US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Oxamyl

When EPA concluded the N-methyl carbamate cumulative risk assessment in September 2007, all tolerance reassessment and reregistration eligibility decisions for individual N-methyl carbamate pesticides were considered complete. N-methyl carbamate Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs.

Combined PDF document consists of the following:

- Completion of the Tolerance Reassessment and Final Reregistration Eligibility Decisions for the N-methyl Carbamate Pesticides (September 24, 2007)
- Oxamyl IRED

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: September 24, 2007

SUBJECT: Completion of the Tolerance Reassessment and Final Reregistration Eligibility Decisions for the N-methyl Carbamate Pesticides

FROM: Steven Bradbury, Ph.D., Director
Special Review and Reregistration Division
Office of Pesticide Programs

TO: Debra Edwards, Ph.D., Director
Office of Pesticide Programs

The Agency has completed its assessment of the cumulative risks from the N-methyl carbamate (NMC) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual NMC pesticides have also been subject to review through the individual chemical review process. The table below details the dates of previous decisions for the individual NMC pesticides.

Chemical	Decision Document	Date
Aldicarb	RED	9/2007
Carbaryl	IRED RED	6/2003 9/2007
Carbofuran	IRED	8/2006
Formetenate HCl	IRED	3/2006
Methiocarb	RED	3/1994
Methomyl	RED	12/1998
Oxamyl	IRED	12/2000
Pirimicarb	NA*	
Propoxur	RED	9/1997
Thiodicarb	RED	12/1998

* Pirimicarb was first registered in 1997 and therefore not subject to reregistration

EPA has concluded that, with the adoption of the risk mitigation measures evaluated in the N-methyl carbamate cumulative risk assessment, all of the N-methyl carbamate pesticide tolerances assessed in this risk assessment meet the safety standard set forth in section 408(b)(2)(a) of the FFDCA. For those tolerances, this conclusion terminates the tolerance reassessment process under section 408(q) of the FFDCA. For all of the chemicals, to the extent that the safety determination for these uses based on the cumulative risk assessment was the only remaining issue to complete the reregistration eligibility determination for a particular chemical under section 4(g)(2)(A) of FIFRA, the Agency now considers that determination (consistent with the risk mitigation measures described in the cumulative assessment) to be complete. As noted in the Introduction to the cumulative risk assessment, certain tolerances and uses were omitted from the risk assessment because EPA had previously determined that these uses or tolerances did not meet the safety standards based on their individual, aggregate risks or should be canceled for other reasons. These tolerances and uses are identified in Appendix II.A of the cumulative risk assessment. The cumulative assessment does not change the Agency's determination with respect to those uses. Should any risk mitigation measures identified in the assessment not subsequently be implemented, EPA will revise the assessment as necessary to take those residues into account.

In June 2006, the Agency determined that 144 of the N-methyl carbamate tolerances were insignificant contributors to the overall dietary exposure to the N-methyl carbamates. The uses associated with these 144 tolerances make an insignificant contribution to the overall N-methyl carbamate cumulative risk. Therefore, EPA counted these tolerances as reassessed before the final N-methyl carbamate cumulative assessment was issued. That determination is not changed by the assessment the Agency is now issuing. As noted above, EPA has now determined that those tolerances assessed in the N-methyl carbamate cumulative risk assessment meet the FFDCA safety standard and that no further risk mitigation is necessary for any of the pesticides involved in the cumulative risk assessment other than the mitigation measures identified in the individual chemical or cumulative assessments.

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-2007-0935).

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-015
October 2000

Interim Reregistration Eligibility Decision (IRED)

Oxamyl

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-00-013 November 2000

Oxamyl Facts

EPA has assessed the risks of oxamyl and reached an Interim Reregistration Eligibility Decision (IRED) for this carbamate pesticide. With the risk mitigation measures required, oxamyl fits into its own "risk cup"-- its individual, aggregate risks are within acceptable levels. Oxamyl also is eligible for reregistration, pending a full reassessment of the cumulative risks.

Used on several vegetables, fruits, and non-food items, oxamyl residues in food and drinking water do not pose risk concerns for the general population. Although oxamyl showed potential aggregate risks to children (1-6 years), the Agency does not expect risks to children due to the rapid reversibility of cholinesterase inhibition. Oxamyl has no residential uses, and fits into its own "risk cup." With required mitigation measures, oxamyl worker and ecological risks are believed to be significantly reduced.

EPA's next step under the Food Quality Protection Act (FQPA) is to complete a cumulative risk assessment and risk management decision encompassing carbamate pesticides that share a common mechanism of toxicity. The interim decision on oxamyl cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be required at that time.

The Carbamate Public Participation Process

The carbamates are a group of related pesticides that affect the functioning of the nervous system. EPA considers them a high priority for review under the Food Quality Protection Act.

EPA encourages the public to participate in the review of the carbamate pesticides. The Agency released the preliminary scientific risk assessments for review and comment earlier and is now releasing the revised scientific risk assessments for oxamyl and its interim reregistration decision. The Docket telephone is 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/reregistration/oxamyl/

EPA is exchanged information with stakeholders and the public about oxamyl to address the uses and risks through stakeholder meetings, conference calls, and other fora. USDA coordinated input from growers and other oxamyl pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual carbamate pesticides, and will make final decisions through a cumulative carbamate assessment.

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

The oxamyl interim decision was made through an abbreviated public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk

assessments and risk management decisions. EPA worked with affected parties to reach the decisions presented in this interim decision document.

Uses

C A systemic and contact insecticide/acaricide and nematicide**,** oxamyl is a restricted use pesticide used on apples, bananas, carrots, celery, citrus, cotton, cucumbers, eggplants, garlic, ginger, muskmelon (including cantaloupe and honeydew melon), onion (dry bulb), peanuts, pears, peppers, peppermint, pineapples, plantains, potatoes, pumpkins, soybeans, spearmint, squash, sweet potatoes, tobacco, tomatoes, watermelons, yams. Oxamyl is also used on Non-bearing apple, cherry, citrus, peach, pear, and tobacco.

- Approximately 800,000 of oxamyl active ingredient (a.i.) are applied annually. Although cotton accounts for most of the usage, 600 thousand pounds a.i. oxamyl is used on only 7 percent of total cotton acreage. Oxamyl is applied 1-2 times per season when it is used, usually at a rate of about 0.4 pounds a.i. per acre. For most other crops, oxamyl is generally applied 1 to 2 times per season around 1 lb. ai/A. Rates as low as 0.2 lb ai/A may be used.

- There are no residential uses.

Health Effects

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

Risks

- Acute dietary risks from food and drinking water are below the level of concern for all segments of the population, except children1-6 years old.

- Chronic dietary risks were not assessed for oxamyl due to the rapid reversibility of ChEI.

- The Agency believes the acute aggregate (food and water) risks to children (1-6 years) is largely an overestimated risk concern because the assessment does not account for the rapid reversibility of ChEI, which occurs within 2 to 3 hours. The Agency believes the results from an ongoing drinking water study will confirm the assessed risks.

- The current occupational assessment indicates risk concerns for all use scenarios at the current maximum label rate. Post-application risks for workers entering treated fields are generally not

of concern under the current restricted entry intervals (REI), except for hand-harvesting of citrus tree crops.

- However, the Agency believes that implementing the mitigation measures which includes rate reductions, engineering controls, additional personal protective equipment, and several voluntary cancellations will effectively reduce exposure and risk to a level that is not of concern to the Agency. The Agency is also increasing the REI for hand-harvesting of citrus tree crops and expects the risks to be reduced to level that is not of concern.

- There may be some acute and chronic risks to avian and mammalian species, as well as, potential concerns for endangered species of freshwater invertebrates. However, the Agency believes that the mitigation measures summarized below and the "restricted" use classification will reduce potential ecological the risks and adequately mitigate risks.

Risk Mitigation

To mitigate risks to handlers and workers:

- Reduce maximum aerial application rate to 1.0 lb ai/A for foliar applications on all crops except cotton.
- Reduce maximum chemigation application rate to 2.0 lb ai/A for all crops except cotton.
- Reduce maximum rate to 0.5 lb ai/A for cotton, except for AZ and CA (1.0 lb ai/A with closed systems); and reduce maximum seasonal rate to 3.0 lb. ai/A/year.
- Reduce maximum soil application rate to 4.0 lb ai/A for all crops, except mint and pineapple, which must be reduced to 2.0 lb ai/A.
- Reduce seasonal maximum applications for all crops to 8 per crop and incorporate all groundboom soil treatments by water or mechanical means.
- Require enclosed cockpits for aerial applicators and closed mixing/loading systems in CA and AZ for cotton use at 1 lb. ai/A.
- Maintain PPE for all uses (baseline and coveralls, chemical resistant shoes, socks, chemical resistant gloves, chemical resistant apron, head gear for airblast, and an organic vapor respirator).

Also, the registrant has decided to voluntarily cancel the following uses:

- Seed piece dip (yams).
- Soybean use.
- Soil broadcast treatment for cotton.

To mitigate the ecological risks:

- Measures mentioned above are expected to affect the ecological concerns.

Next Steps

- The oxamyl IRED is being issued in final (see www.epa.gov/REDs/ or www.epa.gov/pesticides/reregistration/oxamyl), without a formal comment period. The docket remains open, however, and any comments submitted will be considered in any future actions.

- To effect risk mitigation as quickly as possible, the Agency is requiring that all labels must be amended to include the above mitigation and submitted to the Agency within 90 days after issuance of this IRED.

- The registrant must submit the final results of the drinking water study by the year 2001.

- When the cumulative risk assessment for carbamates, including oxamyl is complete, EPA will issue its final tolerance reassessment decision for oxamyl and may require further risk mitigation measures. Similarly, the Agency may reconsider any part of this interim decision based on new information which may come to the Agency's attention. The Agency will revoke fourteen tolerances because there are either no registered uses or because the commodity is no longer considered a significant feed item; and decrease three tolerances because available data supports the decrease. Raising/or establishing new tolerances will be considered once a cumulative assessment is completed.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data for the carbamate pesticide oxamyl. Based on comments received and additional data, the Agency revised the human health and environmental effects risk assessments and made them available to the public on June 28, 2000. 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 June 28, 2000, for a period of at least 30 days.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of oxamyl. EPA is now publishing its interim reregistration eligibility and risk management decision for the current uses of oxamyl and its associated human health and environmental risks. The tolerance reassessment decision for oxamyl will be finalized once a cumulative assessment with similar carbamates is complete. The Agency's decision on the individual chemical oxamyl can be found in the attached document entitled, "Interim Reregistration Eligibility Decision for Oxamyl," which was approved on September 30, 2000, and contains the Agency's decision on the individual chemical oxamyl.

A Notice of Availability for this interim Reregistration Eligibility Decision(RED) for oxamyl is being published in the Federal Register. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502), USEPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Internet at http:www.epa.gov/pesticides/reregistration.

The interim RED is based on the updated technical information found in the oxamyl public docket. The docket not only includes background information and comments on the Agency's risk

assessments, it also now includes the Agency's risk assessments for oxamyl (revised as of September 18, 2000), and a document summarizing the Agency's Response to Comments.

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 carbamate pesticides undergoing reregistration 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.

Please note that the oxamyl risk assessment and the attached interim RED concern only this particular carbamate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to oxamyl alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of oxamyl. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, the Agency will evaluate the cumulative risk, if appropriate, posed by the entire carbamate class of chemicals after completing the risk assessments for the individual carbamates. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of oxamyl. The Agency will issue the final tolerance reassessment decision for oxamyl and finalize decisions on reregistration eligibility once it is determined whether a cumulative assessment for all of the carbamates is warranted.

This document contains generic and/or specific Data Call-Ins (DCI) that outline further data requirements for this chemical. Note that registrants of oxamyl must respond to DCIs issued by the Agency within 90 days of receipt of this letter.

In this interim RED, the Agency has determined that products containing oxamyl 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 oxamyl may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section IV of this interim RED describes labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section 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 oxamyl. Where the

Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action. If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Carmelita White, at (703) 308-7038. For questions about product reregistration and/or the product-specific DCI that accompanies this document, please contact Jane Mitchell, Product Reregistration Branch (PRB) contact, at (703) 308-8061.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

INTERIM REREGISTRATION ELIGIBILITY

DECISION

Oxamyl

LIST A

CASE 0253

TABLE OF CONTENTS

OXAMYL TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI Acceptable Daily Intake. A now obsolete term for reference dose (RfD).
AE Acid Equivalent
ai Active Ingredient
aPAD Acute Population Adjusted Dose
ARC Anticipated Residue Contribution
ARI Aggregate Risk Index
CAS Chemical Abstracts Service
CI Cation
CNS Central Nervous System
cPAD Chronic Population Adjusted Dose
CSF Confidential Statement of Formula
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
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
GLC Gas Liquid Chromatography
GM Geometric Mean
GRAS Generally Recognized as Safe as Designated by FDA
HA Health Advisory. The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT Highest Dose Tested
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
LOEL Lowest Observed Effect Level
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.
µg/g Micrograms Per Gram

GLOSSARY OF TERMS AND ABBREVIATIONS

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.
N/A	Not Applicable
NRCS	Natural Resource Conservation Service
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OPP	Office of Pesticide Programs
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
PHED	Pesticide Handler's Exposure Database
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © 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
UF	Uncertainty Factor
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the most recent revised human health and ecological risk assessments and is issuing its risk management decisions for oxamyl. The decisions outlined in this document do not include the final tolerance reassessment decision for oxamyl; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. The final tolerance reassessment decision (e.g., revocation or other administrative actions) for this chemical will be issued once the Agency determines the scope of cumulative assessment that is needed. The Agency may need to pursue further risk management measures for oxamyl once the cumulative assessment is finalized.

The revised risk assessments are based on review of the data required to support the use patterns of currently registered products. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on oxamyl**.** After considering the risks in the revised assessments, as well as mitigation proposed by DuPont de Nemours, Incorporated (the sole registrant of oxamyl), and comments and mitigation suggestions from other interested parties, EPA developed its risk management decision for uses of oxamyl that pose risks of concern. This decision is discussed fully in this document.

Oxamyl is a carbamate insecticide, acaricide, and nematicide that controls a broad spectrum of insects, mites, ticks, and nematodes on various field crops, vegetables, fruits, and non-bearing trees. There are no registered residential uses of oxamyl. Oxamyl was first registered in 1974. Total oxamyl use is approximately 800,000 pounds of active ingredient (ai) per year. Cotton accounts for the majority of usage (600,000 pounds ai), while intermediate use can be found on several other crops (apples, celery, potatoes, tomatoes). Although cotton accounts for most of the usage, oxamyl is still used on only a small proportion of cotton sown area (7%), and, when used, is applied 1-2 times per season, usually at a rate of about 0.4 pounds ai per acre. When oxamyl is used on other crops, it is generally applied 1-3 times per season at between 0.2 and 1 pound ai per acre, although some rates are higher.

Overall Risk Summary

EPA's human health risk assessment for oxamyl indicates some risk concerns. Acute food risk, which is based on modeling that incorporates data from USDA's Pesticide Data Program (PDP), Food and Drug Administration (FDA) data, field trials and assumes percent crop treated information, is below the Agency's level of concern. The PDP program samples commodities at grocery store distribution points, while the FDA monitoring surveillance program tests food items directly from the field. Similarly, acute drinking water risk estimates based on monitoring data and screening models, for ground and surface water exposure, are not of concern for the general population. However, when drinking water and food risks are aggregated, the results suggest there may be potential risks to children (1-6 years).

There are also concerns for workers who mix, load, and apply oxamyl to agricultural sites. Additionally, there are concerns for workers who reenter fields treated with oxamyl. Dietary Risk

The oxamyl risk assessments are based on oxamyl's ability to cause cholinesterase inhibition as measured in plasma, red blood cells, and brain. Neither of the degradates, oxime or dimethyloxamic acid (DMOA), is expected to inhibit cholinesterase and neither is of toxicological concern. Because the current analytical method does not differentiate between the parent and the degradate (oxime), the tolerance expression for oxamyl includes both.

The Agency's human health risk assessment for oxamyl indicates that the acute dietary risk from food alone for all populations is below the Agency's level of concern. A chronic dietary risk assessment was not performed. The Agency believes oxamyl does not pose a chronic dietary risk because the results of a reversibility study demonstrated that cholinesterase inhibition was reversed completely within 2 to 3 hours. There are no residential uses of oxamyl, therefore, aggregate risk is based only on dietary (food and water) exposures.

Aggregate Risks (food and water)

Again, acute dietary exposure to oxamyl through food alone does not exceed the Agency's level of concern. However, the estimated environmental concentrations (EECs) for oxamyl residues in surface and ground water are below the Agency's drinking water level of comparison (DWLOC) for all population subgroups of concern, with the exception of residues in ground water for children 1-6. The Agency uses a DWLOC, which is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses, in the risk assessment process. The Agency based the ground water assessment on an oxamyl prospective groundwater (PGW) monitoring study on cotton in North Carolina. The EEC value for groundwater sources of drinking water for children 1-6 years old is 4.0 ppb compared to a DWLOC of 1.9 ppb. For children 1-6 years old, food consumes 81% of allowable dietary exposure or acute population adjusted dose (aPAD).

Although aggregate food and water exposure estimates suggest oxamyl poses risks for children 1-6 years old, the Agency believes that the assessment resulted in overestimating exposure and consequently risk because of the rapid reversibility of oxamyl induced cholinesterase inhibition (ChEI) was not accounted for. For example, the aggregate assessment assumes children 1-6 years will consume 3-4 servings of food and 1-liter of water with the highest residue levels detected in each serving within a 24-hour period without consideration that cholinesterase inhibition is reversed within 2 to 3 hours. Other assumptions were also made, which resulted in overestimates of exposure. Therefore, the assessment is likely an overly conservative assessment.

Occupational Risk

Exposure to oxamyl may occur via the dermal and inhalation routes during mixing, loading, and application. For oxamyl, the Agency has determined that the concerns for mixers/loaders and applicators and flaggers involved in groundboom and aerial applications are not of concern after the proposed mitigation measures have been implemented. The Agency believes that there is potential dermal exposure to oxamyl residues for workers reentering treated areas. To adequately protect workers, the reentry intervals (REIs) for some uses need to be extended.

In situations where the endpoint is the same and the target margin of exposure (MOE) is different for each exposure route (dermal and inhalation), the MOEs are combined using the aggregate risk index (ARI). ARIs greater than 1 are not of concern to the Agency. All occupational scenarios (eight conducted) produced ARIs greater than 1 with mitigation (e.g., closed systems for mixer/loaders for aerial and chemigation application, and enclosed cockpits for aerial applicators). The ARIs for aerial and chemigation mixers/loaders and applicators ranged from 1.1 to 2.9 with the use of engineering controls for combined short and intermediate term exposure. ARIs for groundboom, airblast, and mixer/loaders/applicators using handwands ranged from 1.5 to 4.6 with the use of additional personal protective equipment (PPE). Therefore, if these controls are implemented, occupational risks do not exceed the Agency's level of concern.

The Agency calculates that under the present assumptions and proposed use rate changes, the restricted entry interval (REI) for workers who reenter treated fields to perform routine hand labor activities for most crops should be 48 hours (current label REI). For citrus trees only, the Agency calculates that the REI should be extended to 4 days for workers who will be performing high contact tasks.

Ecological Risk

In addition to considering the human health effects associated with exposure to oxamyl, the Agency assessed the environmental fate and ecological risks that could result from the use of oxamyl. Oxamyl dissipates in soil by chemical and microbially-influenced degradation and by leaching. Hydrolysis is pH-dependent, with oxamyl degrading rapidly in neutral to alkaline environments, but persisting longer in acidic conditions. Photolysis appears to be significant in acidic surface water but not in soil. In soil, oxamyl metabolizes with a half-life of 2 to 4 weeks under aerobic conditions and less than one week under anaerobic conditions. In most field studies, half of the applied oxamyl dissipated from the surface in less than a week.

The major transformation products identified in the fate studies were oxime and DMOA. Although results of a prospective ground-water monitoring study in North Carolina suggest that oxime may persist for an extended period in ground water and subsurface water columns, it is not significant because neither of the degradates are of toxicological concern. In contrast, oxamyl which is of toxicological concern, has a low affinity for adsorption and is mobile in a variety of soils.

Data are also available to assess the hazard oxamyl poses to nontarget terrestrial and aquatic organisms. Oxamyl is highly to very highly toxic to birds and mammals, highly toxic to bees, and moderately toxic to fish and aquatic invertebrates. Avian acute risk quotients (RQs) range from 0.70 to 5.65 for all food items, excluding treated seed, which are below the Agency's level of concern (LOC). The chronic RQs ranged from 2.6 to 192.0. Fish and aquatic invertebrates acute RQs range from 0.08 to 5.65 and chronic RQs range from 2.6 to 192. Small mammals acute RQs range from 0.30 to 76.8. The Agency is concerned about the potential acute and chronic risk to these organisms. The Agency believes that reducing the application rate and the number of applications and the voluntary cancellation of some uses (see chapters 4 and 5) will adequately reduce the risks to terrestrial and aquatic organisms.

Risk Mitigation

To mitigate risks of concern posed by the uses of oxamyl, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has determined the need for a number of label amendments to address the worker and ecological concerns. To address human health and ecological risks, the registrant has agreed to implement, the following mitigation measures: (1) reduce the maximum application rate for cotton to 0.5 lb. ai/A in all areas except California and Arizona, which will continue to use 1.0 lb. ai/A with closed systems; (2) eliminate several application methods and uses (handwand, soil broadcast treatment for cotton, soybean use and seedpiece dip in yams); (3) reduce the seasonal maximum number of applications per crop to 8 times/year; (4) reduce foliar applications to 1 lb ai/A; (5) limit soil applications to a maximum of 4 lb ai/A; (6) require that soil applications be incorporated; (7) confine aerial applicators to enclosed cockpits; and (8) extend the REI for citrus tree crops during irrigation and harvesting from 48-hours to 4 days. Results of the risk assessments, and label amendments needed to mitigate those risks, are presented in this interim reregistration eligibility decision (interim RED).

The Agency will issue its final decision regarding interim mitigation for oxamyl after the public comment period on this interim RED document. Neither the tolerance reassessment nor the interim RED for oxamyl will be considered final until the Agency completes a cumulative risk assessment if warranted. The cumulative assessment may result in further risk mitigation measures for oxamyl.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (hereafter referred to as "EPA" or the "Agency") to determine whether a pesticide containing such active ingredient is eligible for reregistration. Thus, 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" criterion 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. FQPA also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Oxamyl belongs to a group of pesticides called carbamates, some which may 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.

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 several new issues for which policies need to be established. These issues were developed and refined through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which is 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 FQPA10-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 carbamate or other pesticides with a common mechanism of toxicity
- selection of appropriate toxicity endpoints for risk assessments of carbamates
- whether and how to use data derived from human studies

The process developed by the TRAC calls for the Agency 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.

Furthermore, to provide an opportunity for public participation in the ongoing tolerance reassessment and reregistration process, the Agency is following a stakeholder process similar to the TRAC process. For oxamyl, the registrant was provided 30 days to review the Agency's preliminary human health and ecological risk assessments and to identify any computational or other errors. The Agency subsequently revised the risk assessments based upon the error-correction comments and opened a Public Docket.

In association with the U.S. Department of Agriculture (USDA), the Agency conferred with stakeholders in a teleconference call on June 8, 2000. The Agency described the revised risk assessments, including the data used in their development and the factors contributing to or driving the risks. The Agency invited stakeholders to comment on the risk assessments and offer their thoughts on risk mitigation options.

The Agency will issue a final RED after completing the cumulative assessment for oxamyl. In the meantime, the Agency is accepting public comments on this interim RED.

This document consists of six sections. Section I introduces the regulatory framework for reregistration and describes the TRAC process and the worker risk management PR Notice that were used in preparing this Interim RED for oxamyl. Section II provides a profile of the use and usage of oxamyl. Section III gives a summary of the human health and ecological risk assessments and provides a general description of oxamyl use patterns and possible alternatives to oxamyl. Section IV discusses the Agency's interim decision regarding measures necessary for the reregistration eligibility of oxamyl. Section V summarizes label changes needed to meet the Agency's interim reregistration eligibility decision set forth in Section IV. Finally, an Appendix lists all related documents and how to access them. The revised risk assessments are not included in this document, but are available in the Public Docket and on the Agency's web page (www.epa.gov/pesticides/reregistration).

II. Chemical Overview

A. Regulatory History

Oxamyl is a carbamate used to control insects, mites, and nematodes. The pesticide was first registered on April 4, 1974 by E.I. DuPont de Nemours, Inc., for use on ornamentals, tobacco, and non-bearing fruit (apple, cherry, peach, pear, strawberry).

The first food uses were added between 1975 and 1980 and include celery, citrus, apple, cotton, tomato, potato, and pineapple. Since that time banana, peppers, root crop vegetables, cucurbits, soybeans, pear, peanut, eggplant, and mint have been added. New uses were commonly initiated as FIFRA Section 24(c) state labels which were then periodically consolidated into the Section 3 Federal label.

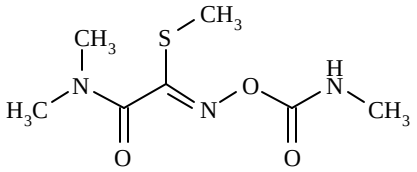
Initial registered application methods included ground foliar spray, soil spray, soil drench, root dip, preplant incorporated, or transplant water. Aerial application was added in 1977, ultra low volume application in 1984, and chemigation in 1987.

A Registration Standard was issued in 1987, which required additional data for animal metabolism, storage stability, product chemistry, spray drift, and certain crop residues. An update to the Registration Standard was issued in 1991. Again, additional data were required for animal metabolism, storage stability, analytical methods, and magnitude of residues in certain plants and processed commodities.

In a December 12, 1989, Federal Register notice, the expression for oxamyl tolerances was changed from oxamyl alone to both oxamyl plus its oxime metabolite. This was due to the inability of the analytical method to separate the parent from the metabolite; however, the oxime metabolite is not of significant toxicological concern.

In recent years the registrant has undertaken a number of voluntary actions to reduce exposures. These include deleting uses (ornamentals, greenhouse use, some non-bearing fruit trees, soil mixing uses), lowering application rates, and establishing seasonal maximums, restricted entry intervals, and pre-harvest intervals for onion, tomato, potato, pineapple, and celery.

B. Chemical Identification



Oxamyl: methyl N',N'-dimethyl-N-[(methylcarbamoyl)-oxy]-1-thiooxamimidate

- **Common Name:** Oxamyl
- **Chemical Name:** Methyl N',N'-dimethyl-N-[(methylcarbamoyl)-oxy]-1-thiooxamimidate
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 23135-22-0
- **OPP Chemical Code:** 103801
- **Empirical Formula:** $C_7H_{13}N_3O_3S$
- **Molecular Weight:** 219.3 g/mole
- **Trade and Other Names:** Vydate®, Vydate L®
- **Basic Manufacturer:** DuPont de Nemours, Inc.

Technical oxamyl is a white crystalline solid with a slight sulfurous odor. The vapor pressure is 3.84×10^{-7} mm Hg at 25° C. Oxamyl is soluble in water (28 g/100 g), methanol (130 g/100 g), acetone (67 g/100 g), ethanol (33 g/100 g), and toluene (1 g/100 g) at 25° C. Oxamyl is stable in solid form, and as a liquid formulation, and in aqueous solutions at pH 5 or lower. Oxamyl hydrolyzes rapidly at pH 9. (See "Revised Occupational Exposure And Risk Assessment Regarding The Use of Oxamyl," August 9, 2000).

C. Use Profile

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

Type of Pesticide: Insecticide/nematicide/acaricide

Summary of Use:

Sites: Terrestrial food and feed crop.

Food: Apple , banana, cantaloupe, carrot, celery, citrus, cotton, cucumber, dry onions, eggplant, garlic, ginger, honeydew, mint, peanut, pears, pepper, pineapples, plantain, pumpkin, soybean, squash, summer

squash, sweet potato, tomato, watermelon, white potato, winter squash, and yam.

Other Uses: Tobacco

Residential: No residential uses.

Other Nonfood: Nursery grown non-bearing fruit trees.

Target Pests: Broad spectrum of insects (e.g., boll weevil, aphids, lygus, plant bug, thrips, mites, leafminer species, pepper weevil and roundworms) and nematodes.

Formulation Types:

Registered: Technical grade (89% ai), a soluble concentrate/liquid (24% and 42% ai) and a solid/technical (42% ai).

Method and Rates of Application:

Equipment - Groundboom sprayer, aerial equipment, airblast sprayer, high pressure handwand, chemigation, and spotgun applicator.

Method and Rate - Foliar spray and soil incorporation applied from 0.25 to 8 lbs ai/acre. Maximum application of 12 times/year. Seed piece dip and shank soil injection.

Timing - Oxamyl end-use products are applied at various times including pre-plant, at planting, or post emergence throughout the growing season depending upon the crop and pest that is targeted. Application generally ranges from 1 to 12 times a year depending on the crop. Most crops have a maximum of 6 seasonal applications.

Trend - According to USDA's National Agricultural Statistics Service and other sources, oxamyl use has generally remained consistent over the last five years. USDA reports that growers are using lower rates (0.46 to 0.62 lb ai/A) and applying the pesticide less frequently (about twice per year compared with the allowable 12 times).

Use Classification: Oxamyl is a “restricted use" chemical due to acute toxicity and toxicity to birds and mammals.

D. Estimated Usage of Pesticide

Based on available information and from consultation with the USDA, the Agency estimates that on average approximately 800,000 pounds of oxamyl active ingredient (ai) are used per year. Cotton accounts for the majority of usage (600,000 pounds ai), while intermediate use can be found on several other crops as well (apples, celery, potatoes, tomatoes). Although cotton accounts for most of the oxamyl usage, it is used on only 7% of cotton produced annually in the United States. Application is 1-2 times per season when it is used, usually at a rate of about 0.4 lb ai per acre. When oxamyl is used on other crops, it is generally applied 1-3 times per season at between 0.2 and 1.0 lb ai per acre (the current label does allow for higher use rates on some crops). Table 1 summarizes the best estimates available for the many oxamyl uses.

Table 1. Oxamyl Usage Summary (current uses)

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl/yr	lb ai/A/appl	(% of total lb ai used on this site)
Fruits											
Grapefruit	194	1	2	0%	1%	1	1	0.7	1.3	0.6	TX 100%
Apples	572	64	102	11%	18%	37	70	0.6	1.1	0.5	WA NY PA MO IL MI 64%
Cantaloupes	113	34	37	30%	33%	6	13	0.2	1.0	0.2	CA 89%
Cherries	128	0	0	0%	0%	0	0	0	0	-	ID MI NY NJ 87%
Melons, Honeydew	27	3	7	12%	24%	4	9	1.3	2.2	0.6	CA 86%
Peaches	212	0	0	0	0%	0	0	0	0	-	PA MI CO NJ SC 87%
Pears	78	1	2	1%	2%	1	2	1.4	1.0	1.4	OR IA MI NJ 80%
Stone-Like Fruit, other	189	0	0	0%	0%	0	0	0	0	-	FL 82%
Tomatoes, Fresh	116	9	13	8%	11%	23	34	2.6	2.6	1.0	FL CA 88%
Tomatoes, Proc.	324	10	32	3%	10%	13	44	1.4	1.4	1.0	CA 100%
Bananas	1	0	0	0%	0%	0	0	0	0	-	HI
Pineapple	21	3	5	15%	24%	-	-	-	-	-	HI
Watermelons	258	6	12	2%	4%	3	6	0.5	1.0	0.5	CA FL AZ 85%
Vegetables											
Garlic	25	0	2	1%	6%	0	2	1.0	1.0	1.0	CA 100%
Ginger	0.350	0	0	0%	0%	-	-	-	-	-	HI
Carrots	108	3	6	3%	6%	3	9	1.0	1.5	0.7	MI TX 85%
Celery	35	19	23	54%	65%	30	36	1.6	2.5	0.6	CA 95%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl/yr	lb ai/A/appl	(% of total lb ai used on this site)
Cucumbers, Fresh	52	7	15	14%	28%	10	19	1.3007	2.7	0.5	FL CA 92%
Cucumbers, Proc.	97	1	6	1%	6%	2	13	2.2	4.2	0.5	FL 100%
Eggplant	4	0	1	13%	35%	1	2	1.6	2.4	0.7	NJ NC FL 89%
Mint	160	30	40	19%	25%	-	-	-	-	-	
Onions, Dry	144	6	19	4%	13%	8	28	1.3	1.6	0.8	OR WA 96%
Peppers, Sweet	77	10	22	13%	29%	12	25	1.2	1.0	1.2	FL CA 93%
Potatoes	1421	7	14	0.5%	1%	7	13	1	1.5	0.676	MI FL ME WI PA WA 59%
Pumpkins	--	0	0	0	0	-	-	-	-	-	
Squash	58	0	1	0.9%	1.8%	-	-	-	-	-	
Sweet potatoes	83	0	0	0%	0%	0	0	-	-	-	
Other Crops											
Cotton	12429	1250	1415	0.101	11%	625	682	0.5	1.4	0.4	TX AR MS LA AZ 86%
Peanut	1450	0	0	0	0						
Soybeans	68000	0	0	0	0	-	-	-	-	-	
Tobacco	695	4	9	1%	1%	3	12	0.9	1.1	0.8	MA PA CT SC 87%
Total		**1465.8778**				**820**					

Weighted average--the most recent years and more reliable data are weighted more heavily (data primarily covers 1990 - 1997).
Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.
Calculations may not appear to agree because they are rounded.
Dash (-) indicates information is unavailable.

In the above table, the calculations are rounded to the nearest 1000 for acres treated or lb. ai (0 equals less than 500) and to the nearest whole percentage point for percent of crop treated (0% equals less than 0.5%). Therefore, the totals do not appear to be exact. Also, the Agency uses a dash to represent sites where the information is either not available or insufficient, sources. Both cherries and peaches refer to use on non-bearing fruit trees.

III. Summary of Risk Assessment

Using relevant data submitted under section 4(g)(2)(A) of FIFRA, published scientific literature, and available surrogate data, the Agency assessed the human health and ecological risks associated with using oxamyl on various crops currently listed on the label. For more detail, see "OXAMYL. The Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated March 24, 2000, and subsequently revised August 11, 2000, and September 18, 2000. The endpoint of concern is cholinesterase inhibition as measured in plasma, red blood cells, and brain. The Agency calculated human health risks from food, water, and occupational exposures. Potential dietary (food) exposure to oxamyl residues may occur through the consumption of various agricultural commodities and through drinking water. There are no residential, recreational, or other non-occupational uses of oxamyl. Therefore, in quantifying aggregate risks, the Agency only considered exposures from food and drinking water. The results of the individual food and drinking water analyses indicate that there may be an acute aggregate dietary risk of concern for children (ages 1-6 years).

The occupational risk assessment for oxamyl considered exposures that could result from mixing/loading and application through chemigation, groundboom, airblast, spotgun, high pressure handwand, aerial equipment, seed piece dipping, as well as, flagging for liquid aerial applications based on maximum label application rates. The results of the occupational risk assessment based on current label rates indicate that there are potential risks for some mixing/loading and applicator scenarios for certain crops and risks for postapplication workers immediately following treatment. The current restricted entry interval (REI) of 48 hours is sufficient for postapplication workers entering fields treated with oxamyl for most crops. Postapplication workers entering citrus tree crop treated with oxamyl need a longer REI.

The Agency considered the toxicity and environmental fate characteristics of oxamyl in its assessment of the potential adverse effects on nontarget aquatic and terrestrial organisms (Environmental Fate and Effects Division RED Chapter for Oxamyl, dated November 9, 1999). Using exposure estimates derived from environmental fate studies, combined with ecological toxicity studies, the risk assessment shows that oxamyl poses acute and chronic risks to avian and mammalian species from unincorporated spray applications. Acute toxicity and reproductive effects to avian and mammalian species may result from one-time, or short-pulse, applications. The Agency does not have any incident/field data for bird and mammal mortality, although the lack of such data does not necessarily negate the potential risks to birds and mammals or imply that mortality is not occurring. Birds and mammals may be exposed, but due to their transient nature, incidents may go unaccounted.

Detecting chronic effects would require years of precise reproduction and population data. Finally, oxamyl may pose risks to honeybees and endangered species freshwater invertebrates.

The purpose of this decision document is to summarize the key features and findings of the human health and ecological risk assessments in order to help the reader better understand the basis for the conclusions reached in this interim reregistration decision document. The risk assessments and related addenda are available on the Agency's web page www.epa.gov/pesticides/reregistration, and in the public docket.

A. Human Health Risk Assessment

The Agency issued its preliminary human health risk assessment for oxamyl on March 24, 2000, following the registrant technical error-correction phase. The risk assessment had acute dietary risks of concern for children 1-6 years based primarily on expected residues in pineapples. The occupational risks were of concern for mixers/loaders and applicators.

The Agency has subsequently revised the preliminary risk assessment to address stakeholder comments and to refine the assessment to the extent practicable using currently available information. The refinements to the human health risk assessment which are discussed below, resulted in acceptable acute dietary risks for food, while the aggregate risks for food and water are still of concern for children 1-6 years old.

The updates or refinement to the risk assessment include:

- Reassessing the acute dietary exposure estimates based on the following additional information:

! Pineapple and apple residue information.
! Processing factors for baked and canned foods.
! Preliminary, single serving, residue monitoring results from the 1999 USDA-Pesticide Data Program for non-blended forms of apple and pear.
! Preliminary carbamate market basket survey data

- Revising transfer coefficients based on new data received from the Agricultural Reentry Task Force (ARTF), which resulted in reevaluating the postapplication risks to determine restricted entry intervals.

- Refining the occupational assessment by using a newly-submitted acute inhalation study in the rat (MRID 45155801), which resulted in a new short- and intermediate-term inhalation endpoint.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted for oxamyl and has determined that the toxicity database is complete and supports an interim reregistration eligibility determination for all currently registered uses. The toxicological database for oxamyl satisfies all of the guideline requirements for reregistration.

Acute Endpoint

The Agency considered the toxicological database and selected an acute neurotoxicity rat study to establish the endpoint to be used in the acute dietary risk assessment. The endpoint is based on clinical signs and cholinesterase inhibition in plasma, red blood cells, and brain with a no observed adverse effect level (NOAEL) of 0.1 mg/kg (MRID 44254401, 44203001, and 44740701). The Agency applied the conventional uncertainty factor (UF) of 100 to account for both interspecies extrapolation (10X) and intraspecies variability (10X). Further details on the toxicity of oxamyl can be found in the July 24, 2000, "Oxamyl: Amended Toxicology Chapter For RED." A brief overview of the study used for the endpoint selection is outlined in Table 2 below:

Chronic Endpoint

The Agency did not conduct a chronic dietary risk assessment for oxamyl because it is typical of most cholinesterase-inhibiting carbamates in that cholinesterase inhibition is fully reversible around the LOAEL, where cholinesterase inhibition lasts for two to three hours (as determined in a cholinesterase reversibility study, MRID 444720-01).

Table 2. Toxicological endpoints selected by the Agency to assess human health dietary risks for oxamyl.

ASSESSMENT	DOSE (mg/kg/day)	ENDPOINT	Acute PAD (RfD)	STUDY*
Acute Dietary	NOAEL=0.1	LOAEL = 1.0 mg/kg/day - clinical signs, and decreased plasma, red cell and brain cholinesterase inhibition in females	0.001 mg/kg	Acute Neurotoxicity - Rat
Chronic Dietary	Cholinesterase inhibition reverses rapidly (within 2 to 3 hours). Due to rapid reversibility chronic risks are not expected.			

* FQPA Safety Factor = 1 and uncertainty factor = 100 (10X intraspecies extrapolation and 10X interspecies variability)

b. FQPA Safety Factor

The 10X FQPA safety factor was reduced to 1X based on the completeness of the toxicity and exposure databases and the lack of increased fetal susceptibility following in utero exposure in developmental toxicity studies in rats (MRID 40859201 and 44737501) and rabbits (MRID 40606501). Further, no increased pup sensitivity was exhibited in the 2-generation reproductive study in the rat. Adequate monitoring data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and non-occupational sources of exposure to provide a screening level drinking water exposure assessment The assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

c. Exposure Assumptions

Revised dietary risk analysis for oxamyl was conducted with the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Acute dietary risk is calculated considering maximum, or high end, single-day exposure to pesticide residues in food. The no observed adverse effect level (NOAEL) and uncertainty factors (UF) are used to establish the "allowable" exposures to a pesticide, which is referred to as the reference dose (RfD).

d. Population Adjusted Dose

The population adjusted dose (PAD) characterizes the dietary risk of a chemical and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). For oxamyl, the FQPA safety factor is 1; therefore, the acute RfD equals the acute PAD. A risk estimate that is less than 100% of the acute PAD does not exceed the Agency's risk concern.

e. Food Risk Characterization

For all populations, the estimated acute dietary food exposure to oxamyl results in risk estimates that are below the Agency's level of concern using anticipated residues and percent crop treated data. For the acute dietary risk assessment, the entire distribution for each food item of single day food consumption was combined with a single residue level to obtain a distribution of exposure. Such a non-probabilistic method results in an upper-bound dietary exposure estimate.

Acute Dietary (Food) Risk

A highly refined, Tier 3 acute probabilistic dietary exposure analysis using the DEEM™ model was conducted for oxamyl. The assessment incorporated percent crop treated information, USDA Pesticide Data Program (PDP) and Food and Drug Administration (FDA) monitoring data, and field

trial data. At the 99.9th percentile, acute dietary risk estimates from all registered uses of oxamyl are below the Agency's level of concern (<100% of the aPAD) for all population subgroups. Children (1-6 years old) are the most highly exposed population subgroup at 81% of the aPAD.

The anticipated residues for apples are a substantial contributor to the estimated exposure for children ages 1-6 and are derived from single serving 1999 PDP data. The residue range and frequency from these data are largely consistent with those found in the Carbamate Market Basket Survey Task Force Report (July 2000). PDP data showed 6.3% of the single serving apple samples to have residues of oxamyl ranging from 0.017 ppm to 0.056 ppm. The Carbamate Market Basket Survey showed 5% of the apples contained oxamyl ranging from 0.001 ppm to 0.038 ppm.

In determining the quantity of residues present on these commodities, PDP monitoring data is based on an analytical method that cannot distinguish between the parent oxamyl and its oxime degradate. Though these data treat residues of parent oxamyl and its oxime degradate indistinguishably, the oxime does not have any toxicological significance. Conversely, the methodology used to detect oxamyl residues in the Carbamate Market Basket Survey, detects the oxamyl parent only. It does not measure the oxime degradate and, therefore, may be a more realistic measure of toxicologically significant oxamyl residues.

In addition, the Agency analyzed consumption over a 24-hour period to determine the potential exposure and risks. The DEEM model assumes that multiple meals are eaten within a 24-hour period and that exposure accumulates over that period. However, for oxamyl, the ChEI reverses within 2-3 hours so that by the time an individual would consume another meal, the effect would have reversed.

Chronic Dietary (Food) Risk

The Agency did not assess chronic dietary risk. The Agency believes chronic risks are not of concern due to the short period of time in which the inhibition of ChEI is reversed.

2. Dietary Risk (Drinking Water)

Drinking water exposure to pesticides can occur through ground water and surface water contamination. For oxamyl, the Agency evaluated only acute drinking water risks because chronic risks are not of concern as discussed previously. Potential surface water exposure was assessed based on PRZM/EXAMS modeling and limited monitoring data. Groundwater environmental concentrations were based on the results of a prospective groundwater (PGW) study conducted in a cotton growing area of North Carolina. These assessments are discussed below.

a. Surface Water

Tier II PRZM-EXAMS modeling provides upper-bound predictions of oxamyl concentrations in surface water. For drinking water originating in surface water bodies, an acute concentration of 1 ppb was used in the assessment based on existing monitoring data in combination with the results of modeling with PRZM-EXAMS. Because of the transient nature of oxamyl in the environment, concentrations as high as 30 ppb shown in modeling may occur but generally will not persist and have not been observed in monitoring. The Agency is unable to verify peak environmental concentrations without chemical-specific monitoring data.

b. Ground Water

Based primarily on a prospective groundwater monitoring study conducted in North Carolina, oxamyl is expected to be very mobile and generally persistent in highly vulnerable soils. The Agency requested two PGW studies be conducted to determine the potential impact of oxamyl on groundwater. The North Carolina site meets the criteria outlined in the "Workshop Draft Guidance For Small-Scale Prospective Ground Water Studies, dated 1995," an EPA PGW-guideline draft. Additionally, the results of a non-chemical specific monitoring study found oxamyl could, in fact, contaminate groundwater.

The non-chemical specific study detected oxamyl in several samples in Suffolk County, Long Island, at extremely high levels. Three detections were above 70 ppb with the highest detection being 395 ppb. Oxamyl has been banned in Suffolk County because of widespread, low level detections and the isolated high levels found in groundwater. The Agency is unable to explain these high detections. However, the Agency believes these detects are atypical because most of the detections in groundwater in Suffolk County, Long Island, were between 1 to 2 ppb.

The North Carolina PGW study on cotton was conducted to represent the worst-case scenario for cotton. While oxamyl is used on a variety of crops, cotton represents the broadest potential use region and is expected to encompass more acreage than other use sites. The maximum concentration of oxamyl detected in this study was 4 ppb, while most detections were in the 1-2 ppb range. The oxime degradate was detected at concentrations up to 4.5 ppb. Preliminary data from an ongoing PGW study on tomatoes in Maryland are consistent with the results of the North Carolina study. The final report for this study is expected to confirm the Agency's groundwater assessment.

The acute groundwater estimated environmental concentration (EEC) value is 4 ppb based on typical maximum values derived from non-targeted study and the monitoring studies. Although higher groundwater concentrations have been reported in some monitoring studies, those values are not typical and represent extremely vulnerable areas. Oxamyl concentrations in groundwater were generally between 1-2 ppb.

a. Drinking Water Levels of Comparison

To determine the maximum contribution of oxamyl from water allowed in the diet, the Agency first calculates the overall risk from food and then determines a drinking water level of comparison (DWLOC). As mentioned above, the Agency uses both monitoring and modeling data to determine the drinking water exposure values for the parent oxamyl. The Agency compares the DWLOCs to the estimated concentrations of oxamyl in surface water and ground water. Based on the oxamyl contribution from food in the diet, the acute DWLOC for water is 1.9 ppb.

As seen in Table 3 below, the Agency's estimated environmental concentrations of oxamyl residues in surface and ground water are less than the acute DWLOCs for the general population, except residues in ground water for children 1-6 years. (Children 1- 6 represent the highest dietary exposure of all subpopulations). The table below shows that 4.0 ppb is expected in groundwater based on monitoring data, while the calculated DWLOC is 1.9 ppb for children 1-6.

Table 3. Acute DWLOC Comparison for Surface and Groundwater

Population	SURFACE WATER EECs[1] (ppb)	Ground Water EECs[2] (ppb)	aPAD (mg/kg/d)	Acute Food Exposure (mg/kg/d)	Allowable Acute Water Exposure (mg/kg/d)	$DWLOC_{acute}$ (ppb)
U.S. Population	1.0	4.0	0.001	0.000433	0.000567	20
Children (1-6)	1.0	4.0	0.001	0.000807	0.000193	1.9

[1] Based on PRZM/EXAMS; [2] Based on monitoring and confirmatory modeling.

3. Residential Risk

There are no residential uses of oxamyl.

4. Aggregate Risk

Aggregate risk considers combined exposures from food, drinking water, and non-occupational uses. As stated previously, there are no residential or other non-occupational (e.g., golf course) uses of oxamyl to consider in an aggregate assessment. Therefore, the aggregate risk for oxamyl includes only exposures from food and drinking water.

The acute aggregate food and groundwater drinking water risk is above the Agency's level of concern for children 1-6 years. As seen in Table 3 above, the EECs are less than the level of comparison for all subpopulations, except children (ages 1-6). However, the Agency believes that these risks are overestimated because oxamyl induced ChEI reverses within 2 to 3 hours. The ChEI reversibility was not considered.

As discussed earlier, the Agency did not perform a chronic aggregate risk assessment, because the ChEI reverses so rapidly. Therefore no chronic aggregate risks are expected.

5. Occupational Risk

The Agency considers the tasks (e.g., mixing, loading, applying); pesticide formulation (e.g., liquid, granular), application method (e.g., aerial, groundboom); application rate and other factors in assessing occupational exposure. The Agency also reviews any available incident data that reports information on various chemicals and identifies any poisoning, fatalities, or other adverse effects that may be attributed to oxamyl.

The Pesticide Handlers Exposure Database (PHED) is used to estimate occupational exposure. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposures for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling or applying pesticides. The database currently contains data for over 1700 monitored exposure events.

a. Toxicity

The toxicity of oxamyl is integral to assessing occupational risks. All risk calculations are based on the most current toxicity information available for oxamyl. The toxicological endpoints, and other factors used in the occupational risk assessment for oxamyl are summarized below in Table 4a.

Table 4a. Summary of toxicological endpoints used for occupational assessment.

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Dermal (Short and Intermediate)	Dermal NOAEL=50 UF=100	LOAEL = 75 mg/kg/day is based on plasma, red blood cell and brain ChEI in females	21-Day Dermal Toxicity - Rabbit (MRID 44751201)
Inhalation (Short & Intermediate)	Inhalation LOAEL= 0.85 mg/kg/day UF=300	LOAEL = 0.85 mg/kg/day is based on clinical signs, and decreased plasma, red cell and brain cholinesterase inhibition in rats	Acute inhalation - Rat (MRID 4555801)

The acute toxicity database indicates that oxamyl is moderately to highly toxic via the oral, dermal, and inhalation routes (toxicity categories I, IV, and II, respectively). Below is the acute toxicity profile table for oxamyl.

Table 4b. Acute Toxicity Profile for Occupational Exposure for Oxamyl

Route of Exposure	Study Type	MRID	Measure	Tox Category
Oral	Acute Oral	00063011	LD_{50}	I
Dermal	Acute Dermal (Rabbit)	40606501	LD_{50}	IV
Inhalation	Acute Inhalation	00066902	LC_{50}	II
Eye Irritation	Primary Eye Irritation	00066894	-	III
Skin Irritation	Primary Skin Irritation	40606501	-	IV
Dermal Sensitizer	Dermal Sensitization	00066900	-	Not a skin sensitizer

b. Exposure

The Agency's first step in performing an occupational exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, long-sleeved shirt, shoes and socks. If the risks assessed at the baseline are of concern, then additional protective measures, such as PPE and engineering controls, are used to recalculate the MOE until exposure is sufficiently reduced.

A MOE is a measure of how close the handlers' exposure comes to the NOAEL taken from animal studies. The Agency uses the MOE as an expression of risk. In situations where the endpoint (ChEI) is the same and the MOEs of concern values are different for different exposure routes (e.g., 100 dermal MOE and 300 inhalation MOE), the MOEs are combined using the aggregate risk index (ARI). ARIs greater than or equal to 1 are not of concern.

The current PPE required for all uses of oxamyl is a short-sleeve shirt and short pants with coveralls, chemical resistant gloves, head gear for airblast, and an organic vapor respirator. The Agency calculated ARIs for oxamyl and used the following levels of protection as the basis for calculating exposure from oxamyl activities:

- **Baseline:** Long pants, long sleeved shirt, shoes and socks, no gloves.
- **Maximum PPE:** Baseline clothing and coveralls, chemical resistant gloves, and an organic-vapor respirator.
- **Engineering controls:** Closed mixing/loading and enclosed cab and cockpit.

Mixer/Loader and Applicator Risk

Inhalation and dermal exposure to oxamyl can result from occupational use. The Agency assessed dermal and inhalation risks for mixers/loaders and applicators during aerial and groundboom applications and for flaggers during aerial application. Oxamyl is not expected to be used on a continuous long-term basis (greater than 6 months a year) resulting in chronic exposure. Therefore, only short- (1-7 days) and intermediate- (one week to several months) term occupational risk assessments were conducted.

The short- and intermediate-term dermal MOEs for occupational handlers were derived based on a comparison of dermal exposure estimates against a NOAEL of 50 mg/kg/day from a 21-day rabbit dermal toxicity study (MRID 44751201). The endpoint is based on cholinesterase inhibition (ChEI) in red blood cells, plasma, and brain. An uncertainty factor of 100X was applied to account for interspecies extrapolation (10X) and intraspecies variability (10X). MOEs greater than 100 do not exceed the Agency's level of concern.

The short- and intermediate- term MOEs for occupational inhalation exposure were based on a comparison of inhalation exposure estimates against a LOAEL from an acute inhalation study (MRID 45155801) in the rat. An uncertainty factor of 100X was applied to account for interspecies extrapolation (10X) and intraspecies variability (10X). Because a NOAEL for ChEI was not established, the Agency also applied an additional 3X to the short-and intermediate term inhalation assessment. As a result, the target MOE for the inhalation exposure assessment is 300. The endpoint is based on ChEI in red blood cells, plasma, and brain and clinical signs.

In reviewing use patterns for oxamyl, the Agency identified eight major exposure scenarios: (1a) mixing/loading liquids for aerial application/chemigation; (1b) mixing/loading liquids for groundboom application; (1c) mixing/loading liquids for airblast application; (1d) mixing/loading liquids for high pressure handwand; (2) applying liquids with aerial equipment; (3) applying liquids with a groundboom sprayer; (4) applying liquids with an airblast sprayer; (5) applying liquids with a high pressure handwand; (6) mixing/loading/applying liquids for spotgun treatment; (7) mixing/loading/applying liquids by seed piece dip; and (8) flagging for liquid aerial applications. Occupational exposure and risk assessments were completed for these scenarios.

The results of these assessments, which are based on current maximum label rates, indicate that both the inhalation and dermal exposures contribute to the overall exposure at about the same level. The combined exposure results in ARIs that are not of concern for almost all assessed exposure scenarios when additional PPE is used. However, aerial and chemigation mixer/loader and applicator scenarios require the use of engineering controls to reduce risks to a level that is not of concern to the Agency based on the number of acres treated and maximum application rates (i.e., cotton [1.0 lb ai/acre] at 1200 acres per day; mint [3 lb ai/acre] and pineapples [4 lb ai/acre] at 350 acres per day).

The Agency does not have surrogate data to assess exposure from mixer/loader and applicator activities associated with the seedpiece dip use. However, the registrant has proposed voluntarily canceling this use; thereby eliminating the need to consider that use. Table 5a lists the individual crops and the respective ARIs for the specific exposure scenarios at the current labeled application rates.

Table 5a. Short- and Intermediate-Term Occupational Risk Concerns (Current Label).

Exposure Scenario (Scenario #)	Application Rate (lb ai/acre)	Crop	Daily Acres Treated	ARI Baseline[a]	ARI with Additional PPE[b]	ARI with Engineering Controls[c]
Mixer/Loader						
Mixing/loading liquids aerial/chemigation (1a)	1	cotton	1200	0.01	0.76	1.3
	3	mint	350	0.01	0.87	1.4
	4	pineapples	350	0.01	0.65	1.1
Mixing/loading liquids airblast (1b)	2	citrus	40	0.14	11	--
Mixing/loading liquids groundboom (1c)	1	cotton	200	0.06	4.6	--
			80	0.14	11	--
	4	celery	80	0.04	2.9	--
	8	carrots		0.02	1.4	--
Mixing/loading liq. high pressure handwand (1d)	0.02 lbs ai/gal	pears	1000 gal/day	0.56	46	--
Applicator						
Applying Liquids with aerial equipment (2)	1	cotton	1200	see eng. controls	see eng. controls	1.7
			350			2.9
	3	mint	350			2.0
Applying liquids with airblast equipment (3)	2	citrus	40	0.38	1.5	--
Applying liquids with groundboom sprayer (4)	1	cotton	200	1.2	--	–
			80	3	--	G
	4	celery*	80	0.76	4.6	G
	8	carrots		0.38	2.3	G
Applying liquids w/ high pressure handwand (5)	0.02 lbs ai/ gal	pears	1000 gal	0.11	1.0	NA
Mixer/Loader/Applicator						
Mixing/loading/applying liquids with spotgun (6)	3.6	banana (plantain)	2	0.05	5.4	NA
Mixing/loading/applying liquid seed piece dip (7)	2 lb ai/100 gallon	yams	no data	no data	no data	NA

Exposure Scenario (Scenario #)	Application Rate (lb ai/acre)	Crop	Daily Acres Treated	ARI Baseline[a]	ARI with Additional PPE[b]	ARI with Engineering Controls[c]
Flagger						
Flagging liquid applications (8)	1	cotton	350	1.4	-	--
	3	mint	350	0.46	2.0	--

* Celery is representative of pineapples for the applicator scenario.

[a] Long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor

[b] Baseline clothing plus coveralls, chemical resistant gloves, and organic vapor respirator

[c] Engineering controls represent the use of closed systems (e.g., closed loading and enclosed cab tractors/cockpit) long pants, long-sleeved shirt, and no gloves (except for closed loading which is based on the use of chemical resistant gloves)

To mitigate worker risks the registrant has proposed reducing the maximum application rate for cotton, mint and pineapple. The proposed reduced rates are 2 lb. ai/A for mint and pineapples, and 0.5 lb. ai/A for cotton. If engineering controls are used (closed systems for mixer/loaders/applicators), then there would be no risk concerns even at the current use rate. Table 5b lists the individual crops and the respective ARIs for the specific exposure scenarios based on the proposed application rate reductions.

Table 5b. Short- and Intermediate-Term Occupational Risk Concerns (Proposed Label).

Exposure Scenario (Scenario #)	Application Rate (lb ai/acre)	Crop	Daily Acres Treated	ARI Baseline[a]	ARI with Additional PPE[b]	ARI with Engineering Control
Mixer/Loader						
Mixing/loading liquids aerial/chemigation (1a)	0.5	cotton	1200	0.02	1.53	-
	1*		1200	0.01	0.76	1.3
	2	mint**	350	0.02	1.3	-
Mixing/loading liquids groundboom (1c)	1*	cotton	200	0.06	4.6	--
			80	0.14	11	--
	4	celery	80	0.04	2.9	--
Applicator						
Applying Liquids with aerial equipment (2)	0.5	cotton	1200	see eng. controls	see eng. controls	3.4
	1*		1200			1.7
			350			5.9
	2	mint	350			3.0
Applying liquids with groundboom sprayer (4)	1*	cotton	200	1.2	--	--
			80	3	--	G
	4	celery	80	0.76	4.6	G

Exposure Scenario (Scenario #)	Application Rate (lb ai/acre)	Crop	Daily Acres Treated	ARI Baseline[a]	ARI with Additional PPE[b]	ARI with Engineering Control
Mixer/Loader/Applicator						
Mixing/loading/applying liquid seed piece dip (7)	N/A	yams	no data	no data	no data	NA
Flagger						
Flagging liquid applications (8)	0.5	cotton	350	2.8	-	--
	1		350	1.4	-	-
	2	mint	350	0.69	2.0	--

* Rate applies to AZ and CA only.

** Mint represents commodities with same rate/type of applications (e.g., pineapples).

[a] Long pants, long sleeved shirt, shoes and socks, no gloves, open mixing/loading, open cab tractor

[b] Baseline clothing plus coveralls, chemical resistant gloves, and organic vapor respirator

Postapplication Risk

The Agency also assessed risks to postapplication workers. Postapplication workers who enter previously treated fields may be exposed to oxamyl when their skin contacts treated surfaces. Exposure is directly related to the type of task that is being performed. The Agency evaluated available information to determine the number of days following application that must elapse before the pesticide residues dissipate to a level where the risk to workers is no longer of concern. Based on the results of the postapplication worker assessment, the Agency decides whether to establish early entry restrictions to allow worker reentry into treated fields for nonroutine hand labor activities or to prohibit entry for a period of time.

For oxamyl, the Agency reviewed dislodgeable foliar residue (DFR) studies (MRIDs 446869-01, 446869-02, and 447048-01) that were conducted on citrus, cucumbers, and tomatoes. Dislodgeable foliar residue studies are used in reentry assessments to determine the amount of pesticide residue to which a worker reentering treated areas may be exposed. These studies measured the average dislodgeable foliar residues. The results were used to determine the restricted entry intervals (REIs) that would provide adequate protection for workers performing tasks in treated fields. In order to calculate the REIs, the Agency assumed an eight-hour workday, used a route specific dermal study for the toxicity endpoint, dislodgeable foliar residue data, and standard transfer coefficient values.

The studies were based on a 1.0 lb. ai/A application rate for tomatoes, cucumbers, and citrus fruits (although the labeled maximum includes a 2 lb. ai/A for soil treatment in tomatoes). The studies were conducted in California, Florida, and Georgia to account for arid and nonarid conditions. Oxamyl may not always be used at the maximum application rate; therefore, the assessment may overestimate the risks in those instances when a lower application rate is used. However, pest pressures could warrant more than one application at the maximum rate. Therefore, the Agency believes the existing

data appropriately measures the highest potential dermal exposure. (See "Revised Occupational Exposure and Risk Assessment Regarding the Use of Oxamyl," dated August 9, 2000).

Based on the current labeled use rates, the Agency determined that the MOEs for dermal risks were above the level of concern (MOE greater than 100) after 48 hours for most crops. Early entry workers must wear coveralls, chemical resistant gloves made out of any waterproof material, and shoes and socks when entering treated fields. The current 48-hour REI for pear, apple, non-bearing trees, cucumbers and other cucurbits, cotton, ginger, and celery was not protective at the current use rates. With the proposed rate reductions, the dermal risks do not exceed the Agency's level of concern after 48 hours for all crops, except hand harvesting of citrus trees. For citrus tree crops, the MOEs were of concern (MOE less than 100) until day 4 for hand harvesting activities. Minimal contact activities that include irrigation, propping, mowing, and handlers acting as scouts have MOEs above 100 after 48 hours. The MOE for cucurbits in California was slightly below the MOE of 100 after 48 hours (MOE was 97). However, the Agency believes 48 hours will be adequately protective. To be adequately protective and support reregistration, Table 6 shows that the REIs for the tree crop hand harvesting activities would need to be increased from 48 hours to 4 days. Below are the results from the REI calculations based on current and proposed label application rates:

Table 6. Summary of Reentry Requirements After Treatment by Crop (Current and Proposed).

Crop Activity		Existing Requirements [a]		Proposed Requirements [a]	
		Application Rate (lbs ai/A)	REIs Days (unless noted)	Application Rate (lbs ai/A)	REI Days (unless noted)
Citrus Trees	Hand harvesting	1	4	N/A*	N/A*
Pear, Apple, and Non-bearing Trees	Hand harvesting, pruning, and propping	2	2	1	1
Cucumbers and other cucurbits[b], Cotton and ginger	Hand harvesting, pruning, and thinning	1	3	N/A*	N/A*
Tomatoes, peppers, and eggplant	Hand harvesting, staking/tying, pruning, and thinning	1	0 (12 hours)	N/A*	N/A*
Pineapples	Hand harvesting	2	0 (12 hours)	1	0 (12 hours)
Celery	Hand harvesting	2	5	1	3[b]
White Potatoes and Peanuts	Irrigating and scouting	1	1	N/A*	N/A*
Yams	Hand harvesting	0.5	1	N/A*	N/A*
Garlic and onions	Irrigation, scouting, thinning and weeding	1	0 (12 hours)	N/A*	N/A*

[a] Day after application when the calculated MOE is greater than the target MOE of 100.

[b] It is important to note that the MOE on day 2 for cucurbits at the California site is only 97 (surrogate data for other crops).

* Unchanged.

Incident Reports

The Agency reviews the Incident Data System to determine whether oxamyl cases have been reported. As of September 4, 1996, there were 13 reports in the system for oxamyl. The reported incidents included 4 cows that died after ingesting oxamyl, some ecological incidents, and eleven human incidents, one of which was an intentional exposure.

The Agency also reviewed the Poison Control Centers data which compiles data reported from 1985 through 1992. This database covered 28 carbamate chemicals. Additional data on all pesticide exposures were obtained for the years 1993-1996. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 70 centers at hospitals and universities. There were only three occupational cases and four non-occupational cases involving exposure to oxamyl alone reported from 1985 through 1992. Two occupational and six non-occupational cases were reported for oxamyl from 1993 through 1996. Non-occupational cases are likely to involve bystanders or workers exposed to spray 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 Environmental Fate and Effects Division chapter, dated November 9, 1999, available in the public docket or at www.epa.gov/pesticides/reregistration/oxamyl.

Currently, the Agency does not assess for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to birds or mammals. The Agency does consider, however, any incident data that is submitted concerning adverse effects on non-target species.

1. Environmental Fate and Transport

Oxamyl dissipates in the soil environment by chemical- and microbially-influenced degradation and by leaching, with estimated half-lives of several days to several weeks. Hydrolysis is pH-dependent. Oxamyl degrades rapidly in neutral to alkaline environments, but persists in acidic conditions. Photolysis appears to be significant in acidic surface water but not on soil. In the soil, oxamyl metabolizes with a half-life of 2 to 4 weeks under aerobic conditions and less than 1 week under anaerobic conditions. In the field, half of the applied oxamyl dissipated from the surface within less than a week in most studies. However, groundwater studies show that significant contamination may result under certain conditions such as vulnerable soils and acidic groundwater. Oxamyl may reach surface waters through spray drift or runoff. The major transformation products identified in the fate studies were oxime and dimethyloxamic acid (DMOA), however neither degradate is of toxicological concern (see Environmental Fate and Effects Division RED Chapter for Oxamyl, November 9, 1999).

2. Ecological Risk Assessment Analysis

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of oxamyl products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as LD_{50} (the median lethal dose at which 50% of the test animals die) or LC_{50} (the median concentration of a substance which causes death to 50% of the test animals). The RQ, a non-probabilistic expression of risk, is simply a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), which provide an indication of the risk that a particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, additional refinements or mitigation are usually undertaken. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment. RQs greater than or equal to 0.5 exceed the Agency's LOC.

Toxicity studies do not include testing on all species of bird, mammal, or aquatic organisms that may be exposed. Toxicity data for only one or two surrogate species each for birds, mammals, and aquatic organisms are used to represent all bird, mammal, invertebrate and fish species in the United States. For mammals, acute studies are usually limited to a Norway rat or house mouse. Neither reptiles nor amphibians are tested. The assessment of risk or hazard to avian and reptiles assumes that the toxicity is similar. This same assumption applies to fish and amphibians.

In addition to the toxicity studies, the Agency reviews any incident data that is submitted concerning adverse effects on non-target species. The Agency reviewed several incident reports that may be attributable to oxamyl. In one report where hundreds of ducks and fish died in a pond, it was expected misuse. Other pesticides were also used in the incident area and rainy conditions may have resulted in runoff, contributing to the fish kills. Oxamyl may also be responsible for honeybee kill incidents reported in a summary of American beekeepers in 22 States for 1995-96. No further information was provided.

a. Risk to Birds

i. Acute Risk To Birds

Oxamyl is acutely toxic to birds. The acute toxicity data for nontargeted terrestrial animals shows cholinesterase inhibition in avian species. For avian species, acute oral studies were performed. Acute LOCs were exceeded for oxamyl based on the LC_{50} using bobwhite quail. The acute RQ's ranged from 0.70 to 5.65 for all food items, except treated seed, which exceeded the Agency's level of concern. Risks from treated seeds were generally below the LOC. Acute risks are high for all bird

species with RQs greater than or equal to 0.5 based on application rates equal to or greater than 1.0 lb ai/A. Results of the risk assessment suggest that oxamyl poses acute risks to avian species from unincorporated spray applications.

ii. Chronic Risks To Birds

For avian species, reproductive effects include reduction in egg production and egg fertility based on the results of a mallard duck study. Chronic LOC's were exceeded for all use patterns for all food items (except for seeds) using maximum and average EECs. The RQs ranged from 2.61 - 192.0.

b. Risks to Mammals

i. Acute Risks To Mammals

Oxamyl is acutely toxic to mammals as indicated in toxicity studies using laboratory rats (LD_{50} of 2.5 mg/kg of body weight for females and 3.1 mg/kg for males). The acute toxicity data for nontarget terrestrial animals show cholinesterase inhibition in mammalian species. Results of the risk assessment suggest that oxamyl poses acute risks to mammalian species from unincorporated spray applications. Risks exceeded the LOC for all use patterns even after just one foliar spray application of equal to or greater than 1 lb ai/A of oxamyl. The acute RQs ranged from 3.8 - 15.1 for all foods except for seed which generally was at a level that did not exceed the Agency's LOC. However, oxamyl dissipates rapidly under most conditions, reducing the probability of prolonged exposure and risk.

ii. Chronic Risks to Mammals

Results from a chronic reproduction study (MRID 41660801) indicate reproductive toxicity at a LOAEL of 75 mg/kg of dry weight of food (NOAEL of 25 mg/kg) with decreased body weight during lactation being the endpoint affected. Reproductive effects to mammalian species may result from one-time, or short-pulse, exposures to oxamyl shortly after application. Multiple applications may pose even greater hazard. The RQs ranged from 13.8 to 111.2, which significantly exceed the LOC. Results of the risk assessment suggest that oxamyl poses chronic risks to mammalian species from unincorporated spray applications.

c. Risks To Beneficial Insects

Oxamyl is moderately to highly toxic to bees on an acute contact basis (MRID 409943-01). Although the Agency does not usually assess risk to nontarget insects, results of acceptable studies are used for recommending appropriate label precautions. Results of a residue on foliage study indicate that residues of oxamyl applied at 1.0 lb ai/acre, may remain toxic to bees for as long as 6 days after

treatment (MRID 409943-01). Because oxamyl is moderately to highly toxic to honeybees, precautions with respect to spray drift to flowering plants should be followed.

d. Risks To Aquatic Animals

Aquatic risks were based on results of a refined risk assessment using PRZM-EXAMS. The results for various species are discussed below.

i. Acute Risks

Acute RQs were less than 0.01 for freshwater fish. For freshwater invertebrates the RQs ranged from 0.14 to 0.2, while estuarine/marine invertebrate RQs ranged from 0.06 to 0.08. The RQs for estuarine/marine fish was 0.01. There are no endangered species concerns.

Due to the rapid degradation of the compound, the Agency does not expect oxamyl to have acute effects to nontarget estuarine/marine fish if it should enter estuarine/marine habitats. The Agency also does not have reports of fish kill incidents in waterbodies that can be directly attributed to oxamyl when used in accordance with the label. Therefore, the Agency believes that oxamyl is unlikely to have adverse impacts or exceed the Agency's level of concern for acute risk to aquatic animals.

ii. Chronic Risks

No chronic level of concern was exceeded for freshwater fish and invertebrates for any use pattern. The chronic RQs for freshwater fish ranged from less than 0.01 to 0.14. based on a fathead minnow study and less than 0.01 to 0.19 for freshwater invertebrates based on a daphnia study. The Agency does not have data to assess the chronic risk for other species. While the absence of these studies results in uncertainties in terms of potential chronic effects to nontarget estuarine/marine organisms, the Agency does not expect chronic risks for estuarine or marine fish, because of the expected rapid degradation of the compound if it should enter estuarine/marine habitats. Therefore, the Agency does not expect the chronic risks to aquatic animals to be of concern.

e. Endangered Species

Acute and chronic risks are possible for avian and mammalian endangered species from oxamyl use. The high acute and chronic toxicity of the compound, as well as, high single application rates, multiple applications and unincorporated applications contribute to the risk. Risks to some aquatic organisms (freshwater and estuarine/marine invertebrates) were evident as well. Results from field studies suggest that endangered/threatened amphibians may also be at risk.

In addition, the Agency consulted with USFWS on oxamyl as part of the corn cluster assessment in 1981. Oxamyl was found to jeopardize the continued existence of two bird species (Attwater's greater prairie chicken and Aleutian Canada goose) and three insect species (delta green ground beetle, Kern primrose sphinx moth and valley elderberry longhorn beetle). Using current information, risk to the Aleutian Canada goose is questionable as this bird is only in the US from October to March and is mainly associated with alfalfa, which is not a registered use of oxamyl. Risks to the Kern primrose sphinx moth which is not found near corn, and the delta green ground beetle which is not found near crops are also not currently considered to be significant. The valley elderberry longhorn beetle is still a concern for the spray applications.

Oxamyl was included in the "reinitiation" of clusters in 1988. The 1989 opinion found jeopardy to the Wyoming toad (extirpated in the wild except on FWS refuges), four fish species, and four bird species. In addition, the Agency had "reasonable and prudent measures" (RPM) to reduce incidental take of approximately 20 fish and aquatic invertebrate species. The decisions in the 1989 opinion were based on an application rate of 4 lb ai per acre. The details of the RPM recommendations are provided in the USFWS 1989 publication.

Many additional species, especially aquatic species, have been federally listed as endangered/threatened since the biological opinion of 1989 was written, and determination of jeopardy to these species has not been assessed for oxamyl. In addition, endangered insects were not considered in the 1989 opinion and need to be addressed. Finally, not only are more refined methods to define ecological risks of pesticides being used but also new data, such as that for spray drift, are now available that were not existent in 1989. The RPMs in the 1989 opinion may need to be reassessed and modified based on these new approaches. This can occur once the program is finalized and in place. (A detailed discussion of potential risks to endangered species is included in the "Environmental Fate and Effects Division RED Chapter for Oxamyl ," dated November 9, 1999.)

f. Non-target Plant Risk

Currently, plant testing is not needed for pesticides other than herbicides and fungicides except on a case-by-case basis. Because oxamyl (Vydate-L; EPA Reg. #352-372) is used as a plant growth regulator, plant testing is needed (see section V). Oxamyl has a residual period in plants of approximately 1 to 2 weeks. Plants take oxamyl up through both leaves and roots.

IV. Risk Management, Reregistration and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after 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., active ingredient specific) data required to support reregistration of products containing oxamyl as an active ingredient.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticides containing the active ingredient oxamyl, including an oxamyl-specific dietary risk assessment that does not consider the cumulative effects of any other pesticides which may share a common mechanism of toxicity. Based on a review of these data and public comments on the Agency's assessments for the active ingredient oxamyl, EPA has sufficient information on the human health and ecological effects of oxamyl 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 oxamyl 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 carbamates support a final reregistration eligibility decision. Label changes are described in Section IV. Appendix B identifies the generic data requirements the Agency reviewed as part of its interim determination of reregistration eligibility of oxamyl, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet determined whether oxamyl shares a common mechanism of toxicity with other pesticides, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of oxamyl.

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

At the time that the Agency determines if a cumulative assessment is warranted, the Agency will address any outstanding risk concerns. For oxamyl, 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 oxamyl if a cumulative risk is warranted for the carbamate 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 carbamate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the carbamates in as timely a manner as possible.

Because the Agency has not yet determined if a cumulative risk assessment is necessary for some of the carbamates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing oxamyl food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has made the final determination on whether a cumulative assessment is warranted, and, if so, when the Agency completes the cumulative assessment, oxamyl tolerances will be reassessed. At that time, the Agency will reassess oxamyl along with the other carbamate 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 oxamyl, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalizing 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 Comments and Responses

When making its interim reregistration decision, the Agency considered all comments received during the 30-day informal comment period (see FR 39898, dated June 28, 2000). The Agency received comments and a risk mitigation proposal from the registrant, DuPont de Nemours, Inc. Details of this proposal are discussed in the next section. Other commenters included the National Cotton Council; Apple Growers Association; Infoscientific.com, Inc.; Mercer Ranch, Quality Washington Grown Vegetables; George Good, New York State Apple Profile; and other nonaffiliated interested stakeholders. Most of the commenters stated the need to retain oxamyl for currently registered uses.

The Apple Growers Association was especially concerned about maintaining oxamyl for postbloom use on apples. The Agency discussed the feasibility of eliminating the postbloom treatment for apples with the Apple Growers Association to reduce the potential residues in apples. Growers indicated that postbloom applications are the primary use for apples and eliminating this treatment would eliminate the key need for oxamyl on apples. Oxamyl is also part of the IPM program for apples. This loss would significantly impact apple growing regions of New York, Washington, California, and Oregon. These states collectively represented 59% of the acreage and 75% of the

apple production in 1997. A summary of the communications with the apple growers is available in the public docket.

C. Tolerance Reassessment

Based on the review of the generic data for oxamyl, the Agency has sufficient information to reassess tolerances for oxamyl. Specific findings are discussed in the following section.

D. Regulatory Position

1. FQPA Assessment

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with oxamyl. The assessment was for this individual carbamate, and does not attempt to fully reassess 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. The Agency will evaluate the cumulative risk posed by pesticides sharing a common mechanism of toxicity with oxamyl once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from food exposure to oxamyl does not exceed its own "risk cup." In other words, without consideration of a cumulative assessment, EPA would be able to conclude today that the tolerances for oxamyl 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 acute food exposures.

An aggregate assessment was conducted for exposures through food and drinking water (no residential uses exist). Results of this aggregate assessment indicate that the human health risks from these combined acute exposures exceed the risk cup for children 1-6 only; that is, combined risks from all exposures to oxamyl do not "fit" within the individual acute risk cup for this population subgroup. However, the Agency believes that the aggregate risks may be overestimated for the following reasons:

- PDP data measures both the parent and the degradate (which is not of toxicological concern);
- Analysis includes some field trial data (which tends to be conservative); and
- Dietary and groundwater consumption data represents a 24-hour period without considering oxamyl induced ChEI reverses in 2-3 hours, and it is unlikely a 1-6 year old would consume a 24-hour dietary burden in 2 to 3 hours.

Even if a 1 to 6 year old were to consume a 24-hour allocation of oxamyl treated foods in a single serving, it is unlikely all foods would contain maximum residue levels. A preliminary review of the

carbamate market basket survey indicates that residues of parent oxamyl may be lower than the combined residues reported by PDP. The data for the market basket separates the parent oxamyl from the oxime degradate.

2. Tolerance Summary

Based on the results of available data, the commodity uses covered by the obsolete "root crop vegetable group" tolerance name are reassigned so as to be covered by individual tolerance names (carrot, garlic, and onion dry bulbs) and the "tuberous and corm vegetable crop group (subgroup 1C)" tolerance (arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chura; dasheen; ginger; leren; potato; sweet potato; tanier; tumeric; yambean; and yam, true). The Agency published a *Federal Register* notice (65 FR 33691, May 24, 2000) that reassigned pineapple bran to 40 CFR § 180.303(a)(2). In the individual assessment, tolerances for residues of oxamyl in/on plant commodities [40 CFR §180.303] are presently expressed in terms of the sum of the residues of the parent oxamyl and its oxime degradate (N',N'-dimethyl-N-hydroxy-1-thiooxamimidate). The Agency determined that oxime is not likely to be a potent acetyl cholinesterase inhibitor and is therefore not of toxicological concern. However, it is not currently possible to exclude oxime from the tolerance expression, because the PDP analytical method cannot distinguish between the parent and the metabolite.

The Agency has determined that there is no reasonable expectation of finite oxamyl residues in animal commodities; consequently, there are no tolerances for meat, milk, poultry, or eggs. Adequate data are available to reassess the established tolerances for oxamyl residues in/on the following commodities: apples, bananas (including plantains), cantaloupe, celery, citrus fruits, cottonseed, cucumbers, eggplants, ginger, honeydews, dry bulb onions, garlic (translated from dry bulb onion data), peanuts, peanut hay, pears, peppermint, peppers (bell and non-bell), pineapples, potatoes, pumpkins, soybeans, spearmint, summer squash, sweet potatoes, tomatoes, watermelon, winter squash and yams (translated from potato data).

The **"root crop vegetable group"** is an obsolete tolerance group name. A tolerance for the uses under the new name, crop subgroup 1C, **"Tuberous and Corm Vegetable"** would cover most of the crops currently on the label without additional data. Based on the tolerance reassessment, the Agency has decided to list carrot, root; onion, dry bulb; and garlic under individual tolerance names; i.e., carrots, dry onion bulb, and garlic. No additional data is needed. If the registrant or other interested party desires tolerances on any commodities for crop subgroup 1C no additional field trial data would be required. To establish a crop group tolerance for all Crop Group 1 commodities, additional field trial data would be required for radish and sugar beet. Also, if data are submitted and support establishment of a Crop Group 1 tolerance, then Agency would recalculate the dietary exposure estimates since the present estimates will likely be underestimated.

Because the Agency no longer considers peanut forage and hulls, pineapple forage, and soybean straw to be significant livestock feed items, the established tolerances for these commodities should be revoked.

The proposed new tolerances are summarized below in Table 7 below.

Table 7. Tolerance Summary for Oxamyl.

Commodity	Current Tolerance (ppm)	Tolerance* Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.303(a)(1):			
Apples	2	2.0	*[Apple*]
Bananas	0.3	0.30	*[Banana*]
Cantaloupe	2.0	2.0	*[Muskmelon]*
Honeydews	2.0		
Celery	3	10	Available data (reflecting a 14-day PHI) support tolerance increase pending cumulative assessment.
Citrus fruits	3	3.0	*[Fruit, citrus, Group]*
Cottonseed	0.2	0.20	*[Cotton, undelinted seed]*
Cucumbers	2.0	2.0	*[Cucumber]*
Eggplants	2.0	2.0	*[Eggplant*]
Peanuts	0.2	0.10	Available data support tolerance decrease for Codex harmonization. *[Peanut]*
Peanut, forage	2.0	Revoke	No longer considered a significant feed item (Table 1, OPPTS 860.1000).
Peanut, hay	2.0	2.0	*[Peanut, hay]*
Pears	2.0	2.0	[*Pear]*
Peppermint, hay	10.0	6.0	Available data support tolerance decrease. *[Peppermint, tops]*
Peppers (bell)	3	2.0	Available data support tolerance decrease for Codex harmonization. [*Pepper, bell*]
Pepper, non-bell	5.0	5.0	
Pineapples	1	1.0	*[Pineapple]*
Pineapples, forage	10	Revoke	No longer considered a significant feed item (Table 1, OPPTS 816.1000).
Pumpkins	2.0	0.20	Available data support tolerance decrease. [*Pumpkin]*
Root Crop Vegetables	0.1	Reassign 0.10	*[Carrot]*, individual tolerance
	0.1	Reassign 0.10	The tolerance should be reassigned concomitant with the establishment of tuberous corm crop (subgroup 1C).[c] [*Crop, Subgroup 1C, tuberous and corm Vegetable]*
	0.1	0.20	Reassign from root crop vegetable group and establish individual tolerance. Available data (reflecting a 14-day PHI) support tolerance increase pending cumulative assessment.*[Garlic, bulb]*

Commodity	Current Tolerance (ppm)	Tolerance* Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
	0.1	0.20	Reassign from root crop vegetable group and establish individual tolerance. Available data (reflecting a 14-day PHI) support tolerance increase pending cumulative assessment. *[Onion, dry bulb]*
	0.1	Revoke	Beet, no registered uses exist
	0.1	Revoke	Chicory, no registered uses exist
	0.1	Revoke	Green onion, no registered uses exist
	0.1	Revoke	Parsnip, no registered uses exist
	0.1	Revoke	Radish, no registered uses exist
	0.1	Revoke	Rutabaga, no registered uses exist
	0.1	Revoke	Salsify, no registered uses exist
	0.1	Revoke	Shallot, no registered uses exist
	0.1	Revoke	Spring Onion, no registered uses exist
	0.1	Revoke	Sugar Beet, no registered uses exist
	0.1	Revoke	Turnip, no registered uses exist
Soybeans	0.2	0.10	*[Soybean]*
Soybean straw	0.2	Revoke	No longer considered a significant feed item (Table 1, OPPTS 860.1000).
Spearmint, hay	10.0	6.0	Available data support tolerance decrease. *[Spearmint, Tops]*
Summer Squash	2.0	2.0	*[Squash, summer]*
Tomatoes	2	2.0	*[Tomato]*
Winter Squash	2.0	0.20	Available data support tolerance decrease. *[Squash, winter]*
Watermelon	2.0	2.0	
Tolerances to be Proposed:			
Cotton, gin byproducts	--	TBD[a]	The Agency now considers cotton gin byproducts to be a raw agricultural commodity and data is needed.
Tolerances Listed Under 40 CFR §180.303(a)(2):			
Pineapple bran	6	2.0	Feed additive. No tolerance is currently established for oxamyl residues in animal commodities. *[Pineapple, process residue]*

[a]To be determined because additional data are needed in the establishment of any new tolerances, pending the outcome of the cumulative assessment.

[b]Old group name included tolerance for beet, carrot, chicory, garlic, green onion, parsnip, potato, radish, rutabaga, salsify, shallot, spring onion, sugar beet, sweet potato, turnip, and yam.

[c] Includes arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chura; dasheen; ginger; leren; potato; sweet potato; tanier; tumeric; yambean; and yam, true.

* The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be further reassessed only upon completion of the cumulative risk assessment of carbamates deemed to share a common mechanism of toxicity, as required by law. Rather, it provides a tolerance level for this single chemical., if no cumulative assessment was required, that is supported by all of the submitted residue data. The raising of any tolerances will be deferred, pending the determination of whether a cumulative assessment is warranted.

3. Endocrine Disruptor Effects

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

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

4. Labels

The Agency has determined that, for oxamyl to be eligible for reregistration, the oxamyl label needs to be amended to mitigate aggregate, occupational, and ecological risks. The use of additional PPE, reduced application rates, and closed systems in California and Arizona, in addition to existing label requirements, will reduce risks to levels that are no longer of concern. With regard to worker post-application risks, the Agency is recommending the continuance of REIs currently on the label for all crops, other than citrus tree crop. The REI for citrus tree crop must be increased from 48-hours to 96 hours (4 days). The Agency believes that the agreed-upon rate reductions for cotton, pineapples, mint, and aerial/chemigation foliage treatment (particularly for cotton) will reduce ecological risk. Provided the following risk mitigation measures are incorporated in their entirety into labels for oxamyl-containing products, the Agency finds that all currently registered uses of oxamyl (except seedpiece dip, soybean use, and high-pressure broadcast treatment for cotton, which are being voluntarily canceled) are eligible for interim reregistration, pending a decision on cumulative assessment of any pesticides that show a common mechanism of toxicity with oxamyl. The regulatory rationale and the mitigation measures are discussed below for each area of concern.

E. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary (food) Mitigation

Acute dietary risk is below the Agency's level of concern based on a highly refined, acute probabilistic dietary exposure analysis using the DEEM model which incorporates percent crop treated information, PDP, FDA monitoring data, and field trial data. The percent aPAD value is 81% based solely on food for the most highly exposed population subgroup, children 1-6 years old. As mentioned previously, the Agency did not perform a chronic risk assessment because oxamyl induced ChEI reverses within 2 to 3 hours. Therefore, no additional risk mitigation measures are necessary at this time to address dietary risk from food.

The Agency found that apples (raw, juice) are the major food contributor to the children's aPAD, contributing approximately 45 % of acute exposure. The amount of pesticide to which an individual is exposed is determined by combining the consumption data (USDA) and residue data. Qualitatively it follows, that if there is high consumption of a type of food with a relatively low amount of pesticide, the exposure would be similar to a type of food where a low consumption and a high pesticide level is found. Apples are an example of a food type that has low residues of oxamyl and high consumption. Hence, when combined with a low dietary toxicological endpoint, it becomes a significant contributor to the acute dietary risk. One of the limitations to the DEEM model is that a daily consumption of a particular type of food is added together then combined with the residue data. In other words, if someone were to eat three apples in a single day, the model assumes they all have the same residue value; thus, the DEEM model may provide a somewhat conservative assessment for some foods. In this case as previously stated, apples account for about 45% of the aPAD dietary risk cup for food.

b. Dietary (water) Mitigation

Data show that oxamyl can persist and reach groundwater. Based primarily on monitoring (North Carolina Cotton Study), oxamyl is expected to be very mobile or generally persistent in highly vulnerable soils. The registrant is currently completing an additional prospective groundwater study on tomatoes in Maryland, which will further characterize the fate of oxamyl. The preliminary data from this study confirm that groundwater contamination can occur at levels consistent with the results of the North Carolina study.

Potential surface water and groundwater drinking water exposures do not exceed the acute DWLOC values for the general subpopulation, but the acute DWLOC is exceeded for children (1-6 years old) from groundwater sources of drinking water. To evaluate this exposure, the Agency reviewed non-chemical specific studies that showed similar results to those in the PGW monitoring study, except for Suffolk County where some detects were higher. This non-chemical specific monitoring study detected a combination of the parent and degradates. The Agency also considered, the North Carolina prospective groundwater (PGW) monitoring study. The PGW detected the parent oxamyl only. Finally, the Agency considered preliminary results from an ongoing PGW study on tomatoes in Maryland that have replicated the estimated water concentrations used in this assessment.

The acute DWLOC for children (ages 1-6) allows only 1.9 ppb for drinking water, while the expected concentration in groundwater could reach 4.0 ppb based on the results of PGW monitoring studies. The registrant has agreed to reduce the application rate for cotton from 1 lb ai/A to 0.5 lb ai/A, which the Agency believes will reduce potential residues in groundwater. Due to soil conditions, the Agency does not expect leaching to groundwater in Arizona and California, where the l.0 lb ai/A rate will be allowed. As stated earlier, the ongoing PGW monitoring study is expected to substantiate the Agency's determination that groundwater contamination above the 4 ppb level is unlikely.

The Agency is requesting reductions in the rate and number of applications (e.g., cotton, mint, pineapple, etc) for various crops. The registrant has committed to these reductions, and the Agency believes these measures will reduce the potential for oxamyl to reach groundwater.

c. Aggregate (food and water) Mitigation

Aggregate risk is limited to food and water since there are no residential uses. The acute aggregate risk for food and water does not exceed the Agency's level of concern for the general population. For children 1 to 6 years old, the acute aggregate risk for food and water appear to be of concern based on the Agency's DWLOC. Although the Agency's acute aggregate risk assessment shows potential concern for children from 1 to 6 years of age, the Agency believes that the assessment included assumptions that overestimate dietary risk. As mentioned previously, the analysis assumes an individual consumes 3-4 servings of food and 1-liter of water (children 1-6) with the highest residue levels detected in each serving within a 24-hour period. The Agency does not expect that a child, 1 to 6 years old, would consume 3-4 servings of food and 1-liter of water at a single meal. And, if it were to happen, it is unlikely that each food item would be contaminated at the highest residue levels of oxamyl. As mentioned previously, the effects of oxamyl on ChEI are of a short duration, and reverses within 2 to 3 hours. Therefore, oxamyl residues would need to be present in all and food and water consumed within a 2-4 hour period to result in an acute dietary concern. The Agency believes such exposure is unlikely.

As discussed earlier, the groundwater monitoring studies detected oxamyl in several samples at extremely high levels (mainly Suffolk County, Long Island). Oxamyl has been banned in Suffolk Co. because of widespread, low level detections and isolated high levels in groundwater. The groundwater pH in the areas where the samples were taken was acidic. The pH ranged between 4 and 5. While the Agency is unable to explain these high detections, half of the applied oxamyl dissipated from the surface within less than a week in most field studies. Therefore, the Agency believes that these detection levels are atypical. The Agency based the risk assessment on 4 ppb and treated the higher detects as outliers.

Considering the underlying assumptions and their corresponding effect on the aggregate dietary risk analysis and the pending application reductions on the use of oxamyl, the Agency believes the assessment is overly conservative for children 1-6 years. The Agency believes the proposed label modifications will further reduce the risk.

d. Residential Mitigation

There are no residential uses. Therefore, no mitigation is warranted.

e. Occupational Mitigation

i. Mixers/loader/applicators

Although the current label requires PPE beyond the baseline level, the Agency initially conducted the occupational assessment assuming handlers wore baseline attire according to current policy. Risks, assuming the baseline protection and current maximum labeled application rates, exceed the Agency's level of concern for all scenarios. However, registrant proposed reduced application rates, use deletions, and the use of PPE are sufficient to mitigate risks to levels that are not of concern to the Agency for all scenarios except use on cotton at the 1.0 lb/ai/A application rate. The registrant has requested the cotton use rate remain at 1.0 lb ai/A for cotton in California and Arizona only in order to control lygus pests. Because oxamyl is only effective against the targeted pests at the higher rate, and these pests are not present in other areas of the country, the Agency believes that the use of oxamyl at 1.0 lb ai/a for cotton in California and Arizona is beneficial.

The Agency also believes that California and Arizona represent a relatively small percentage of all cotton grown nationwide. The soil and groundwater conditions are not as vulnerable as those at the sites where oxamyl was detected in groundwater. Therefore, the Agency is allowing the use of 1.0 lb ai/A on cotton in Arizona and California, provided engineering controls are used. Changes in application rates and other measures necessary to mitigate occupational risks are summarized below:

Personal Protective Equipment:

- Maintain PPE for all uses (baseline and coveralls, chemical resistant shoes, socks, chemical resistant gloves, chemical resistant apron, head gear for airblast, and an organic vapor respirator).

Engineering Controls:

- Enclosed cockpits for aerial applicators
- Closed mixing/loading systems in CA and AZ for cotton use

Application Rates:

<u>Aerial:</u>

- Reduce maximum application rate to 1.0 lb ai/A for foliar applications on all crops except cotton (see below)

Chemigation:

- Reduce maximum application rate to 2.0 lb ai/A for all crops except cotton (see below)

Soil:

- Reduce maximum soil application rate to 4.0 lb ai/A for all crops, except mint and pineapple, which must be reduced to 2.0 lb ai/A.

Cotton:

- Reduce maximum rate to 0.5 lb ai/A, except in areas mentioned below.
- Maintain 1.0 lb ai/A use in California and Arizona only (use closed systems as discussed above)
- Reduce maximum seasonal rate to 3.0 lb. ai/A/year

Other:

- Reduce seasonal maximum applications to 8 per crop
- Incorporate all groundboom soil treatments by water or mechanical means

Voluntary Cancellations:

- Seed piece dip (yams)
- Soybean use
- Soil broadcast treatment for cotton

ii. Post-application workers and handlers

The Agency is also concerned about postapplication exposure and risks to workers performing routine tasks (i.e., irrigation, harvesting) and crop advising/scouting tasks in the treated area. Based on the results of DFR studies, the Agency is requesting the following mitigation measures, which are consistent with the WPS requirements outlined under WPS for risk at this level, except for citrus tree crops (see Section III.5.b).

- Although, cucurbits showed some risks up to 3 days, the Agency believes that 48 hours is adequately protective because the MOE is 97 within 48 hours after treatment. Maintain 48-hour REI for all crops, except citrus tree crops (see below).

- For citrus tree crops, the REI is 4 days, EXCEPT: In addition to early-entry exceptions specified in WPS, after 48-hours, workers may enter treated fields to perform irrigation, propping and mowing without restriction, and handlers acting as scouts may enter without the specified PPE.

The Agency believes the measures discussed below are necessary to protect postapplication workers.

- Early Entry workers (as defined by WPS): Due to the severity of the cholinesterase endpoint, early-entry personnel must use protective equipment of coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical resistant shoes, and socks. Early-entry personnel should follow the above restrictions for 48-hours after treatment for all crop treatment except citrus tree crops. For hand-harvesting citrus tree crops, the above restrictions should be followed for 4 days after treatment.

f. Ecological Mitigation

As discussed previously, the acute and chronic risk quotients for avian and mammalian species for most food items are based on a single foliar broadcast application of $\geq$ 1 lb ai/A exceeds the Agency's level of concern. Using a refined assessment, the acute and chronic risks for freshwater and estuarine/marine fish did not exceed the Agency's level of concern for any use. While there is some concern for endangered species freshwater invertebrates, the risks may be mitigated through restricted use classification. Oxamyl is currently registered as a "restricted use" pesticide and needs to continue to be restricted.

After considering and discussing several options with interested stakeholders, the Agency believes the following modifications, which include reducing application rates, incorporating soil applications immediately, reducing the number of applications for crops per year, and removing soil broadcast treatment for cotton will reduce the risks to the affected species and will adequately mitigate the mammalian and avian risks. No further mitigation is needed at this time.

2. 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 oxamyl. For the specific labeling statements, refer to Section V of this document.

a. Spray Drift

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in section V of this document . The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language.

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

"Do not allow this product to drift"

For outdoor liquid products that are applied aerially, further label language is necessary for spray drift management. Specific label language is outlined in Table 8, "Summary of Labeling Changes for Oxamyl" of this document.

b. 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 will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

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, by submitting label amendments and meeting the data requirements described in this section.

A. Manufacturing-Use Products

1. Additional Generic Requirements

The generic data base supporting the reregistration of oxamyl for the eligible uses has been reviewed and determined to be substantially complete. At this time the Agency is requiring the following studies:

Product Chemistry:

- Description of Materials Used to Produce the Product (Guideline 830.1600).
- UV/Visible Absorption (Guideline 830.7050).

Residue Chemistry:

- Directions for Use (Guideline 860.1200).
- Crop Field Trials for Cotton Gin Byproducts (Guideline 860.1500).

Ecological:

- Aquatic plant growth study (Guideline 122-2)
- Vegetative Vigor (Guideline (Guideline 122-1b)
- Seed Germ/Seedling Emergence (Guideline 122-1a)

The pending tomato prospective groundwater monitoring study is considered confirmatory data. If the Agency finds that new studies identify additional risks of concern, the Agency may reconsider any or all the measures established in this interim RED.

2. Labeling Requirements for Manufacturing-Use Products

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

All registrants need to submit applications for amended reregistration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all label amendments outlined in Table 8 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended

labels need to be submitted within eight months of signature of this document to the Product Reregistration Branch. The contact is Jane Mitchell at (703) 308-8061.

B. End-Use Products

1. Additional Generic 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 Agency acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

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

2. Labeling End-Use Products

Label changes are necessary to implement the mitigation measures outlined in Section IV above. These changes include reduction in application rates, additional engineering controls for AZ and CA and specific Personal Protective Equipment; incorporate all soil treatments by water or mechanical means; and retain the restricted-use classification due to acute toxicity and toxicity to birds and mammals. Specific language to incorporate these changes is specified in Table 8 at the end of this section. Registrants need to submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all label amendments outlined in Table 8 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels need to be submitted within eight months of signature of this document to the Product Reregistration Branch. The contact is Jane Mitchell at (703) 308-8061.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 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 24 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 oxamyl products bearing old labels/labeling for 12 months from the date of issuance of this interim RED. Persons other than the registrant may distribute or sell such products for 24 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 8. Summary of Labeling Changes for Oxamyl		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into an insecticide/acaricide/nematocide."	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)."	
Environmental Hazards Statements	"**Environmental Hazards**" "This chemical is toxic to aquatic organisms and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards.
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE". "Due to acute toxicity and toxicity to birds and mammals. For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification."	Top of Front Panel

IRED PPE Requirements	"Personal Protective Equipment Some materials that are chemical resistant to this product are (Registrant inserts 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-resistant category selection chart. Mixers, loaders, applicators, flaggers, and other handlers must wear: - coveralls over long-sleeved shirt and long pants**,** - chemical-resistant footwear plus socks, - chemical-resistant gloves, - chemical-resistant apron when mixing, loading and cleaning equipment, - chemical-resistant head gear for overhead exposures, - Respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or He prefilter. See engineering controls for additional requirements." <u>NOTE:</u> The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum personal protective equipment, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7. <u>NOTE:</u> The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil."	Precautionary Statements: Following the 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 or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Following the PPE requirements

Engineering Controls	"Engineering Controls" "Mixers and loaders supporting use on cotton in California and Arizona must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)]. The system must be designed by the manufacturer to remove a liquid pesticide from its container and transfer it through connecting hoses, pipes, and/or couplings that are sufficiently tight to prevent dermal or inhalation exposure of any person to the pesticide concentrate, use dilution, or rinse solution and must be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant footwear, and the type of respirator required for handlers on this labeling. In addition, handlers – may wear long-sleeved shirt and long pants, socks and shoes, chemical resistant gloves and a chemical resistant apron, instead of the PPE required for mixers and loaders on this label, -- must wear protective eyewear if the system operates under pressure. 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 handlers use closed systems, or enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: (Immediately following User Safety Requirements.)
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: Immediately Following the Engineering Controls. (Must be placed in a box.)

Environmental Hazards	"Environmental Hazards: This pesticide is toxic to aquatic organisms and extremely toxic to birds and mammals. Cover or disc all spill areas. Birds and mammals feeding in treated areas may be killed. Do not apply directly to water, or to area where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." This product can contaminate surface water through ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.	Precautionary Statements .
Restricted-Entry Interval	"Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 48 hours for all crops except citrus. For citrus the REI is 4 days, EXCEPT: In addition to early entry exceptions specified under WPS, after 48- hours, workers may enter treated fields to perform irrigation, propping, and mowing without restriction, and handlers acting as scouts may enter without specified PPE.	Directions for Use, Agricultural Use Requirements Box
Personal protective equipment required for early entry	"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 - Chemical resistant gloves made of any waterproof material - Socks and shoes	

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. "Do not allow this product to drift." "Applications to cotton by handwand or soil broadcast are prohibited" "Seed treatments are prohibited" "All applications to soil must be incorporated by water or by mechanical means." The maximum aerial application rate for all crops except cotton is 1.0 lb ai/A per application. The maximum chemigation rate for all crops except cotton is 2.0 lbs ai/A per application. The maximum application rate for cotton (except for Arizona and California) is 0.5 lb ai/A per application. The maximum application rate for Arizona and California rate is 1.0 lb ai/A per application. The maximum soil application rate for all crops except mint and pineapples is 4lbs ai/A per application. The maximum soil application rate for mint and pineapples is 2.0 lbs ai/A per application. The maximum number of applications for all crops per growing season is 8. The maximum amount of ai that can be applied to cotton per growing season is 3 lbs.	Directions for Use immediately preceding the Agricultural Use Requirements box.
Aerial Spray Drift Label Language	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
Aerial Spray Drift Label Language	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use

Continued... Aerial Spray Drift Label Language	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"CONTROLLING DROPLET SIZE"** " **!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use

Continued... Aerial Spray Drift Label Language	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
Continued... Aerial Spray Drift Label Language	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"TEMPERATURE AND HUMIDITY**" "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"TEMPERATURE INVERSIONS**" "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use

Continued... Aerial Spray Drift Label Language	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

VI. Related Documents and How to Access Them

This Risk Management Proposal is supported by documents that are presently maintained in the OPP docket. The following sections indicate the means to view or obtain copies of paper or electronic versions of these documents and lists titles of documents that are now in the docket files.

Availability at OPP Docket Room

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

The docket initially contained preliminary risk assessments and related documents as of [insert date of docket opening]. Sixty days later the first public comment period closed. The Agency then considered comments, revised risk assessments, and then added proposed reregistration eligibility and risk management decision documents, response to comments, and revised risk assessments to the docket on [insert date of second comment period opening].

All documents, in hard copy form, may be viewed in the OPP docket room or viewed or downloaded or viewed via the Internet **(http://www.epa.gov/oppsrrd1/op/)**

Documents Added to Docket After July 28, 2000 open comment period.

Revised HED Assessment
Revised EFED Assessment
Response to Comments (chemical specific)
Response to Generic Comments
Registrant Meeting Minutes

VII. APPENDICES

Appendix A. Oxamyl (Case 0253): Use Patterns Eligible For Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Apple						
Broadcast application Delayed dormant and/or foliar Ground equipment	2 lb/gal SC/L [352-372]	2 lb/A or 0.5 lb/100 gal [50-400 gal/A of finished spray]	Not specified (NS)	2 lb/A	14	Foliar applications may be made as needed or at 7- to 14-day intervals. Applications at bloom or within 30 days after bloom are prohibited. Grazing of livestock in treated orchards is prohibited.
Dilute spray application After full bloom (between 5 and 30 days) Ground equipment	2 lb/gal SC/L	1 lb/A or 0.5 lb/100 gal	2	2 lb/A	14	Use limited to PA, VA, WV, or NJ. Application may be made alone or as a tank mix with other pesticides. Grazing of livestock in treated orchards is prohibited.
Broadcast application Delayed dormant Aerial equipment	2 lb/gal SC/L	0.5 lb/A	1	2 lb/A	14	Use limited to WA. Application may be made in 5-15 gal/A. Additional applications may be made with ground equipment only. Grazing of livestock in treated orchards is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Banana						
Foliar or soil treatment At planting and post plant Ground equipment (spotgun applicator)	2 lb/gal SC/L [352-372]	2.4 g per corm or "seed"	NS	4 lb/A	1	Use limited to PR. At plant application is made in the planting hole; a second application may be made as a foliar or soil treatment 2-3 months after planting. Subsequent applications may be made at 3- to 4-month intervals. Grazing or foraging of animals in treated areas is prohibited.
Carrot						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372]	8 lb/A	NS	8 lb/A	14	Use prohibited in CA. Applications may be made in a minimum of 20 gal/A. Foliar applications are made beginning at the onset of damage and may be repeated twice at 2- to 3-week intervals.
Soil in-furrow treatment At planting Ground equipment		4 lb/A	NS			
Directed spray application Foliar Ground equipment		1 lb/A	3			
Celery						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	1	6 lb/A	21	Use limited to FL, MI, PA, and TX. Preplant application is made as a band (8-16 inches) treatment using 20 gal/A.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Transplant application Foliar Ground equipment	2 lb/gal SC/L [352-372]	2 lb/A	1	6 lb/A	21	Use limited to FL and OH. Application may be made in a minimum of 100 gal/A by ground.
	2 lb/gal SC/L	2 lb/A	NS	NS	21	
Directed spray application Foliar Ground equipment	2 lb/gal SC/L [352-372]	2 lb/A	2	6 lb/A	21	Use limited to FL. Application may be made in a minimum of 100 gal/A by ground. The first application is made three weeks after transplanting and the second application is made three weeks later.
Celery (continued)						
	2 lb/gal SC/L	2 lb/A	2	6 lb/A	21	Use limited to OH. Application may be made in a minimum of 10 gal/A by ground. The first application is made three weeks after transplanting and the second application is made three weeks later.
Directed spray application Foliar Ground equipment	2 lb/gal SC/L	1 lb/A	3	6 lb/A	21	Use limited to MI, PA, and TX. Applications may be made in 20 gal/A at 2- to 3-week intervals.
Broadcast application Foliar Ground or aerial equipment	2 lb/gal SC/L [352-372]	1 lb/A	NS	6 lb/A	21	Use limited to FL. Applications may be made in a minimum of 5 gal/A by air. Applications are made when insects first appear and may be repeated at 5- to 7-day intervals or as needed.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
	2 lb/gal SC/L	1 lb/A	NS	6 lb/A	21	Use limited to AZ. Applications may be made in a minimum of 10 gal/A by air. Applications are made when insects first appear and may be repeated at 5- to 7-day intervals or as needed.
Broadcast application Foliar Ground or aerial equipment	2 lb/gal SC/L	1 lb/A	NS	NS	21	Use limited to CA. Applications may be made in a minimum of 10 gal/A by air. Applications are made when insects first appear and may be repeated at 5- to 7-day intervals or as needed.
Citrus						
Foliar treatment Ground equipment	2 lb/gal SC/L [352-372]	1 lb/A or 0.25 lb/100 gal [400 gal/A of finished spray]	6	6 lb/A	7	Applications may be made as needed at 2- to 6-week intervals. Grazing of livestock in treated orchards is prohibited.
		1 lb/A [100-500 gal/A of finished spray]	NS			Applications may be made when new growth is about 3-4 inches long and repeated as needed. Grazing of livestock in treated orchards is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Foliar treatment Ground or aerial equipment	2 lb/gal SC/L	1 lb/A	NS	6 lb/A	7	Applications may be made in 10-20 gal/A by air when new growth is about 3-4 inches long and repeated as needed. Grazing of livestock in treated orchards is prohibited.
Chemigation Flood irrigation water or drip irrigation systems	2 lb/gal SC/L	2 lb/A	NS	6 lb/A	7	Use limited to CA. Applications may be made by metering into flood irrigation water or drip irrigation systems with a maximum application of 2 lb ai/A in any 30-day period. Grazing of livestock in treated orchards is prohibited.
Cotton						
Broadcast application Foliar Ground or aerial equipment	3.77 lb/gal SC/L [352-532]	1 lb/A	NS	4 lb/A	14	Applications may be made in sufficient refined vegetable oil (minimum of 3 pt/A) or water for thorough coverage at 6- to 8-day intervals. Grazing or feeding treated cotton to livestock is prohibited.
		0.25 lb/A	NS	2.5 lb/A		Multiple applications may be made in sufficient refined vegetable oil (minimum of 3 pt/A) or water for thorough coverage as needed. Grazing or feeding treated cotton to livestock is prohibited.
Broadcast application Foliar Ground equipment	2 lb/gal SC/L [352-372]	1 lb/A	4	4 lb/A	21	Applications may be made at 6- to 8-day intervals. Grazing or feeding treated cotton to livestock is prohibited.
		0.25 lb/A	NS	2.5 lb/A		Multiple applications may be made as needed. Grazing or feeding treated cotton to livestock is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Cucumber						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	6 lb/A	1	Application may be made as a broadcast or band treatment; use a proportionately lower rate for band application.
Broadcast application Foliar Ground equipment		1 lb/A	NS			Applications are made when insects first appear and may be repeated at 7-day intervals or as needed. Applications may be made in sufficient water for uniform coverage.
Eggplant						
Broadcast application Foliar Ground equipment	2 lb/gal SC/L [352-372]	1 lb/A	NS	6 lb/A	1	Applications may be repeated at 1 to 3 week intervals as need.
Soil band treatment After transplanting Ground equipment		2 lb/A	NS		7 (soil/foliar)	Nematode use prohibited in CA. Soil applications are to be made 2-3 weeks after transplanting and again 4 weeks later. Two to four weeks after soil treatments, two foliar applications may be made at 1- to 2- week intervals. A 7-day PHI has been established for soil applications followed by foliar applications; a 1-day PHI has been established for foliar applications only.
Broadcast application Foliar Ground equipment		1 lb/A	2		1 (foliar only)	
Garlic						
In-furrow drench treatment At planting Ground equipment	2 lb/gal SC/L	2 lb/A	NS	4.5	14	Use limited to OR. Applications may be made in 100-150 gal/A.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
In-furrow band treatment At planting Ground equipment	2 lb/gal SC/L	4 lb/A	NS	4.5	14	Use limited to OR. Applications may be made in 20-50 gal/A.
Broadcast or band treatment Postemergence Ground equipment		4 lb/A	NS			Use limited to OR. Use a proportionately lower rate for band application. Applications may be made in 20-50 gal/A.
In-furrow spray application At planting Ground equipment	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	Use limited to CA. Follow application with irrigation water. Tops of treated garlic may not be harvested.
Soil band application Ground equipment						Use limited to CA. Applications may be made in 20-40 gal/A. Follow application with irrigation water. Tops of treated garlic may not be harvested.
Irrigation application Sprinkler or furrow irrigation equipment	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	Use limited to CA. Injector equipment should be adjusted to 0.5-1 hour treatment periods. Tops of treated garlic may not be harvested.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Ginger						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L	4 lb/A	NS	10 lb/A	30	Use limited to HI. Application may be made as a broadcast or band treatment; use a proportionately lower rate for band application.
Broadcast application Postplant (foliar) Ground equipment		1 lb/A	NS	10 lb/A	30	Use limited to HI. Applications may be made at monthly or every other month intervals.
Soil band treatment Postplant Ground equipment	2 lb/gal SC/L	1 lb/A	NS	10 lb/A	30	Use limited to HI. Applications may be made at monthly or every other month intervals.
Muskmelon (including cantaloupe and honeydew melon)						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	6 lb/A	1	See "Cucumber."
Broadcast application Foliar Ground equipment		1 lb/A	NS			
Onion, bulb						
In-furrow drench treatment At planting Ground equipment	2 lb/gal SC/L [352-372]	2 lb/A	NS	4.5 lb/A	14	Use limited to ID, MI, OR, TX, and WA. Applications may be made in 100-150 gal/A. Tops of treated onions may not be harvested.
	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
In-furrow band treatment At planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	4.5 lb/A	14	Use limited to MI, OR, TX, and WA. Applications may be made in 20-50 gal/A. Tops of treated onions may not be harvested.
Onion, bulb (continued)						
Broadcast application Foliar Ground equipment	2 lb/gal SC/L [352-372]	0.5 lb/A	NS	4.5 lb/A	14	Use limited to ID, MI, OR, TX, and WA. Applications may be made in a minimum of 5 gal/A. Applications are made when insects first appear and may be repeated at 14-day intervals. Tops of treated onions may not be harvested.
	2 lb/gal SC/L	1 lb/A	NS	4.5 lb/A	14	
Broadcast application Foliar Ground or aerial equipment	2 lb/gal SC/L	0.5 lb/A	NS	4.5 lb/A	14	Use limited to NM. Applications may be made in 20-50 gal/A by ground or 5-10 gal/A by air. Applications are made when insects first appear and may be repeated at 5- to 7-day intervals.
	2 lb/gal SC/L	4 lb/A	NS	4.5 lb/A	14	
Broadcast or band treatment Postemergence Ground equipment	2 lb/gal SC/L	4 lb/A	NS	4.5 lb/A	14	Use limited to ID and OR. Use a proportionately lower rate for band application. Applications may be made in 20-50 gal/A. Tops of treated onions may not be harvested.
	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	
In-furrow spray application At planting Ground equipment	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	Use limited to CA. Follow application with irrigation water. Tops of treated onions may not be harvested.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Soil band application Ground equipment		2 lb/A	NS			Use limited to CA. Applications may be made in 20-40 gal/A. Follow application with irrigation water. Tops of treated onions may not be harvested.
Onion, bulb (continued)						
Irrigation application Sprinkler or furrow irrigation equipment	2 lb/gal SC/L	2 lb/A	NS	4.5 lb/A	14	Use limited to CA. Injector equipment should be adjusted to 0.5- to 1-hour treatment periods. Tops of treated onions may not be harvested.
Broadcast Foliar Ground Equipment	2 lb/gal SC/L	0.5 lb/A	NS	4.5 lb/A	14	Use limited to ID. Make applications when insects first appear in significant numbers and repeat at 14-day intervals. Do not harvest tops of treated onions.
Broadcast application Foliar Ground or aerial equipment	2 lb/gal SC/L UT990004	1 lb/A	NS	4.5 lb/A	14	Use limited to UT. Apply in a minimum of 5 gals. of water.
Broadcast In-furrow spray application at planting	2 lb/gal SC/L NY99000	4 lb/A	NS	4.5 lb/A	14	Use limited to NY. Apply 2 gals./A in a minimum of 20 gals. of water within one week of planting.
		2 lb/A				Use limited to NY. Apply 3/4 to 1 gal/A as an in-furrow drench using 100-150 gals. of water per A, or 1 ½ to 2 gals. /A as an in-furrow band spray using 20-50 gals. of water/A. Do not harvest tops of treated bulbs. Do not use on green onions.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Peanut						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	3 lb/A	NS	5 lb/A	NS	Use prohibited in CA. Application may be made as a band treatment in a minimum of 10 gal/A.
Broadcast application Foliar Ground equipment	3.77 lb/gal SC/L [352-532]	1 lb/A	2			Use prohibited in CA. Foliar applications must be used following soil fumigation or preplant or at planting soil application. The first foliar application should be made three weeks postemergence and the second application three weeks later. Applications may be made in 20-40 gal/A.
Pear						
Broadcast application Foliar Ground equipment	2 lb/gal SC/L [352-372]	2 lb/A [100-600 gal/A of finished spray]	NS	2 lb/A	14	Use prohibited in CA. Applications may be made as needed. Applications at bloom or within 30 days after bloom are prohibited. Grazing of livestock in treated orchards is prohibited.
Pepper						
Broadcast application Foliar Ground equipment	2 lb/gal SC/L [352-372]	1 lb/A	NS	6 lb/A	7	Use prohibited in CA. Applications may be made at 1- to 2-week intervals or as needed.
	2 lb/gal SC/L	1 lb/A	NS	6 lb/A	7	Use limited to CA. Applications may be made at 2-week intervals.
	2 lb/gal SC/L	1 lb/A	7	6 lb/A	7	Use limited to NM and TX on non-bell peppers. Applications may be made in a minimum of 20 gal/A by ground or 5 gal/A by air at 1- to 2-week intervals or as needed.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Transplant water treatment	2 lb/gal SC/L [352-372]	0.5 lb/A	1	6 lb/A	7	Use prohibited in CA. Application may be made in a minimum of 200 gal/A and as a supplement to foliar applications.
	2 lb/gal SC/L	0.5 lb/A	NS	6 lb/A	7	Use limited to CA. Application may be made in a minimum of 200 gal/A and as a supplement to foliar applications.
Soil treatment Drip irrigation equipment	2 lb/gal SC/L	1 lb/A	NS	6 lb/A	7	Use limited to CA. Application may be made in 40-200 gal/A.
Greenhouse foliar treatment Ground equipment	2 lb/gal SC/L	1 lb/A or 2 tsp/1,000 sq. ft	NS	6 lb/A	7	Use limited to CA. Application may be made in 100-200 gal/A or 2-5 gal/1,000 sq. ft.
Peppermint						
Soil/foliar application As mint breaks dormancy and active root growth begins Ground equipment	2 lb/gal SC/L	3 lb/A	2	4 lb/A	21	Use limited to ID, MI, MT, OR, WA, and WI. Application may be made in a minimum of 10 gal/A. Sprinkler irrigation (½ to 1 inch) must be applied within 7 days of treatment to wash oxamyl into the root zone unless rainfall occurs.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Pineapple						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	8 lb/A	30	Use prohibited in CA. A 30-day pregrazing interval has been established.
Soil broadcast treatment or soil application via drip irrigation Postplant (within 1 week)		4 lb/A	NS			
Soil application via drip irrigation Postplant		2 lb/A	NS			Multiple soil drip applications may be made at 2- to 8-week intervals. A 30-day pregrazing interval has been established.
Foliar treatment Ground equipment		2 lb/A	NS			Multiple foliar applications may be made at 2- to 4- week intervals. A 30-day pregrazing interval has been established.
Plantain						
Foliar or soil treatment At planting and post plant Ground equipment (spotgun applicator)	2 lb/gal SC/L [352-372]	2.4 g per corm or "seed"	NS	4 lb/A	1	See "Banana."

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Potato						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372] [352-532]	4 lb/A	6	9 lb/A	7	Use prohibited in CA, Northeast and Mid-Atlantic states. Application may be made as a broadcast or band treatment within one week of planting. Application may be made in a minimum of 20 gal/A.
In-furrow treatment At planting Ground equipment		4 lb/A	NS			Use prohibited in CA. Application may be made in a minimum of 20 gal/A.
Broadcast application Foliar Ground or aerial equipment		1 lb/A	6	6 lb/A		Use prohibited in CA. Use limited to Northeast and Mid-Atlantic States. Application may be made in sufficient water for thorough coverage using ground equipment or in a minimum of 4 gal/A by air. Applications are made when pests first appear and may be repeated at 5- to 7-day intervals or as needed.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Pumpkin						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	6 lb/A	1	See "Cucumber."
Broadcast application Foliar Ground equipment		1 lb/A	NS			
Soybean						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372] [352-532]	4 lb/A	NS	4 lb/A	NS	Use prohibited in CA. Application may be made as a broadcast treatment in 10-20 gal/A. The cutting for hay or feeding of treated forage to livestock is prohibited.
		1 lb/A	NS			Use prohibited in CA. Application may be made as a band treatment in 10-20 gal/A. The cutting for hay or feeding of treated forage to livestock is prohibited.
In-furrow treatment At planting Ground equipment		1 lb/A	NS			

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Spearmint						
Soil/foliar application As mint breaks dormancy and active root growth begins Ground equipment	2 lb/gal SC/L	3 lb/A	2	4 lb/A	21	see "peppermint"
Squash						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	6 lb/A	1	See "Cucumber."
Broadcast application Foliar Ground equipment		1 lb/A	NS			
Sweet potato						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372]	6 lb/A	NS	6 lb/A	NS	Use prohibited in CA. Application may be made as a broadcast or band treatment; use a proportionately lower rate for band application. Broadcast application may be made in a minimum of 20 gal/A. Planting must be made within one week of treatment.
In-furrow treatment At planting Ground equipment		4 lb/A	NS			Use prohibited in CA. Application may be made in a minimum of 200 gal/A of transplant water.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Tobacco						
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372] 3.77 lb/gal SC/L [352-532]	2 lb/A	NS	2 lb/A	NS	Application may be made as a bed, broadcast, or band treatment in a minimum of 20 gal/A (band) or 40 gal/A (bed or broadcast). Plants should be transplanted into treated soil within 24 hours.
Tomato						
Broadcast application Foliar Ground or aerial equipment	2 lb/gal SC/L [352-372]	1 lb/A	NS	8 lb/A	3	Application may be made in sufficient water for thorough coverage (minimum of 100 gal/A) using ground equipment or in a minimum of 4 gal/A by air. Applications are made when pests first appear and may be repeated at 5- to 7-day intervals or as needed.
Broadcast Foliar Ground Equipment	2 lb/gal SC/L	1 lb/A	NS	8 lb/A	3	Application may be made in sufficient water (minimum 100 gallons) in ground equipment or in minimum of 10 gallons per acre by air to obtain uniform coverage. Make applications when insects first appear and repeat at 5 to 7 day intervals, or as needed.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Soil Application Drip Irrigation	2 lb/gal SC/L	2 lb/A	NS	8 lb/A	3	Apply directly to the soil via drip irrigation system. Apply with first irrigation and repeat at 14 day intervals as needed. Use 1-2 quarts per acre every 7 to 14 days early in the crop cycle when plants are small. As growth continues and plants roots and tops expand, increase dosage progressively from 3 pints/A to 4 quarts/A at 7 to 14 day intervals
Soil Application At-planting Sprinkler or Furrow Irrigation	2 lb/gal SC/L	1.25 lb/A	NS	8 lb/A	3	Using an injection shank during the planting operation, apply "Vydate L" immediately adjacent to the planter furrow. Application must be made to moist soil and must be followed as soon as possible with either sprinkler or furrow irrigation water to activate "Vydate L".
Watermelon						
Soil incorporated treatment Preplant or at planting Ground equipment	2 lb/gal SC/L [352-372]	4 lb/A	NS	6 lb/A	1	See "Cucumber."
Broadcast application Foliar Ground equipment		1 lb/A	NS			

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1, 2]
Yam						
Seed piece dip treatment	2 lb/gal SC/L [352-372]	2 lb/100 gal [2400 ppm]	NS	Not applicable (NA)	NA	Use limited to PR. Apply as a dip treatment for 15 minutes; allow seed piece to dry for 24 hours before planting.
Foliar treatment Ground equipment		0.5 lb/A	12	12 lb/A	60	Use limited to PR. Foliar applications may be made as a supplement to seed piece dip treatments; the first foliar application is made when adequate foliage is present. Applications may be made in sufficient water for thorough coverage (minimum of 25 gal/A) at 2-week intervals.
Nonbearing Crops (including apples, cherries, citrus, peaches, pears, and that will not bear fruit within 12 months)						
Foliar treatment Ground equipment	2 lb/gal SC/L [352-372]	1 lb/100 gal [200 gal/A of finished spray] or 2 lb/A [600 gal/A of water]	NS	8 lb/A	NA	Foliar applications may be made alone or as a supplement to preplant treatments; the first foliar application is made at first full leaf or when the plants are in active growth phase. Applications may only be made to plants that will not bear fruit within 12 months.
Soil incorporated treatment Preplant Ground equipment	2 lb/gal SC/L [352-372]	8 lb/A	NS	8 lb/A	NA	Applications may only be made to plants that will not bear fruit within 12 months.

Appendix B. Table Of Generic Data Requirements And Studies Used To Make The Interim Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0253 (oxamyl) covered by this Interim RED. It contains generic data requirements that apply to oxamyl in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

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

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number,

but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1550	61-1	Product Identity and Composition	ALL	40499701, 40790001, 42830301
830.1600	61-2A	Start. Mat. & Mnfg. Process	ALL	40499701, 42830301
830.1670	61-2B	Formation of Impurities	ALL	40499701, 42830301
830.1700	62-1	Preliminary Analysis	ALL	40790001, 41118201, 42830302
830.1750	62-2	Certification of limits	ALL	40499701, 40790001, 42830301
830.1800	62-3	Analytical Method	ALL	40790001, 42830302
830.6302	63-2	Color	ALL	40499702, 40499704
830.6303	63-3	Physical State	ALL	40499702, 40499704
830.6304	63-4	Odor	ALL	40499702, 40499704
830.7050	None	UV/Visable Absorption	ALL	Data Gap
830.7200	63-5	Melting Point	ALL	40499702
830.7220	63-6	Boiling Point	N/A	
830.7300	63-7	Density	ALL	40499702, 40499704

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
830.7840	63-8	Solubility4	ALL	40499702
830.7950	63-9	Vapor Pressure	ALL	40499702, 42526101
830.7370	63-10	Dissociation Constant	ALL	40499702
830.7550	63-11	Octanol/Water Partition Coefficient	ALL	40499702
830.7000	63-12	pH	ALL	40499702, 40499704
830.6313	63-13	Stability	ALL	40499702
830.6314	63-14	Oxidizing/Reducing Action	ALL	40499704
830.6315	63-15	Flammability	ALL	40499704
830.6316	63-16	Explodability	ALL	40499704
830.6317	63-17	Storage Stability	ALL	00081618, 41468002-41468007, 41936401-41936414, 42607008-42607014, 43504901
830.7100	63-18	Viscosity	ALL	40499704
830.6319	63-19	Miscibility	ALL	40499704
830.6320	63-20	Corrosion characteristics	ALL	40499704
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Oral Toxicity Test		00094660
850.2200	71-2	Avian Dietary Toxicity Test		406065-11/12
850.2300	71-4	Avian Reproduction Test		00116610
850.1075	72-1	Freshwater Fish		40098001
950.1010	72-2	Freshwater Invertebrate Acute		40098001
None	72-3A	Estuarine/Marine - Fish		40901101

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
None	72-3B	Estuarine/Marine - Mollusk		00113414
None	72-3C	Estuarine/Marine - Shrimp		00113412
None	72-4A	Fish- Early Life Stage		40901101
850.1500	72-5	Life Cycle Fish		Not required
	122-1(a)	Seed Germ./Seedling Emergence		Data Required
	122-1(b)	Vegetative Vigor		Data Required
	122-2	Aquatic Plant Growth		Data Required
	144-1	Honey Bee Acute Contact		05001991
	141-2	Honey Bee Residue on Foliage		40994301

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
TOXICOLOGY				
870.1100	81.1	Acute Oral-Rat		00063011
870.1200	81-2	Acute Dermal-Rabbit		40606501
870.1300	81-3	Acute Inhalation-Rat		00066902
870.2400	81-4	Primary Eye Irritation		00066894
870.2500	81-5	Primary Skin Irritation		40606501
870.2600	81-6	Dermal Sensitization		00066900
870.6100	81-7	Delayed Neurotoxicity		Waived
870.6200	81-8	Acute Neurotoxicity		44254401, 44420301, 44740701
870.3100	82-1	Subchronic 90 Day Oral Toxicity		44504901
870.3200	82-2	21-Day Dermal - Rabbit/Rat		44751201
870.4100	83-1	Chronic Toxicity		41697901, 42052701
870.3700	83-3A	Developmental Toxicity-Rat		40859201, 44737501
870.3700	83-3B	Developmental Toxicity - Rabbit		00063009
870.3800	83-4	2-Generation Reproduction - Rat		41660801
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity		00076813
870.7485	85-1	General Metabolism		41520801
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation		44686901, 4486902. 44704801
ENVIRONMENTAL FATE				

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
835.2120	161-1	Hydrolysis of Parent and Degradates		40606516
835.2240	161-2	Photodegradation - Water		40606515
835.2410	161-3	Photodegradation - Soil		00147704
835.4100	162-1	Aerobic Soil Metabolism		42820001, 41346201, 00063012 ,00040494, 000154748
835.4200	162-2	Anaerobic Soil Metabolism		42820001, 41346201, 00040494, 000113366
835.4300	162-4	Aerobic Aquatic Metabolism		No studies are available
835.1240	163-1	Leaching/Adsorption/Desorption		40606514, 000141395, 000154748, 00040494
835.6100	164-1	Terrestrial Field Dissipation		41573201, 41963901, 00040494, 00045302, 00049231
None	165-4	Bioaccumulation in Fish		

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY				
860-1200	171-3	Directions for Use		Data Gap
860.1300	171-4B	Nature of Residue - Livestock		00028728, 00039511, 00040496, 00040597, 00040605, 00083525, 00134709
860.1300	171-4B	Nature of Residue - Plants		00028732, 41469601, 41469602, 43365401, 43431801
860.1340	171-4C	Residue Analytical Method - Plants		00081618, 00113341, 00113357
860.1340	171-4D	Residue Analytical Method - Animals		00113341
		- Plant commodities		00081618, 00113341, 00113357
		- Animal commodities		00113341
860.1380	171-4E	Storage Stability		00081618, 41468002, 1468007, 41936401, 41936414, 42607008, 42607014, 43504901
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		
		- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep		00039513, 00040592
		- Eggs and the Fat, Liver, Meat, and Meat Byproducts of Poultry		00083524
860.1500	171-4K	Crop Field Trials		

REQUIREMENT			USE PATTERN	CITATION(S)
		Root and Tuber Vegetables Group:		
		- Carrots		00113339, 41402601, 42725401, 44751202
		- Ginger		41632701, 42725416
		- Potatoes		00040607, 00113339, 00113370, 41402602, 42725408
		- Sweet potatoes		00113339
		- Yams [1]		
		Bulb Vegetables Group:		
		- Garlic [2]		
		- Onions, dry bulb		41402603, 41468008, 41936415, 42725406, 43365403
		Leafy Vegetables (except Brassica Vegetables) Group:		
		- Celery		00037130, 00061648, 00113410, 00147614, 41402604, 42725402, 43365402 44654301
		Legume Vegetables Group:		
		- Soybean seed and aspirated grain fractions; Soybean forage and hay		00030920
		Fruiting Vegetables (Except Cucurbits):		
		- Eggplants		00081618
		- Peppers		PP#9F2266, 40481701, 40817501, 40845101
		- Tomatoes		00040603, 00048060, 00084889, 00113419, 44751203
		Cucurbits Vegetables Group:		
		- Cantaloupe		00143312
		- Cucumbers		00143312

REQUIREMENT			USE PATTERN	CITATION(S)
		- Honeydew melon		00143312
		- Pumpkins		
		- Squash, summer		00143312
		- Squash, winter		00143312
		- Watermelon		00143312
		Citrus Fruits Group:		
		- Grapefruit		00113343, 41402605, 42725404
		- Lemons		00113343
		- Oranges		00113343, 41402605, 42725404
		- Tangelos/Tangerines		00113343
		Pome Fruits Group:		
		- Apples		00067234, 00113373
		- Pears		00063016
		Miscellaneous Commodities:		
		- Bananas		00113389, 00129354, 00142126
		- Cottonseed and cotton gin byproducts		00113341, 41016701, 41402606-41402608, 42725412-42725414
		- Peanuts and peanut hay		00083522, 00113357, 41402609, 42725407
		- Peppermint		PP#3E2860
		- Pineapples		00113380
		- Plantain		
		- Spearmint		PP#3E2860

Data Supporting Guideline Requirements for the Reregistration of Oxamyl

REQUIREMENT			USE PATTERN	CITATION(S)
		- Tobacco		41402610, 41593301, 41911201
		Nonbearing Crops :		
		- Apples, cherries, citrus, peaches.		41732401, 42725405
860-1520		- Apples		00067234, 00113373
		- Citrus		00113343, 41572401, 42725403
		- Cottonseed		00113341, 41016701, 41572406, 42725415
		- Peanuts		00083522, 41572402, 42016801
		- Peppermint		PP#3E2860
		- Pineapples		00113380, 41632702, 42725417
		- Potatoes		41572403, 42725408
		- Soybeans		41572404, 42725409
		- Spearmint		PP#3E2860
		- Tomato		00040603, 00048060, 41572405, 42725411
860-1850		Rotational Crops (Confined)		41697902
860-1900		Rotational Crops (Field)		42178201

Appendix C. Technical Support Documents

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

The docket initially contained the preliminary risk assessments and related documents as of (date). The Agency considered comments on the revised risk assessments and added the formal "Response to Comments" document and the revised risk assessment to the docket on September 24, 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:

www.epa.gov/pesticides/

Appendix D. Citations Considered To Be Part Of The Database Supporting the Interim Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

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

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

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

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

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

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

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

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

(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.

Appendix D
Oxamyl BIBLIOGRAPHY

MRID Number

00028728 E.I. du Pont de Nemours & Company (1974) Metabolism of Oxamyl. Summary of studies 097651-B through 097651-F. (Unpublished study received Jun 14, 1976 under 352-372; CDL:097651-A)

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41732401 Lin, W.; Hay, R. (1990) Magnitude of Oxamyl Insecticide/Nematicide Residues in Stone Fruit when Applied to Non-Bearing Trees: Lab Project Number: AMR-1031-88. Unpublished study prepared by E.I. du Pont de Nemours and Co. 33 p.

41911201 Lin, W.; Hay, R. (1991) Residues of Oxamyl In Fresh and Dried Tobacco: Lab Project Number: AMR-1708-90. Unpublished study prepared by Mckenzie Laboratories, Inc. 30 p.

41936401 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Pineapple: Lab Project Number: AMR-1401-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Lab, Inc. 24 p.

41936402 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Peanuts: Lab Project Number: AMR-1399-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs. 24 p.

41936403 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Soybeans: Lab Project Number: AMR-1399-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and Mckenzie Labs, Inc. 25 p.

41936405 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Onions: Lab Project Number: AMR-1397-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 26 p.

41936404 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Mint: Lab Project Number: AMR-1396-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 24 p.

41936406 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Cucumbers: Lab Project Number: AMR-1402-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs. 24 p.

41936407 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Apples: Lab Project Number: AMR-1398-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 24 p.

41936408 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Tomatoes: Supplement #1 to MRID 41468005: Lab Project Number: AMR-1015-87. Unpublished study prepared by Mckenzie Labs, Inc. 19 p.

41936409 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Oranges: Supplement #1 to MRID 41468003: Lab Project Number:AMR-1013-87. Unpublished study prepared by McKenzie Labs, Inc. 19 p.

41936410 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Potatoes: Supplement #1 to MRID 41468004: Lab Project Number: AMR-1014-87. Unpublished study prepared by McKenzie Labs, Inc. 19 p.

41936411 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Celery: Supplement #1 to MRID 41468002: Lab Project Number: AMR-012-87. Unpublished study prepared by McKenzie Labs, Inc. 19 p.

41936412 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Cottonseed: Supplement #1 to MRID 41468006: Lab Project Number: AMR-1016-87. Unpublished study prepared by McKenzie Labs, Inc. 20 p.

41936413 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Cottonseed Oil: Supplement #1 to MRID 41468007: Lab Project Number AMR-1017-87. Unpublished study prepared by McKenzie Labs Inc. 19 p.

41936414 Lin, W.; Tomic, D. (1991) Freezer Storage Stability of Oxamyl in Soil: Supplement #1 to MRID 41468001: Lab Project Number: AMR-999-87. Unpublished study prepared by McKenzie Labs, Inc. 19 p.

41936415 Lin, W. ; Tomic, D. (1991) Magnitude of the Residues of Oxamyl Insecticide/Nematicide When Applied to Onions--a 1990 Study: Lab Project Number: AMR-1696-90. Unpublished study prepared by McKenzie Labs, Inc. 27 p.

42016801 Lin, W.; Tomic, D. (1991) Residues of Oxamyl Insecticide/Nematicide in Peanuts and Their Processed Fractions: Lab Project Number: AMR-1697-90: Unpublished study prepared by E.I. du Pont de Nemours and Co., Texas A&M University System and McKenzie Labs, Inc. 35 p.

42052701 Dickrell, L. (1991) 52-Week Dietary Toxicity Study with IND-1410 (Oxamyl) in Male Dogs: Lab Project Number: HLA 6129-166: HLO 555-90. Unpublished study prepared by Hazleton Laboratories America, Inc. 337 p.

42103401 Boeri, R.; Ward, T. (1991) Acute Flow-through Toxicity of DPX-D1410-196 (Oxamyl) to the Sheepshead Minnow, Cyprinodon variegatus: [Final Report]: Lab Project Number: MR-4581-919. Unpublished study prepared by EnviroSystems in coop with Dupont Haskell Labs. 33 p.

42178201 Lin, W.; Tomic, D. (1992) Rotational Crops Study with Vydate L Insecticide/Nematicide: Lab Project Number: AMR 1695-90. Unpublished study prepared by E. I. Du Pont de Nemours and Co. in coop with McKenzie Labs. 108 p.

42607008 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Mint: Supplement No. 1: Lab Project No. AMR-1396-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 28 p.

42607009 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Onions: Supplement No. 1: Lab Project Number: AMR-1397-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 28 p.

42607010 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Apples: Supplement No. 1: Lab Project Number: AMR-1398-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 28 p.

42607011 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Soybeans: Supplement No. 1: Lab Project Number: AMR-1399-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 34 p.

42607012 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Peanuts: Supplement No. 1: Lab Project Number: AMR-1400-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 30 p.

42607013 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Pineapple: Supplement No. 1: Lab Project Number: AMR-1401-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 29 p.

42607014 McClory, J.; Sumpter, S.; Tomic, D. (1992) Freezer Storage Stability of Oxamyl in Cucumbers: Supplement No. 1: Lab Project Number: AMR-1402-89. Unpublished study prepared by DuPont and McKenzie Labs, Inc. 28 p.

42725401 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide When Applied to Carrots: Supplement No. 1: Lab Project Number: AMR-1027-88. Unpublished study prepared by E. I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 14 p.

42725402 Sumpter, S. (1993) Magnitude of Residue of Oxamyl Insecticide/Nematicide when Applied to Celery: Supplement No. 1: Lab Project Number: AMR-1028-88. Unpublished study prepared by E. I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 15 p.

42725403 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Citrus and Their Processed Fractions: Supplement No. 1: Lab Project Number: AMR-1029-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., Lake Alfred Citrus Research Center, University of Florida and McKenzie Labs, Inc. 16 p.

42725404 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Oranges and Grapefruit: Supplement No. 1: Lab Project Number: AMR-1030-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., McKenzie Labs, Inc. 14 p.

42725405 McClory, J. (1993) Magnitude of Oxamyl Insecticide/Nematicide Residues in Stone Fruit when Applied to Non-Bearing Trees: Supplement No. 1: Lab Project Number: AMR-1031-88. Unpublished study prepared by E. I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 14 p.

42725406 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide when Applied to Onions: Supplement No. 2: Lab Project Number: AMR-1032-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., and McKenzie Labs, Inc. 17 p.

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42725408 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Potatoes and their Processed Fractions: Supplement No. 2: Lab Project Number: AMR-1035-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., The National Food Lab, Inc. and McKenzie Labs, Inc. 25 p.

42725409 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Soybeans and their Processed Fractions: Supplement No. 1: Lab Project Number: AMR-1036-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., The Texas A&M University System and McKenzie Labs, Inc. 26 p.

42725411 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Tomatoes and their Processed Fractions: Supplement No. 1: Lab Project Number: AMR-1038-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., National Food Lab, Inc. and McKenzie Labs, Inc. 24 p.

42725412 McClory, J. (1993) Magnitude of Residue of Oxamyl Insecticide/Nematicide in Cottonseed Grown in California or Arizona when Applications are Made with Water as the Diluent: Supplement No. 1: Lab Project Number: AMR-1147-88. Unpublished study prepared by E. I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 14 p.

42725413 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Cottonseed when Applications are Made with Vegetable Oil as the Diluent: Supplement No. 1: Lab Project Number: AMR-1148-88. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 16 p.

42725414 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Cottonseed when Applications are Made with Water as the Diluent: Supplement No. 1: Lab Project Number: AMR-1149-88. Unpublished study prepared by E. I. du Pont de Nemours and Co. and McKenzie Labs, Inc. 14 p.

42725415 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Cottonseed and its Processed Fractions: Supplement No. 1: Lab Project Number: AMR-1150-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., The Texas A&M University System and McKenzie Labs, Inc. 24 p.

42725416 Sumpter, S. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Ginger Root: Supplement No. 1: Lab Project Number: AMR-1382-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. and Hawaiian Sugar Planters Association Experimental Station. 14 p.

42725417 McClory, J. (1993) Magnitude of Residues of Oxamyl Insecticide/Nematicide in Processed Fractions of Pineapple: Supplement No. 1: Lab Project Number: AMR-1390-89. Unpublished study prepared by E. I. du Pont de Nemours and Co. and Hawaiian Sugar Planters Association. 19 p.

42820001 Spare, W. (1991) Anaerobic Soil Metabolism of (carbon 14)-Oxamyl in Madera, California Soil: Lab Project Number: 1712: AMR-1851-90. Unpublished study prepared by Agrisearch Inc. 53 p.

43365401 Li, Y. (1994) The Metabolism of (carbon 14)-Oxamyl in Lactating Goats: Lab Project Number: AMR-2578-92: SC920240. Unpublished study prepared by DuPont Agricultural Products and Battelle. 275 p.

43365402 McClory, J.; Tomic, D. (1994) Magnitude of Residues of Oxamyl in Celery Following Application of Vydate L Insecticide/Nematicide at Maximum Label Rates: Lab Project Number: AMR-2568-93. Unpublished study prepared by DuPont Agricultural Products and McKenzie Labs, Inc. 130 p.

43365403 Sumpter, S.; Tomic, D. (1994) Magnitude of Residues of Oxamyl in Bulb Onions Following Application of Vydate L Insecticide/Nematicide at Maximum Label Rates: Lab Project Number: AMR-2567-93. Unpublished study prepared by DuPont Agricultural Products and McKenzie Labs, Inc. 115 p.

43431801 Behmke, C.; Scott, M.; Stringer, D. (1994) Metabolism of (carbon 14) Oxamyl in Laying Hens: Lab Project Number: SC920239: AMR-2546-92. Unpublished study prepared by DuPont Agricultural Products. 379 p.

43504901 Sumpter, S.; Orescan, D. (1994) Freezer Storage Stability of Oxime in Crops: Lab Project Number: AMR-2488-92. Unpublished study prepared by McKenzie Labs, Inc. 152 p.

44254401 Malley, L. (1997) Acute Oral Neurotoxicity Study of Oxamyl Technical in Rats: Lab Project Number: HLR 1118-96: 10730-001: 1118-96. Unpublished study prepared by DuPont Haskell Lab for Toxicology and Industrial Medicine. 629 p. (Relates to L0000163 and L0000168).

44420301 Malley, L. (1997) Acute Oral Neurotoxicity Study of Oxamyl Technical in Rats: Supplement No. 1: Lab Project Number: 11268-001: 10730-001: 1118-96. Unpublished study prepared by E.I. du Pont de Nemours and Co. 67 p.

44504901 Malley, L. (1998) Oxamyl Technical: Subchronic Oral Neurotoxicity Study in Rats: Lab Project Number: 10730: HL-1998-00708. Unpublished study prepared by DuPont Haskell Laboratory for Toxicology and Industrial Medicine. 457 p.

44654301 McClory, J.; Summers, S. (1998) Magnitude of Residues of Oxamyl in Celery Following Application of Vydate L Insecticide/Nematicide at Maximum Label Rates: Lab Project Number: AMR 3437-95. Unpublished study prepared by DuPont Agricultural Products. 220 p.

44686901 Merricks, D.; McNeal, H. (1998) Dissipation of Dislodgeable Foliar Residues of Oxamyl from Citrus Following Application of Vydate L Insecticide in the U.S.A.--Season 1997: Lab Project Number: AMR 4391-97: 1757. Unpublished study prepared by Agrisearch Incorporated., Research for Hire and EPL BioAnalytical Services. 111 p.

44686902 Merricks, D.; McNeal, H. (1998) Dissipation of Dislodgeable Foliar Residues of Oxamyl from Cucumbers Following Application of Vydate L Insecticide in the U.S.A.--Season 1997: Lab Project Number: AMR 4393-97: 1758. Unpublished study prepared by Agrisearch Incorporated., Research for Hire and Research Options Inc. 108 p.

44704801 Merricks, D.; McNeal, H. (1998) Dissipation of Dislodgeable Foliar and Soil Residues of Oxamyl Following Application of Vydate L Insecticide to Tomatoes in the U.S.A.-Season 1997 and 1998: Lab Project Number: AMR 4392-97: 1759. Unpublished study prepared by Agrisearch Incorporated, Research for Hire and Research Options, Inc. 138 p.

44737503 Van Pelt, C. (1999) DuPont's Position on the NOEL in Male Dogs Following Chronic Dietary Exposure to Oxamyl (DuPont Reports HLR 381-90 and HLO 555-90): Lab Project Number: DUPONT-2019. Unpublished study prepared by E.I. du Pont de Nemours and Company. 10 p.

44740701 Van Pelt, C. (1999) DuPont's Position on the NOEL in Rats Following Acute Neurotoxicity Testing with Oxamyl: Lab Project Number: DUPONT20-20: HLR 1118-96. Unpublished study prepared by E.I. du Pont de Nemours and Company. 22 p.

44751202 McClory, J. (1999) Magnitude of Residues of Oxamyl in Carrots Following Application of Vydate L Insecticide/Nematicide at Maximum Label Rates: Lab Project Number: AMR 3301-95. Unpublished study prepared by DuPont Agricultural Products. 95 p.

44751203 McClory, J. (1999) Magnitude of Residues of Oxamyl in Tomatoes Following Application of Vydate L Insecticide/Nematicide at Maximum Label Rates: Lab Project Number: AMR 4347-97. Unpublished study prepared by DuPont Agricultural Products. 325 p.

44938101 Austin, H. (1999) Oxamyl 10L (10% w/w): A Laboratory Study to Evaluate the Effects on the Predatory Mite, Typhlodromus pyri Scheuten (Acari: Phytoseiidae): Lab Project Number: DUPONT-2608: HMA330: ER-99-18. Unpublished study prepared by Ecotex Ltd. 36 p.

44938102 Austin, H. (1999) Oxamyl 10L (10% w/w): A Laboratory Study to Evaluate the Effects on the Aphid Parasitoid Aphidius rhopalosiphi (Hymenoptera: Braconidae): Lab Project Number: DUPONT-2609: HMA331: ER-99-21. Unpublished study prepared by Ecotex Ltd. 32 p.

Appendix E. Generic Data Call-In

Generic DCI (P1 of 6)

Generic DCI (P3 of 6)

Generic DCI (P5 of 6)

Appendix F. Product-Specific Data-Call-In

PDCI (p 1 of 5)

PDCI (P 2 of 5)

PDCI (P 4 of 5)

PDCI (P 5 of 5)

Appendix G. List of All Registrants Sent This Data Call-in

Appendix H. EPA's Batching of Oxamyl Products for Meeting the 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 oxamyl as the primary active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note the Agency is not describing batched products as "substantially similar" since some products with in a batch may not be considered chemically similar or have identical use patterns.

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

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

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

registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

(Fill-in) products were found which contain oxamyl as the active ingredient. These products have been placed into (fill-in) batches in accordance with the active and inert ingredients and type of formulation.

Batch 1	EPA Reg. No.	Percent Oxamyl	Formulation Type
	352-400	42.0	Liquid
	352-532	42.0	Liquid

No Batch	EPA Reg. No.	Percent Oxamyl	Formulation Type
	352-372	24.0	Liquid

Appendix I. List of 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@epamail.epa.gov.

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

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

Date of receipt
EPA identifying number
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 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 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.

a. Health and Environmental Effects Science Chapters.
b. Detailed Label Usage Information System (LUIS) Report.

[1] No field residue data have been submitted for yams. Because the use of oxamyl on yams (seed piece dip and foliar treatments) differs greatly from that for sweet potatoes (preplant or at-planting treatment only), data cannot be translated from sweet potatoes. Nevertheless, residue data from foliar and pre-plant applications *to potatoes* are available. Since the PHI for potatoes is 1 day while that for yams is 60 days, HED believes that the residue levels in yams following treatment at the maximum label rate are unlikely to exceed the 0.1 ppm tolerance level for potatoes. Therefore, CBRS concludes that the available data indicate that a 0.1 ppm tolerance in yams is appropriate.

[2] The available residue data for dry bulb onions can be translated to garlic.