compilation; unpublished study received Mar 26, 1981 under 3125-111; CDL:244767-A)

00074356 Mobay Chemical Corporation (1981) Addition to Synopsis of Metasystox-R Residue Chemistry on Various Crops. (Compilation; unpublished study received Jun 9, 1981 under 3125-111; CDL:245258-A)

00074357 Thornton, J.S.; Olson, T.J. (1967) Determination of Metasystox-R Residues in Lettuce and Sugar Beets by Thermionic Emission Gas Chromatography: Report No. 21000. Method dated Oct 15, 1971. (Unpublished study received Jun 9, 1981 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:245258-B)

00075902 Mobay Chemical Corporation (1966) Synopsis of Analytical and Residue Information for Metasystox-R on Walnuts. (Compilation; unpublished study received Oct 2, 1966 under 7F0540; CDL: 090663-A)

00075903 Loeffler, W.W. (1963) Colorimetric Determination of Meta-systox-R Residues in Plant Material: Report No. 11,476. (Unpublished study received Oct 2, 1966 under 7F0540; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090663-B)

00075906 Mobay Chemical Corporation (1965) Synopsis of Analytical, Residue, and Flavor Information for Metasystox-R on Various Crops. (Compilation; unpublished

study received Oct 2, 1966 under 7F0540; CDL:090663-I)

00090456 Mobay Chemical Corporation (1977) Metasystox-R: Residue Chemistry on Alfalfa and Clover Grown for Seed: Supplement No. 2. (Compilation; unpublished study received Oct 10, 1978 under 3125-111; CDL:235324-A)

00095522 Mobay Chemical Corporation (1963) Meta-systox-R: Analytical and Residue Information in Various Crops. Includes method dated Jun 14, 1963. (Compilation; unpublished study received Dec 30, 1963 under 3125-111; CDL:006932-A)

00095523 Mobay Chemical Corporation (1965) Synopsis of Analytical and Residue Information on Metasystox-R in Sugar Beet Foliage. Includes method dated Jun 14, 1963. Summary of studies 006934-C through 006934-E and 090533-N. (Compilation; unpublished study received Apr 26, 1965 under 3125-111; CDL:006934-A)

00096458 Interregional Research Project Number 4 (1977) [Residue Data on Metasystox: Peaches, Lettuce, Sugar Beets]. Includes method dated Oct 15, 1971. (Compilation; unpublished study received Feb 26, 1982 under 2E2652; CDL:070706-A)

00103284 Interregional Research Project No. 4 (1977) Summary of Residue Chemistry Data. (Compilation; unpublished study received Jun 14, 1982 under 2E2710; CDL:070928-A)

00107030 Mobay Chemical Corp. (1965) [Metasystox-R: Residues in Corn, Turnips, Cucumbers and Soil]. (Compilation; unpublished study received Aug 6, 1965 under 7F0540; CDL:090661-A)

00107031 Mobay Chemical Corp. (1966) [Metasystox-R: Residues in Various Fruits, Vegetables, Grains, Milk and Meat]. (Compilation; unpublished study received on unknown date under 7F0540; CDL: 090662-A)

00115769 J.J. Mauget Co. (1967) [Metasystox-R Residue Determination in Various Products]. (Compilation; unpublished study received on unknown date under unknown admin. no.; CDL:127531-A)

00116221 Shaw, H. (1975) Determination of Soil-bound Residues and Uptake by Rotational

Crops from Soil Treated with Metasystox-R: Report No. 43971. Rev. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, MO;CDL:094450-N)

00117130 Mobay Chemical Corp. (1963) Metasystox-R: Analytical and Residue Information in Various Crops. (Compilation; unpublished study received Dec 30, 1963 under 3125-111; CDL:119843-A)

00118527 Mobay Chemical Corp. (1975) Addition No. 1 to Brochure Entitled: Metasystox-R: Residue Chemistry on Various Crops: Document No. AS76-110. (Compilation; unpublished study received Jan 28, 1976 under 3125-312; CDL:223923-A)

00120076 Mobay Chemical Corp. (1967) [Meta-Systox-R Residue on Pears and Other Crops]. (Compilation; unpublished study received Jul 18, 1968 under 8F0695; CDL:091204-D)

00120078 Mobay Chemical Corp. (1967) Meta-Systox-R: Analytical, Residue, and Flavor Information on Strawberries. (Compilation; unpublished study received Jan 8, 1968 under 8F0695; CDL:091205-A)

00120079 Mobay Chemical Corp. (1967) Meta-Systox-R: Analytical and Residue Information on Lettuce and Sugar Beets. (Compilation; unpublished study received Dec 27, 1967 under 8F0695; CDL:091206-A)

00120207 Mobay Chemical Corp. (1970) Supplement No. 1 to Brochure Entitled: Meta-systox-R: Analytical and Residue Information on Various Fruits, Vegetables, Nut, Field, and Forage Crops. (Compilation; unpublished study received on unknown date under 9F0806; CDL: 091391-A)

00120208 Mobay Chemical Corp. (1970) [Meta-Systox-R Residue on Alfalfa and Clover Grown for Seed]. (Compilation; unpublished study received Apr 29, 1969 under 9F0806; CDL:091392-A)

00120209 Mobay Chemical Corp. (1972) Supplement No. 1 to Brochure Entitled: Meta-Systox-R: Analytical and Residue Information on Alfalfa and Clover Grown for Seed. (Compilation; unpublished study received on unknown date under 9F0806; CDL:091394-A)

00124231 Mobay Chemical Corp. (1982) Metasystox-R: Residue Chemistry on Various Fruits, Vegetables, Nuts, Field and Forage Crops: Addition No. 3 (Brussels Sprouts), Brochure No. 1174: AS 83-15. (Compilation; unpublished study received Jan 13, 1983 under 3125-111; CDL:249304-A)

00135473 Mobay Chemical Corp. (1976) Addition No. 1 to Brochure Entitled: Metasystox-R: Residue Chemistry on Various Crops Dated March 14, 1975: A576-110. (Compilation; unpublished study received Jan 28, 1976 under 5F1644; CDL:098572-A)

00140798 Mobay Chemical Corporation (1970) Supplement to Synopsis of Analytical and Residue Information on Meta-systox-R in Corn, Cucumbers and Turnips: Supplement No. 1. (Compilation; unpublished study received on unknown date under 9F0806; CDL: 091393-A)

00141183 Morse Laboratories, Inc. (1981) Residues of Metasystox-R in Strawberries. Unpublished compilation. 17 p.

00152371 Mobay Chemical Corp. (1983) Metasystox-R Residues in Agricultural Crops. Unpublished compilation with analysis performed by Morse Laboratories, Inc. and Craven Laboratories, Inc. and others. 557 p.

00156398 Mobay Chemical Corp. (1985) Metasystox-R Residue Chemistry on Various Crops; Addition No. 7 (Grapes); July 12, 1985. Brochure No. 1402 to the Brochure Entitled: Metasystox-R; Analytical, Metabolic, Residue and Flavor Information on Various Crops. (Dated March 14, 1975): Report No.1402. Unpublished study. 96 p.

40404901 Smyser, B.; Halpin, R. (1987) Metabolism of Metasystox-R in Cabbage: Mobay Project ID Report No. 95012. Unpublished study prepared by Mobay Corp. 31 p.

40404902 Wagner, K.; Oehlmann, L. (1987) Studies on the Metabolic Behavior of Demeton-s-methyl in Wheat: Laboratory Project ID Report No. 95004. Unpublished study prepared by Bayer AG. 76 p.

40404903 Hawkins, D.; Kirkpatrick, D.; Till, C. (1987) Metabolism of [Carbon 14]-Metasystox-R in Sugar Beet: Project No. ID Report No. 94948. Unpublished study prepared by Huntingdon Research Centre Ltd. 72 p.

40404904 Preiss, U. (1986) Degradation of Demeton-s-methyl Sulfoxide by Cell Cultures of Tomatoes and Sugar Beets: Laboratory Project ID Report No. 94773. Unpublished study prepared by Bayer AG. 40 p. 40404905 Merricks, D. (1987) {Carbon 14]-Metasystox-R Goat Metabolism Study: Laboratory Project ID Report No. 94956. Unpublished study prepared by Agrisearch, Inc. 53 p.

40404906 Marsh, J.; Iden, B.; Lawrence, L. (1987) Quantitative Characterization of Residues in Tissues and Eggs of Laying Hens Treated Orally for Three Consecutive Days with Metasystox-R-[Carbon 14]: Laboratory Project ID Report No. 94955. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 79 p.

40404907 Pither, K. (1987) Recovery of Metasytox-R in Animal Tissue: Laboratory Project ID Report No. 94896. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories, Inc. 179 p.

40404908 Smyser, B.; Halpin, R. (1987) Residues in Tissues and Milk of Dairy Cows Fed Metasystox-R: Laboratory Project ID Report No. 94916. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories, Inc. 78 p.

40404909 Lee, S.; Wood, S. (1987) Residue in Tissues and Eggs of Chickens Fed Metasystox-R: Report No. 94886. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories. 170 p.

40670001 Baron, J. (1988) Oxydemeton-methyl--Magnitude of Residue on Swiss Chard: Project ID: PR-2003. Unpublished study prepared by IR-4 Western Region Analytical Laboratory. 24 p.

41085801 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Cabbage: Project ID MS111601: Report No. 98548. Unpublished study prepared by Colorado Analytical Research and Development Corp. 40 p.

41085802 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Cabbage: Objective No. 1012: Report No. 98496. Unpublished study prepared by Colorado Analytical Research and Development Corp. 106 p.

41085806 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Green Peppers: Metasystox-R Objective No. 1822: Report No. 98549. Unpublished study prepared by Colorado Analytical Research and Development Corp. 117 p.

41085807 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Hot Peppers: Metasystox-R Objective No. 1823: Report No. 98550. Unpublished study prepared by Colorado Analytical Research and Development Corp. 70 p.

41085808 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Cantaloupes: Metasystox-R Objective No. 1310: Report No. 98551. Unpublished study prepared by Colorado Analytical Research and Development Corp. 93 p.

41085809 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Watermelon Pulp and Peel: Project ID MS111601: Report No. 98491. Unpublished study prepared by Colorado Analytical Research and Development Corp. 125 p.

41085810 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Watermelons: Metasystox-R Objective No. 1340: Report No. 98552. Unpublished study prepared by Colorado Analytical Research and Development Corp. 88 p.

41085811 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Strawberries: Project ID MS111601: Report No. 98559. Unpublished study prepared by Colorado Analytical Research and Development Corp. 71 p.

41085812 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Strawberries: Metasystox-R Objective No. 5520: Report No. 98498. Unpublished study prepared by Colorado Analytical Research and Development Corp. 109 p.

41085813 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Walnuts: Metasystox-R Objective No. 5813: Report No. 98104. Unpublished study prepared by Colorado Analytical Research and Development Corp. 62 p.

41085815 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Sweet Corn: Metasystox-R Objective Nos. 3060 & 3066: Report No. 99112. Unpublished study prepared by Colorado Analytical Research and Development Corp. 143 p.

41085819 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Cottonseed: Project ID MS111601: Report No. 98488. Unpublished Corp. 55 p.

41085820 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Cotton: Metasystox-R Objective No. 3713: Report No. 98499. Unpublished study prepared by Colorado Analytical Research and Development Corp. 120 p.

41085821 Lenz, C.; Smyser, B. (1989) Storage Stability of Metasystox-R in Frozen Cabbage: Mobay Project ID 98553. Unpublished study prepared by Colorado Analytical Research and Development Corp. 14 p.

41085822 Keatley, K. (1989) Metasystox-R and Metasystox-R-Sulphone Multiresidue Method trial: Project ID 1093: Mobay Project ID MS161-601. Unpublished study prepared by Colorado Analytical Research and Development Corp. 268 p.

41146701 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Snap Beans: Project ID 1513: Report No. 99106. Unpublished study prepared by Colorado Analytical Research and Development Corp. 111 p.

41146702 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Lima Beans: Project ID 1514: Report No. 99107. Unpublished study prepared by Colorado Analytical Research and Development Corp. 82 p.

41146703 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Field Peas: Project ID 1521: Report No.99113. Unpublished study prepared by Colorado Analytical Research and Development Corp. 113 p.

41146704 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Field Corn: Project IDs 3064 & 3065: Report No. 99111. Unpublished study prepared by Colorado Analytical Research and Development Corp. 189 p.

41146705 Leslie, W. (1989) Metasystox-R: Method Validation and Recoveries on Alfalfa, Hay and Forage: Project ID MS111601: Report No. 98562. Unpublished study prepared by Colorado Analytical Research and Development Corp.192 p.

41146706 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Alfalfa Project ID 3221; Report No. 99110. Unpublished study prepared by Colorado Analytical Research and Development Corp. 122 p.

41146707 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Clover: Project ID 3222: Report No. 99109. Unpublished study prepared by Colorado Analytical Research and Development Corp. 97 p.

41247601 Leslie, W. (1989) Oxydemeton-Methyl--Magnitude of the Residue on Oranges: Project ID MS521289R01: Mobay Study No. 99636. Unpublished study prepared by Mobay Corp. 82 p.

41288901 Leslie, W. (1989) Metasystox-R Magnitude of the Residue on Corn Processed Products: Metasystox-R Project No. MS306588R02: Unpublished study prepared by Colorado Analytical Research and Development Corp. 131 p.

41288902 Leslie, W. (1989) Metasystox-R Magnitude of the Residue on Cotton Processed Products: Lab Project Number: MS371388R02. Unpublished study prepared by Colorado Analytical Research and Development Corp. 97 p.

41319001 Schmidt, B. (1989) Metasystox R--Magnitude of the Residue on Unprocessed Raw Sugar Beet and Sugar Beet Processed Products: (Mobay) 99781; Study RA-951/89; Lab Project ID R806269, etc. Unpublished study prepared by Bayer AG Versuchsgut Hoefchen, Tech. Univ. Berlin Institut fuer Zuckertechnologie and Bayer AG Pflanzenschutzzentrum Monheim. 97 p.

41514501 Schmidt, B. (1989) Metasystox-A: Magnitude of the Residue on Raw Sugar Beet and Sugar Beet Processed Products (Rev. Report): Lab Project Number: R806269: R806250. Unpublished study prepared by Bayer AG. 97 p.

41514502 Leslie, W. (1989) MetaSystox R: Magnitude of the Residue on Hot Peppers: Lab Project Number: 1823. Unpublished study prepared by Colorado Analytical Research and Development Corporation. 70 p.

44000501 Hatton, C.; Krautter, G. (1995) The Metabolism of (carbon 14)Oxydemeton-methyl in Laying Hen: Lab Project Number: 896E/506W: 896E/506W-1. Unpublished study prepared by PTRL West, Inc. and PTRL East, Inc. 263 p.

44016101 Jalali, K.; Hiler, R.; Downs, J. (1996) The Metabolism of (carbon 14)Oxydemeton-methyl in the Lactating Goat: Lab Project Number: 895E/505W: 895E/505W-1: 895. Unpublished study prepared by PTRL West, Inc. and PTRL East, Inc. 296 p.

44032501 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Cabbage Raw Agricultural Commodities: (Final Report): Lab Project Number: AA950501: 95-0037: AA950501/CA. Unpublished study prepared by American Agricultural Services, Inc and EN-CAS Analytical Labs. 249 p.

44032502 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Alfalfa Raw Agricultural Commodities: (Final

Report): Lab Project Number: AA950503: 95-0039: AA950503/CA. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs. 266 p.

44041101 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Sweet Corn Raw Agricultural Commodities: (Final Report): Lab Project Number: AA950502: 95-0038: 150995 PURITY AI. Unpublished study prepared by American Agricultural Services, Inc. (AASI) and EN-CAS Analytical Laboratories. 210 p.

44048201 Rose, J.; Sprinkle, R. (1996) A Metabolism Study with Oxydemeton-methyl in Cabbage: Lab Project Number: 508W: 508W-1: 895E/505W. Unpublished study prepared by PTRL West, Inc. 287 p.

44048202 Sprinkle, R.; Rose, J. (1996) A Metabolism Study with Oxydemeton-methyl in Sweet Corn: Lab Project Number: 509W: 509W-1: 895E/505W. Unpublished study prepared by PTRL West, Inc. 398 p.

44065201 Rose, J.; Sprinkle, R. (1996) A Metabolism Study with Oxydemeton-methyl in Sugarbeet: Lab Project Number: 507W-1: 507W. Unpublished study prepared by PTRL West, Inc. 302 p.

44128101 Hiler, R.; Kimmel, E.; Jalali, K. (1996) A Confined Rotational Crop Study with Oxydemeton-Methyl Using Radish, Lettuce, and Wheat: (Final Report): Lab Project Number: 511W: 95.102: 511W-1. Unpublished study prepared by PTRL WEST, Inc. and Plant Sciences, Inc. 747 p.

44228501 Jalali, K.; Hiler, R. (1997) Storage Stability of Oxydemeton-methyl and its Sulfone Metabolite in Lettuce, Sugarbeet, Sweet Corn, Broccoli, Pears, and Walnuts: Lab Project Number: 519W-1: 519W. Unpublished study prepared by PTRL West. Inc. 274 p.

Ecological Effects and Environmental Fate MRID References

00143057 Pither, K.; Puhl, R. (1978) Stability of Metasystox-R in Sterile Aqueous Buffer Solutions: Report No. 66500. Unpublished study prepared by Mobay Chemical Corp. 18 p.

40781501 Kesterson, A.; Marsh, J.; Lawrence, B.; et al. (1988) Solution Photolysis of Carbon 14 Metasystox-R in Natural Sunlight: Report No. 1158: Project NO. 221. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 64 p.

40789701 Jackson, S.; Kesterson, A.; Lawrence, L. (1988) Soil Surface Photolysis of Carbon 14 Metasystox-R in Natural Sunlight: Report No. 1156: Project No. 222. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 65 p.

42830501 Schmidt, J.; Anderson, T.; Dyer, D. (1993) Aerobic Soil Metabolism of (carbon 14)--Oxydemeton-methyl: Lab Project Number: MS042103: 39618: 105038. Unpublished study prepared by ABC Laboratories, Inc. 101 p.

42901801 Schmidt, J.; Anderson, T. (1993) Anaerobic Aquatic Metabolism of (Carbon 14)-Oxydemeton-methyl: Lab Project Number: 105039: MS042401: 39617. Unpublished study prepared by ABC Labs, Inc. 116 p.

40884201 Daly, D. (1987) Soil Adsorption/Desorption with carbon 14-Metasystox-R: Project ID: ABC Final Report No. 36355. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 41 p.

40884202 Arzu, I. (1988) Soil Adsorption/Desorption of Oxydemeton-methylsulfide and Oxydemeton-methylsulfone: Project ID: Report No. 98402. Unpublished study prepared by Mobay Corp. 32 p.

40908801 Coody, P. (1988) Volatility of Oxydemeton-methyl from Sandy Loam Soil Under Laboratory Conditions: Rept. No. 98407. Unpublished study prepared by Mobay Chemical Corp. 31 p.

00060636 Lamb, D.W.; Jones, R.E.; Roney, D.J. (1972) Acute Oral Toxicity of Metasystox-R Technical to Bobwhite Quail: Report No. 35022. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL: 092011-W)

00160000 Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.

00022923 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)

40747202 Beavers, J.; Marselas, G.; Jaber, M. (1988) Metasystox-R Technical: A One-generation Reproduction Study with the Bobwhite (Colinus virginianus): Proj. No. 149-135. Unpublished Mobay study 97436 prepared by Wildlife International Ltd. 90 p.

40747201 Beavers, J.; Marselas, G.; Jaber, M. (1988) Metasystox-R Technical: A One-generation Reproduction Study with the Mallard (Anas platyrhynchos): Proj. No. 149-136. Unpublished Mobay study 97435 prepared by Wildlife International Ltd. 88 p.

00036935 Eigenburg, T.; Hastings, T. (1992) A Male Fertility Study in Rats Using Technical Grade Oxydemeton Methyl Administered via the Diet: Lab Project Number: 91-672-MM: 103251-1. Unpublished study prepared by Miles Inc. 11 p.

05001991 Stevenson, J.H. (1978) The acute toxicity of unformulated pesticides to worker honey bees (Apis mellifera). Plant Pathology 27(1):38-40.

00060628 Johansen, C.A.; Eves, J. (1965) Bee Poisoning Investigations, 1965: Report No. G-1705; Report No. 17338. (Unpublished study, including letter dated Jun 12, 1973 from C.A. Johansen to A.D. Cohick, received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., Dept. of Entomology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:092011-I)

00074486 Atkins, E.L.; Kellum, D. (1980) Effect of Pesticides on Apiculture: Maximizing the Effectiveness of Honey Bees as Pollinators: Project No. 1499. 1980 annual rept. (Unpublished study received Jun 8, 1981 under 241-259; prepared by Univ. of California--Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology, submitted by American Cyanamid Co., Princeton, N.J.; CDL:070148-G)

00060638 Lamb, D.W.; Jones, R.E. (1973) Toxicity of Metasystox-R 2 Lbs/Gal Spray Concentrate to English Sparrows, Bobwhite Quail and New Zealand Rabbits under Simulated Field Conditions: Report No. 35119. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL: 092011-Y)

41054501 Cohle, P. (1989) Early Life Stage Toxicity of Metasystox-R (Oxydemeton

methyl) to Rainbow Trout (Salmo gairdneri) in a Flow- Through System. Unpublished study prepared by analytical Bio- Chemistry Laboratories, Inc. 45 p.

40286801 Forbis, A. (1987) Acute Flow-through Toxicity of Metasystox R to Daphnia magna: ABC Final Report #35432. Unpublished study pre- pared by ABC Laboratories, Inc. 165 p.

40986601 Burgess, D. (1989) Chronic Toxicity of Metasystox R (Oxydemeton Methyl) to Daphnia magna Under Flow-through Test Conditions: ABC Final Rept. #36799. Unpublished Mobay study 98519 prepared by Analytical Bio-Chemistry Laboratories, Inc. 39 p.

42830501 Schmidt, J.; Anderson, T.; Dyer, D. (1993) Aerobic Soil Metabolism of (carbon 14)--Oxydemeton-methyl: Lab Project Number: MS042103: 39618: 105038. Unpublished study prepared by ABC Laboratories, Inc. 101 p.

40747202 Beavers, J.; Marselas, G.; Jaber, M. (1988) Metasystox-R Technical: A One-generation Reproduction Study with the Bobwhite (Colinus virginianus): Proj. No. 149-135. Unpublished Mobay study 97436 prepared by Wildlife International Ltd. 90 p.

Toxicology MRID References

40779801 Sheets, L. (1988) Acute Oral Toxicity of Metasystox-R Technical in Rats: Laboratory Project ID 88-011-03. Unpublished Report No. 97420 prepared by Mobay Corp. 20 p.

00143350 Mihail, F. (1984) Determination of the Acute Dermal Toxicity to Rats: Report No. 12828. Unpublished study prepared by Bayer AG. 11 p.

00151801 Thyssen, J. (1981) Test for Irritation of the Skin and Mucosae: Rept No. 86452. Unpublished study prepared by Bayer AG. 5 p.

40779802 Thyssen, J. (1981) Test for Irritation of the Skin and Mucosae: Rept No. 86452. Unpublished study prepared by Bayer AG. 5 p.

40779803 Sheets, L. (1988) Acute Oral Toxicity of Metasystox-R 50 percent Concentrate in Rats: Laboratory Project ID 88-011-04. Unpublished study prepared by Mobay

Corporation. 22 p.

40779804 Sheets, L. (1988) Acute Dermal Toxicity of Metasystox-R 50 percent Concentrate in Rats: Study No. 88-023-03. Unpublished study prepared by Mobay Corp. 23 p.

40779805 Shiotsuka, R. (1988) Acute Four-hour Inhalation Toxicity Study with Metasystox-R 50 percent Concentrate in Rats: Study No. 88-041- 03. Unpublished study prepared by Mobay Corp. 37 p.

40779806 Sheets, L. (1988) Primary Eye Irritation of Metasystox-R 50 percent Concentrate in Rabbits: Study No. 88-333-01. Unpublished study prepared by Mobay Corp. 19 p.

40779807 Sheets, L. (1988) Primary Dermal Irritation of Metasystox-R 50 per- cent Concentrate in Rabbits: Study No. 88-323-02. Unpublished study prepared by Mobay Corp. 18 p.

00151806 Hayes, R. (1984) Chronic Feeding/Oncogenicity Study of Oxydemeton Methyl (Metasystox-12 in Rats: Study No. 80-271-05. Unpublished study prepared by Mobay Chemical Corp. 928 p.

40865203 Hayes, R. (1984) Chronic Feeding/Oncogenicity Study of Oxydemeton- Methyl (Metasystox-R) in Rats: Project ID. 87481. Unpublished study prepared by Mobay Corp. 551 p.

40865201 Hayes, R. (1984) Chronic Feeding/Oncogenicity Study of Oxydemeton- Methyl ((Metasystox-R) in Rats: Project ID. 87481. Unpublished

40865202 Hayes, R. (1984) Chronic Feeding/Oncogenicity Study of Oxydemeton- Methyl (Metasystox-R) in Rats: Project ID 87481. Unpublished study prepared by Mobay Corp. 9 p.

44141301 Beyrouty, P. (1996) Group Mean and Individual Brain Cholinesterase Data for BioResearch Report No. 97434-A: A 13 Week Study of the Potential Effects of Oxydemeton-methyl on Behavior, Neurochemistry and Neuromorphology in Rats: Lab Project Number: 97434. Unpublished study prepared by Bio-Research Labs, Ltd. 49 p.

42576601 Christenson, W.; Moore, K.; Elcock, L.; et al. (1992) Technical Grade

Oxydemeton Methyl (Metasystox-R): An Oncogenicity Feeding Study in the CD-1 Mouse: Lab Project Number: 88-271-BE: 103295. Unpublished study prepared by Miles Inc. 2816 p.

00151805 Hoffman, K.; Ruhl, C. (1984) R 2170 (Common Name: Oxydemeton Methyl): Chronic Toxicity to Dogs on Oral Administration (12- month Stomach Tube Study): Rept No. 12 734. Unpublished study prepared by Bayer AG. 181 p.

41082201 Hoffman, K.; Ruhl-Fehlert, C. (1988) R 2170 (C.N. Oxydemeton- methyl) Chronic Toxicity to Dogs on Oral Administration (12-month Study by Gavage): Report No. 86797. Unpublished study prepared by Bayer AG. 163 p.

41980801 Hoffman, K.; Mager, H. (1990) Addendum B to Bayer Report No. 12734, June 7, 1984 Entitled: R 2170 (Common Name: Oxydemeton methyl) Chronic Toxicity to Dogs on Oral Administration (12-Month Study by Gavage): Lab Project Number: 86797. Unpublished study prepared by Bayer AG. 106 p.

43454201 Eigenberg, D. (1993) Addendum C to Bayer Report No. 12734, June 7, 1984, Entitled: "R 2170 (Common Name: Oxydemeton Methyl): Chronic Toxicity to Dogs on Oral Administration (12-Month Study by Gavage)": Lab Project Number: 86797: 86797-3. Unpublished study prepared by Bayer Ag. 36 p.

00146812 Clemens,G.; Bare, J.; Hartnagel, R. (1985) A Teratology Study in the Rat with Metasystox-R: Report No. 88926. Unpublished study prepared by Mobay Chemical Corporation. 350 p.

00158342 Clemens, G. (1986) Response to EPA Comments on Metasystox-R Rat Teratology Study: Report No. 13:Project No. MB12-332. Unpublished study prepared by Miles Labs. 348 p.

00146989 Clemens, G.; Hartnagel, R. (1984) A Teratology Study in the Rabbit with Metasystox-R: Report No. 20. Unpublished study prepared by Miles Laboratories, Inc. 129 p.

00153606 Clemens, G.; Hartnagel, R. (1984) A Teratology Study in the Rabbit with Metasystox-R. Unpublished study prepared by Miles Labs., Inc. 170 p.

42859901 Clemens, G.; Hartnagel, R. (1993) A Teratology Study in the Rabbit with Metasystox-R: Supplemental Submission: Lab Project Number: 86391: 86391-5. Unpublished study prepared by Miles Inc Toxicology--Healthcare. 15 p.

00260513 Kroetlinger, F.; Kaliner, G. (1985) Two-generation Study with Rats: R 2170 (c.n. Oxydemeton-methyl). Unpublished report prepared by Bayer AG. 224 p. (MRID 0155396)

00153606 Clemens, G.; Hartnagel, R. (1984) A Teratology Study in the Rabbit with Metasystox-R. Unpublished study prepared by Miles Labs., Inc. 170 p.

41461901 Eigenberg, D. (1990) Two-generation Dietary Reproduction Study in Rats Using Oxydemeton Methyl (Metasystox-R): Lab Project Number: 87-671-01/87-671-02. Unpublished study prepared by Mobay Corp. 3088 p.

00146091 Herbold, B (1980) Salmonella/Microsome Test for Detection of Point-mutagenic Effects: R 2170: Report No. 8847. Unpublished study prepared by Bayer AG. 18p.

00146102 Witterland, W. (1984) Mutagenicity Evaluation of R 2170 C.N. Oxy- demeton-methyl in the Mouse Lymphoma Forward Mutation Assay: Final Report: Genetics Assay No. E-9220. Unpublished study pre- pared by Litton Bionetics. 16 p.

42136901 Herbold, B. (1991) R 2170: Spot Test on Cross-Bred C57B1/6J x T Stock Mouse Fetuses to Evaluate for Induced Somatic Changes in the Genes of the Coat Pigment Cells: Lab Project Number: 101927. Unpublished study prepared by Bayer Ag. 33 p.

40658502 Putman, D. (1988) Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells: Metasystox-R: Final Report: Laboratory Study No. T5572.337. Toxicology Report No. 1005. Unpublished Mobay Report No. 96706 prepared by Microbiological Associates, Inc. 30 p.

40534501 Taalman, R. (1987) Clastogenic Evaluation of R2170 in an in vitro Cytogenetic Assay Measuring Chromosome Aberration Frequencies in Chinese Hamster

Ovary (CHO) Cells: Report No. 95604. Unpublished study prepared by Hazleton Biotechnologies. 25 p.

41236301 Herbold, B. (1989) R 2170 C.N. Oxydemeton-methyl Cytogenetic Testing of the Bone Marrow of the Chinese Hamster in vivo to Check for Chromosome Damage: Project ID 99651: Report No. 17575. Unpublished study by Bayer AG. 36 p.

41667701 Herbold, B. (1989) R 2170 C. N. Oxydemeton-Methyl Cytogenetic Testing of the Bone Marrow of the Chinese Hamster In Vivo to Check for Chromosome Damage: Supplement to MRID 41236301: Lab Project Number 17575A; 99651. Unpublished study prepared by Bayer Ag. 10 p.

40628201 Putman, D. (1988) Dominant Lethal Mutations in Mice: Metasystox-R Technical: Final Report: Supplemental Study: Project ID: T5572. 11202. Unpublished study prepared by Microbiological Associates Inc. 41 p.

40988001 Filler, R. (1989) Male Reproductive Effects of Metasystox-R (MSR) after Short Term Exposure: Project ID: MBA Study No. R-3039.900. Unpublished study prepared by Microbiological Associates Inc. 1205 p.

40658503 Curren, R. (1988) Unscheduled DNA Synthesis in Rat Primary Hepatocytes: Test Article Matasystox-R, Lot No. Pt808406113: Final Report: Laboratory Study No. T6572.380: Toxicology Report No. 1006. Unpublished study prepared by Microbiological Associates, Inc. 32 p.

40658501 Putman, D. (1988) Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) Cells: Final Report: Laboratory Study No. T5572.334: Toxicology Report No. 1004. Unpublished Mobay Report No. 96705 prepared by Microbiological Associates, Inc. 30 p.

43776101 Brendler-Schwaab, S. (1995) R 2170: Alkaline Elution in vitro for the Detection of Induced DNA-Single Strand Breaks in CHO Cells: Lab Project Number: 23935: T 5039210: 107000. Unpublished study prepared by Bayer AG. 36 p.

43776103 Brendler-Schwaab, S. (1995) R 2170: Alkaline Elution in vitro for the Detection

of Induced DNA-Single Strand Breaks in Rat Primary Testes Cells: Lab Project Number: 23896: T 2039208: 107002. Unpublished study prepared by Bayer AG. 28 p.

43776102 Brendler-Schwaab, S. (1995) R 2170: Alkaline Elution in vivo for the Detection of Induced DNA-Single Strand Breaks in Rat Testes: Lab Project Number: 24019: T 3039309: 107001. Unpublished study prepared by Bayer AG. 29 p.

00152368 Weber, H.; Patzschke, K.; Wegner, L. (1978) [Radiolabeled Carbon] Demeton-S-methyl Sulphoxide (Metasystox R Active Ingredient): Biokinetic Studies on Rats:Pharma Report No. 7473. Unpublished study prepared by Bayer Ag, Institute fuer Pharmakokinetik. 33 p.

41310201 Walter, B.; Kane, V. (1989) Disposition and Metabolism of (Carbon 14) Metasystox-R in Male and Female Sprague-Dawley Rats: Lab Project Nos. 99123; MS041801. Unpublished study prepared by Mobay Corp. 57 p.

00152368 Weber, H.; Patzschke, K.; Wegner, L. (1978) [Radiolabeled Carbon] Demeton-S-methyl Sulphoxide (Metasystox R Active Ingredient): Biokinetic Studies on Rats: Pharma Report No. 7473. Unpublished study prepared by Bayer Ag, Institute fuer Pharmakokinetik. 33 p.

00146105 Hathaway, T. (1984) Acute Delayed Neurotoxicity of Metasystox-R 50% Concentrate: Study Numbers 83-418-02 and 83-498-02. Unpublished study prepared by Mobay Chemical Corp. 32 p.

40860001 Hathaway, T. (1984) Acute Delayed Neurotoxicity of Metasystox-R 50% Concentrate: Project ID: 86693. Unpublished study prepared by Mobay Corp. 15 p.

41348201 Sheets, L. (1989) Subchronic Delayed Neurotoxicity Study with Technical Grade Oxydemeton Methyl (Metasystox-R) in Hens: Lab Project Number: 88/418/BN. Unpublished study prepared by Mobay Corp. 130 p.

43929901 Beyrouty, P. (1995) An Acute Study of the Potential Effects of Orally Administered Oxydemeton-Methyl on Behaviour, Neurochemistry and

Neuropathology in Rats: Lab Project Number: 97362: TB10-01-01. Unpublished study prepared by Bio-Research Labs Ltd. 531 p.

44189501 Beyrouty, P. (1996) A 13-Week Dietary Study of the Potential Effects of Oxydemeton-methyl on Behavior, Neurochemistry and Neuropathology in Rats: Lab Project Number: 97434. Unpublished study prepared by Bio-Research Labs., Ltd. 724 p.

40499303 Hayes, R. (1987) Fourteen-Day Cholinesterase Activity Study of Oxydemeton Methyl Technical (Metasystox-R) with Rats by Oral Gavage: Laboratory Project ID 86-111-01. Unpublished study performed by Mobay Corporation. 43 p.

40499304 Hayes, R. (1987) Fourteen-Day Cholinesterase Activity Study of Oxydementon Methyl (Metasystox-R) with Rats by Dermal Application: Laboratory Project ID 86-121-01. Unpublished study performed by Mobay Corporation. 42 p.

44141301 Beyrouty, P. (1996) Group Mean and Individual Brain Cholinesterase Data for BioResearch Report No. 97434-A: A 13 Week Study of the Potential Effects of Oxydemeton-methyl on Behavior, Neurochemistry and Neuromorphology in Rats: Lab Project Number: 97434. Unpublished study prepared by Bio-Research Labs, Ltd. 49 p.

40865203 Hayes, R. (1984) Chronic Feeding/Oncogenicity Study of Oxydemeton- Methyl (Metasystox-R) in Rats: Project ID. 87481. Unpublished study prepared by Mobay Corp. 551 p.

40463001 Eigenberg, D. (1987) Male Reproductive Toxicity Study in Rats with Oxydemeton Methyl in the Diet: Study No. 86-671-01. Un- published study prepared by Mobay Corp. 505 p.

41834003 Eigenberg, D.; Hastings, T. (1987) Male Reproductive Toxicity Study in Rats with Oxydemeton Methyl (Metasystox-R) in the Diet: Supplement: Lab Project Number: 94986. Unpublished study pre- pared by Mobay Corp. 33 p.

41834002 Eigenberg, D. (1991) Evaluation of Sperm Motility in Rats Treated with Oxydemeton Methyl for One, Two, and Three Months in the Diet Using the

National Toxicology Program Method: Lab Project Number: 89-672-EF. Unpublished study prepared by Mobay Corp. 302 p.

42499001 Eigenberg, D.; Hastings, T. (1992) A Male Fertility Study in Rats Using Technical Grade Oxydemeton Methyl Administered via the Diet: Lab Project Number: 91-672-MM: 103251. Unpublished study prepared by Miles Inc. 182 p.

42500101 Eigenburg, T.; Hastings, T. (1992) A Male Fertility Study in Rats Using Technical Grade Oxydemeton Methyl Administered via the Diet: Lab Project Number: 91-672-MM: 103251-1. Unpublished study prepared by Miles Inc. 11 p.

00039839 Doull, J.; Cross, R.; Arnold, J.; et al. (1947) Effect of Metasystox-R on Human Plasma and RBC Cholinesterase Activity: Report No. 35525. (Unpublished study received Jun 18, 1975 under 5F1644; prepared by Univ. of Kansas, Medical Center and Truman Medical Research Laboratory, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094451-Z)

Acute and Chronic Dietary MRID References

44594401 Hawk, R.; Codrea, E. (1998) Oxydemeton-Methyl (Metasystox-R Insecticide): Monte Carlo Acute Dietary Exposure Analysis: Lab Project Number: RA9801. Unpublished study prepared by Gowan Company. 121 p.

Occupational and Residential MRID References

00158006 Inkmann-Koch, A. (1984) Measurement of Applicator Exposure during Application of Metasystox-R on Fruit Trees: Report No. RA-977/ 291B: [Includes Assessment Report No. 85-T-023]. Unpublished Mobay Report No. 89094 prepared by Bayer AG. 23 p.

00158208 Maddy, K.; Edmiston, S.; Alcoser, D. (1985) Degradation of Oxydemeton-methyl (Metasystox-R) Residues on Cauliflower and Broccoli Foliage; Salinas Valley, 1984: Rev.: HS-1293. Unpublished Mobay study no. 90318 prepared by California Dept. of Food and Agriculture. 10 p.

00158209 Maddy, K.; Kilgore, S.; Smith, C.; et al. (1984) Degradation of Dislodgeable Metasystox-R Residue on Cauliflower and Broccoli Foliage in Santa Barbara and San Luis Obispo Counties: HS-1266. Unpublished Mobay study no. 90319 prepared by California Dept. of Food and Agriculture. 16 p.

00158210 Maddy, K.; Meinders, D.; Margetich, S. (1985) Degradation of Dis- lodgeable Metasystox-R Residue on Grape Foliage San Joaquin County, 1984: HS-1275. Unpublished Mobay study no. 90320 prepared by California Dept. of Food and Agriculture. 8 p.

41201701 Knarr, R. (1989) Addendum to Mobay Report No. 89094 'Measurement of Applicator Exposure During Application of Metasystox-R on Fruit Trees": Report No. 89094-1. Unpublished study prepared by Mobay Corp. 9 p.

43821401 Delk, J.; Calovich, C. (1988) Oxydemeton Methyl--Dislodgeable Residues on Various Crops: Lab Project Number: 8620: 95081: HET 51009. Unpublished study prepared by Harris Environmental Technologies, Inc. 277 p.

Appendix E. Generic Data Call-in

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

The following documents are part of the Generic Data Call-In.

DCI Response

Requirements Status and Registrant's Response

Footnotes and Key Definitions for Guideline Requirements

Appendix F. Product Specific Data Call-In

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

Appendix G. EPA's Batching of Oxydemeton-Methyl Products for Meeting Acute Toxicity Data Requirements for Reregistration

Appendix G. EPA'S BATCHING OF *OXYDEMETON-METHYL (ODM)* 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 ***Oxydemeton-methyl (ODM)*** 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., encapsulated, 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.

Four products were found which contain ***Oxydemeton-methyl (ODM)*** as the active ingredient. These products have been placed into ***two batches*** in accordance with the active and inert ingredients and type of formulation.

Batch 1	EPA Reg. No.	Percent ODM	Formulation Type
	10163-219	50.0	Liquid
	7946-10	50.0	Liquid (Capsule)
	64014-9	50.0	Liquid (Capsule)

Batch 2	EPA Reg. No.	Percent ODM	Formulation Type
	10163-220	25.0	Liquid

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

Appendix I. List of Available Related Documents and Electronically Available Forms

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 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 No 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements

b. 84-1 Clarification of Label Improvement Program

c. 86-5 Standard Format for Data Submitted under FIFRA

d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

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

a. Registration Division Personnel Contact List

B. Biopesticides and Pollution Prevention Division (BPPD) Contacts

C. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' website.

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

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

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

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

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at 1-800- 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.