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7012620

US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Naled

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

Combined PDF document consists of the following:

- Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006)

- Naled IRED

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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

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

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

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Attachment A:
Organophosphates included in the OP Cumulative Assessment

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

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United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-02-008
January 2002

Interim Reregistration Eligibility Decision for Naled

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United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substances (7508C)
EPA 738-F-02-007
January 2002

Naled Facts

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

Used mainly to control mosquitos and to control insects on a variety of agricultural crops, naled residues in food and drinking water do not pose risk concerns. Naled may no longer be used in and around the home by residents or professional applicators. However, residents can be exposed as by-standers from wide-area mosquito control applications. Sergeant's, the sole end-use registrant for pet collars, is voluntarily cancelling all of its naled products. With mitigation limiting homeowners' and children's exposure naled fits into its own "risk cup." With other mitigation measures, naled's worker and ecological risks will also be below levels of concern for reregistration.

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

The OP Pilot Public Participation Process

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

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

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

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

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

The naled interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk

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assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in this interim decision document, which concludes the OP pilot process for naled.

Uses

- An insecticide, naled is used primarily to control adult mosquitos. It is also registered to control blackflies, and leaf eating insects on a variety of fruits, vegetables, and nuts.

- Annual domestic use is approximately 1,000,000 pounds of active ingredient, with approximately 70% used in mosquito control and approximately 30% in agriculture.

Health Effects

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

Risks

- Dietary exposures from eating food crops treated with naled are below the level of concern for the entire U.S. population, including infants and children. Drinking water is not a significant source of exposure.

- The only remaining residential risks have been addressed by the voluntary cancellation of naled pet collar products.

- EPA also has risk concerns for workers who mix, load, and/or apply naled to agricultural sites, and for black fly control.

- Acute and chronic risks are of concern for fish and other freshwater organisms.

Risk Mitigation

In order to support a reregistration eligibility decision for naled, the following risk mitigation measures are necessary:

To mitigate risks to agricultural workers:

- Require closed mixing/loading systems for all agricultural uses (except greenhouses and hand-held application) and public health uses involving control of mosquitos and black flies.
- Require enclosed cabs for ground application or enclosed cockpits for aerial application, for all agricultural uses and public health uses involving control of mosquitos and black flies.
- Prohibit manual activation of hotplates.

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- Prohibit manual activation of ventilation equipment in greenhouses.
- Delete backpack sprayers and hand-held foggers.
- Delete the greenhouse heat/steam pipe painting use.
- Delete use in apartments, motels, hotels and drive-in theaters.
- Reduce the maximum application rate for use on almonds and peaches to 1.875 lbs ai/A and prohibit aerial use on almonds and peaches.
- Prohibit ready to use formulation.
- Delete wet and dry bait uses.
- Delete spot treatment for cockroach control.
- Prohibit human flaggers.
- Establish 48 hour reentry intervals after application to field crops.
- Establish 24 hour reentry intervals after application in greenhouses.

To mitigate risk to residents and children, the following measures are needed:

- The sole manufacturer of pet collars (Sergeant's) has requested voluntary cancellation of these uses.
- Prohibit all residential uses either by resident or professional applicator. Use in residential areas by mosquito control districts would still be allowed.

To mitigate risk to non-target species:

- Reduce application rates for control of black fly from 0.25 to 0.1 lbs/ai/A, and reduce rates on peaches and almonds from 2.8 to 1.875 lbs/ai/A.
- Require buffer zones around permanent bodies of water to reduce runoff.
- Establish spray setbacks to reduce spray drift for agricultural uses.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The Naled IRED therefore is issued in final (see www.epa.gov/REDs/ or www.epa.gov/pesticides/op), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.

- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for naled and may request further risk mitigation measures. However some tolerance actions for naled will be undertaken prior to completion of the final tolerance reassessment, including lowering of tolerances, changing of commodity definitions, and other administrative actions. For all OPs, raising and/or establishing tolerances will be considered once cumulative risk is considered.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate (OP) pesticide naled. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on October 6, 1999. Additionally, the Agency held a Technical Briefing on October 13, 1999, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on October 20, 1999, and closed on December 20, 1999.

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 naled. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of naled and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for naled will be finalized once the cumulative risks for all of the OP pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Naled," which was approved on ***January 28, 2002***, contains the Agency's decision on the individual chemical naled.

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

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The interim RED is based on the updated technical information found in the naled public docket. The docket includes background information and comments on the Agency's preliminary risk assessments, the Agency's revised risk assessments for naled and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, and responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket also includes comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For naled, a proposal was submitted by Amvac Chemical Corporation, the technical registrant on November 16, 2001.

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 OP pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the OP pesticides are following this new process.

Please note that the naled risk assessment and the attached interim RED concern only this particular OP pesticide. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to naled alone. The Agency has also concluded its interim assessment of the ecological, worker and residential risks associated with the use of naled. Because the FQPA directs the Agency to consider available information on the cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the OPs through a common biochemical interaction with the cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire OP class of chemicals after considering the risks for the individual OPs. Currently, EPA is working towards completion of a methodology to assess cumulative risk. The individual risk assessments for each OP are necessary elements of any cumulative assessment.

The Agency has decided to move forward with individual chemical assessments, identifying mitigation measures whenever possible to address those human health and environmental risks associated with the current uses of naled. The Agency will issue the final tolerance reassessment decision for naled and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophophates are considered, including the assessment of the naled metabolite, dichlorvos (DDVP), which is also a registered OP pesticide.

This document contains a summary of the generic and product-specific Data Call-In(s) (DCI) that outlines further data requirements for this chemical. Note that the complete DCIs, with all pertinent instructions, are being sent to registrants under separate cover. For

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product-specific DCIs, the first set of required responses to is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

In this interim RED, the Agency has determined that naled 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 some current uses of naled may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in 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 naled. 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 for naled, Tom Myers, in the Special Review and Reregistration Division. He can be reached at 703-308-8589. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen Jones at 703-308-8047.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

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Interim Reregistration Eligibility Decision for

Naled

Case Number 0092

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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	weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell

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RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

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Executive Summary

EPA is issuing interim risk management decisions for the pesticide naled in this document, based on human and ecological risk assessments conducted by EPA and a review of public comments on the revised risk assessments. The decisions outlined in this document do not include the final tolerance reassessment decision for naled, since that decision will be made following consideration of the cumulative risks for all organophosphate (OP) pesticides, including an assessment of the naled metabolite, dichlorvos (DDVP). However, some tolerance actions for naled will be undertaken prior to completion of the final tolerance reassessment, including lowering of tolerances, changing definitions, and other administrative actions. Raising or establishing new tolerances will be deferred until after cumulative risks are considered. The Agency may need to pursue further risk management measures for naled once the cumulative risks are considered.

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

Naled, first registered in 1959 in the United States, is an organophosphate (OP) insecticide used on a variety of insects. AMVAC purchased naled from Valent in November of 1998. The Agency issued a Registration Standard for naled in September, 1983 (NTIS #PB-84-158989), which required certain data to support the registered uses. In November, 1991, the Agency issued a Data Call-In for naled requiring certain ecological effects, and occupational/residential exposure data. Additional occupational and residential exposure data were called in during 1993. In 1995, naled was also included in a Data Call-In for all chemicals applied to turf, as well as the DCI for exposure data related to worker reentry into agricultural fields. Developmental neurotoxicity data has also been required of OP insecticides, including naled.

The interim tolerance reassessment included in this document is based on naled alone and does not include risks from dichlorvos, a metabolite of naled and also an OP pesticide. Risks from dichlorvos resulting from the use of naled will be dealt with later in the Reregistration Eligibility Decision (RED) for dichlorvos.

Overall Risk Summary

EPA's human health risk assessment for naled indicates some risk concerns. Food risk, both acute and chronic, is well below the Agency's level of concern. Similarly, drinking water risk estimates, based on modeling data for both ground and surface water for acute and chronic

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exposures, are not of concern. There are, however, concerns for workers who mix, load, and apply naled to certain agricultural sites and those who mix, load and apply naled for mosquito/black fly control. Individuals in residential areas can be exposed to naled as bystanders from mosquito/black fly control application, however EPA does not have risk concerns for these individuals. Finally, the Agency has concerns for residential, particularly children's, exposure to pets wearing naled flea collars.

To mitigate risks of concern posed by the uses of naled, EPA considered the mitigation proposal submitted by the technical registrant, and has decided on a number of label amendments to address the worker, residential, and ecological concerns. This interim RED contains the results of the risk assessments, detailed risk mitigation and the necessary label amendments to mitigate those risks.

Dietary Risk

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

Occupational Risk

Occupational exposure to naled is of concern, and it has been determined that a number of mitigation measures are necessary. For agricultural and mosquito control uses of naled, certain mixer/loader and applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than 100). In most cases these risks can be mitigated to an acceptable level with the following label restrictions: closed mixing/loading systems and closed cabs or cockpits for most applicators, and maximum PPE for any remaining hand-held applications. The following label changes will also reduce exposure and risk to naled: prohibiting hand-held foggers and backpack sprayers; prohibiting the use of human flaggers; reducing the maximum application rate for black fly control; and establishing post-application reentry intervals.

Residential Risk

Naled may no longer be used in and around the home by residents or professional applicators. However, residents can be exposed as bystanders from wide-area mosquito control applications. Sergeant's, the sole end-use registrant for pet collars, is voluntarily canceling all four of its naled products. As a result, residents will no longer be exposed to naled from this use. This action addresses EPA's risk concerns for these collars.

Ecological Risk

Ecological risks are also of concern to the Agency. The registrant has adopted a variety of measures to reduce ecological risks in its 1999 labeling including: adopting application setbacks to reduce drift; providing uncultivated buffer zones; and prohibiting aerial application

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for almonds and peaches. In addition, Amvac has proposed the following measures; reducing the maximum application rate for mosquito/black fly control, and reducing the application rate for almonds beyond the reduction put in place in 1999.

With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that, until cumulative risks for all of the OPs have been considered, all currently registered uses, except pet collars which are being voluntarily canceled by the sole end-use registrant, are eligible for reregistration.

The Agency is issuing this interim Reregistration Eligibility Document (IRED) for naled. A Notice of Availability will be published in the *Federal Register*. This interim RED document includes guidance and time frames for complying with any necessary label changes for products containing naled, and that the time frames for compliance with the label changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC (Tolerance Reassessment Advisory Committee), which sought to open up the process to interested parties, the Agency's risk assessments for naled have already been subject to numerous public comment periods, and a further comment period for naled was deemed unnecessary. The Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to complying with the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for naled can be considered final, however, until the cumulative risks for all OP pesticides are considered. Further risk mitigation measures for naled may be necessary at that time.

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I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment by 2006 of all tolerances in effect at the time of the enactment of the FQPA. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. FQPA also amends the Federal Food Drug and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Naled belongs to a group of pesticides called OPs, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

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

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

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

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

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

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

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

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II. Chemical Overview

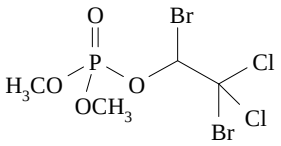
A. Regulatory History

Naled was first registered in the United States in 1959 for use as an insecticide-acaricide. AMVAC Chemical Corporation is the technical registrant for naled. Amvac purchased naled from Valent in November of 1998. The Agency issued a Registration Standard for naled in September, 1983 (NTIS #PB-84-158989), which required certain data to support the registered uses. In November, 1991, the Agency issued a Data Call-In (DCI) for naled requiring certain ecological effects and occupational/residential exposure data. Additional occupational and residential exposure data were called in during 1993. In 1995 naled was also included in two DCIs for exposure data for all chemicals applied to turf and agricultural crops.

Dichlorvos (DDVP), a registered OP insecticide, is a metabolite of naled. This document is only concerned with risk from naled per se and residues on food expressed as naled equivalents. The risks (both human and ecological) associated with dichlorvos resulting from the application of naled will be discussed in another document at a later date.

B. Chemical Identification

Naled



- **Common Name:** naled
- **Chemical Name:** 1,2-dibromo-2, 2-dichloroethyl dimethyl phosphate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 300-76-5
- **OPP Chemical Code:** 034401
- **Empirical Formula:** $C_4H_7O_4PBr_2Cl_2$
- **Molecular Weight:** 381
- **Trade and Other Names:** Dibrom®
- **Basic Manufacturers:** AMVAC Chemical Corporation

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Pure naled is a white solid with a melting point of 27° C. The vapor pressure is 2×10^{-4} mm Hg at 20° C. Naled is practically insoluble in water, has limited solubility in aliphatic solvents, and is highly soluble in oxygenated solvents such as ketones and alcohols.

C. Use Profile

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

Type of Pesticide: Insecticide, acaricide.

Food and Feed: Almonds, beans (dry and succulent), broccoli, Brussels sprouts, cabbage, cauliflower, celery, collards, cottonseed, cucumbers, eggplant, grapefruit, grapes, hops, kale, lemons, lettuce, melons, mushrooms, oranges, peaches, peas (succulent), peppers, pumpkins, rice, safflower seed, spinach, strawberries, summer and winter squash, Swiss chard, sugar beets (roots and tops), tangerines, tomatoes, turnips, walnuts, and grasses.

Public Health/Residential: Wide area/general outdoor treatment for mosquito (public health use) and blackfly control, pet flea collars.

Other Nonfood: Greenhouse ornamentals, alfalfa (grown for seed only), cotton.

Target Pests: Mosquitos, blackflies, leaf eating insects.

Formulation Types Registered: Technical grade active ingredient (90% a.i.), emulsifiable concentrate (36% - 85% a.i.), impregnated collar/tag (7% - 15% a.i.), liquid ready to use (1% - 78% a.i.), soluble concentrate/liquid (20% - 87.4% a.i.).

Method and Rates of Application:

Equipment: Air and ground equipment, hot plate/hot pan (in greenhouses), and impregnated pet collars.

Method and Rates: Agricultural 0.7 - 2.8 lb ai/A; Non-agricultural 0.05 - 0.25 lb ai/A. ULV application for mosquitos.

Timing: Applied when needed to control pests, with limitations on total number of pints applied per season, and a minimum of seven days between applications.

Use Classification: Naled is a general use pesticide.

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D. Estimated Usage of Naled

This section summarizes the best estimates available for many of the pesticide uses of naled, based on available pesticide usage information for 1987 to 1997. A full listing of all uses of naled, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 1,000,000 lbs a.i. of naled are used annually, according to Agency and registrant estimates, including approximately 700,000 lbs. for mosquito/blackfly control, 280,000 lbs. for agricultural uses, and 20,000 lbs. for pet collars. For mosquito/blackfly control, approximately 98% is used to control mosquitos with 95% of the mosquito use being applied aerially. Table 1 shows the estimated average annual usage of naled.

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Table 1. Naled Estimated Usage for Representative Sites

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate[3]			States of Most Usage
		Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai)
Tangerines	24	0	1	1%	3%	0	1	1.0	1.0	1.0	CA 100%
Grapefruit	194	0	0	0%	0%	0	0	0.5	3.0	0.2	AZ CA FL TX .
Lemons	63	0	0	0%	0%	0	0	1.1	1.0	1.1	CA 100%
Oranges	770	8	18	1%	2%	14	26	1.8	1.3	1.5	CA AZ 100%
Peaches	212	1	2	1%	1%	3	6	3.1	1.0	3.1	CA 94%
Strawberries	50	3	8	7%	16%	6	15	1.9	2.2	0.8	CA 85%
Grapes	795	20	43	3%	5%	27	53	1.4	1.2	1.1	CA 100%
Almonds	429	2	8	1%	2%	7	21	3.0	1.2	2.5	CA 100%
Walnuts	205	3	8	1%	4%	8	23	2.8	1.9	1.5	CA 100%
Celery	34	2	6	7%	18%	4	7	1.7	1.8	1.0	CA MI 100%
Kale	6	-	-	-	-	3	-	-	-	-	
Lettuce	268	1	2	0%	1%	4	17	5.2	2.9	1.8	CA 100%
Spinach	36	0*	0*	0*	0*	0*	0*	-	-	-	
Broccoli	107	7	11	6%	10%	8	18	1.2	1.0	1.2	CA 100%
Brussels Sprouts	4	1	3	28%	83%	4	6	3.9	3.4	1.1	
Cabbage	84	5	9	6%	11%	5	9	0.9	1.0	0.9	FL CA 87%
Cauliflower	57	2	15	4%	26%	5	30	2.1	1.1	2.0	FL CA 100%

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Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate[3]			States of Most Usage
		Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai)
Collards	15	1	1	4%	7%	1	2	1.3	1.0	1.3	FL SC 91%
Swiss Chard	-	-	-	-	-	-	-	-	-	-	
Cucumbers	151	0*	0*	0*	0*	0*	0*	-	-	-	-
Pumpkins	41	0*	0*	0*	0*	0*	0*	-	-	-	-
Squash	69	0*	0*	0*	0*	0*	0*	-	-	-	-
Melons	368	0	2	0%	0%	1	5	2.9	1.5	2.0	CA 100%
Eggplant/Peppers	119	0	0	0%	0%	0	0	0.8	1.2	0.7	CA FL 100%
Tomatoes	500	0	1	0%	0%	0	1	1.0	1.3	0.8	CA FL 83%
Beans/Peas-Green	723	0	4	0%	1%	0	1	1.4	1.4	1.0	FL CA 100%
Beans-Dry	2,181	1	2	0%	0%	1	4	1.1	1.4	0.8	CA 86%
Alfalfa	23,949	23	41	0%	0%	32	67	1.4	1.6	0.9	ID OR 90%
Safflower	243	22	33	9%	14%	17	25	0.8	1.2	0.7	CA 100%
Rice	2,991	0*	0*	0*	0*	0*	0*	-	-	-	
Cotton	12,689	90	176	1%	1%	120	250	1.3	1.2	1.1	CA LA 100%
Sugar Beets	1,434	4	8	0%	1%	4	8	0.9	1.0	0.9	CA 88%
Hops	-	-	-	-	-	-	-	-	-	-	
Mushrooms	-	-	-	-	-	-	-	-	-	-	-
Total Ag. Use						**274**	**572**				-

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Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate[3]			States of Most Usage
		Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	Wtd[1] Avg	Est[2] Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai)
Mosquito Abatement Districts (MADS)	103,500[4]	7,000[5]	12,000	-	12%[6]	700	1,200			0.1	
Dogs & Cats						20	30				
Grand Total						**994**	**1,802**				

Notes:

Usage data covers 1987- 96 for agriculture, and up to 1997 for nonagricultural.
Calculations of the above numbers may not appear to agree because they are displayed as rounded:
to the nearest 1000 for acres treated or lb. a.i. (Therefore < 500 = 0)
to the nearest whole percentage point for % of crop treated. (Therefore < 0.5% = 0.0%)

0* = Available EPA sources indicate that no usage is observed in the reported data for this site, which implies that there is little or no usage.
A dash (-) indicates that information on this site is NOT available within EPA or is insufficient to provide an estimate.

1. Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily.
2. Est Max = Estimated maximum, which is estimated from available data.
3. Average application rates = calculated from the weighted averages.
4. Available acres (000) for treatment
5. Acre treatments (000)
6. % of available acres treated.

SOURCES: EPA data (1987-97), USDA (1990-96), and National Center for Food and Agricultural Policy (1992 data).

III. Summary of Naled Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the OP pesticide naled. This summary is based on the following documents which can be found in the public docket for naled: "Revised HED Risk Assessment for the RED (PC Code 034401)," dated October 12, 1999, and "EFED's Reregistration Chapter for Naled," dated November 14, 1997 and "Naled: Addendum to EFED's Reregistration Chapter," dated March 18, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, which serve as the basis for the interim reregistration eligibility decision for naled.

These risk assessments for naled were presented at an October 13, 1999 Stakeholders Meeting in Orlando, Florida, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's interim risk management decision for naled only. The Agency must consider cumulative risks of all the OP pesticides, as well as the contribution of naled exposure to the risks of dichlorvos (DDVP), before any final decisions can be made

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for naled October 12, 1999. (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessment was updated and refined. Major revisions to the human health risk assessment include: review and inclusion of naled specific dislodgeable foliar residue (DFR) data, revised transfer coefficients from the Agricultural Reentry Task Force, and revision of the dermal NOAEL used in the worker risk assessment from 1 mg/kg/day to 10 mg/kg/day based on new data supplied by the registrant.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all submitted toxicity studies, has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of naled can be found in the October 12, 1999 Human Health Risk Assessment and subsequent addenda. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

The Agency has determined that there is evidence of non-carcinogenicity in humans for naled per se (i.e., naled is a Group E chemical). Dichlorvos (DDVP), a metabolite of naled, has been classified as a Group C (possible human) carcinogen. The risks from dichlorvos resulting from naled use will be assessed in the forthcoming dichlorvos interim RED.

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b. FQPA Safety Factor

The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies, and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in these studies. No clinical evidence of behavioral alterations was observed in pups from the two-generation reproduction study in rats. The toxicology data base is complete, and there are no data gaps for the assessment of hazard to infants and children. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

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

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	NOAEL = 1.0 mg/kg/day	cholinergic signs, plasma, and brain ChE inhibition	28 - day oral (MRID 00088871)	100	1X	**0.01 mg/kg/day**
Chronic Dietary	NOAEL = 0.2 mg/kg/day	Brain ChE inhibition	Two year chronic rat gavage study (MRID 00141784)	100	1X	**0.002 mg/kg/day**

Note: UF = 100 fold uncertainty factor that includes a 10X uncertainty for extrapolating from animal toxicity studies to humans and a 10X uncertainty factor to account for differing sensitivities to chemical exposure among humans.

c. Population Adjusted Dose (PAD) and Reference Dose (RfD)

The Population Adjusted Dose (PAD) characterizes the dietary risk of a chemical adjusting the Reference Dose (RfD), either acute or chronic, to account for the FQPA safety factor (RfD/FQPA safety factor). The RfD is an estimate of the level of exposure to a pesticide residue that is believed to have no significant deleterious effects. A 100-fold uncertainty factor is included in the RfD that accounts for uncertainties in extrapolating from animal data to human exposures, and for varying sensitivities among humans to pesticide exposure. In the case of naled, the FQPA safety factor is 1; therefore, the acute and chronic RfD equals the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

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d. Exposure Assumptions

Acute and chronic dietary risk were evaluated with the Dietary Exposure Evaluation Model (DEEM™). DEEM is a dietary exposure analysis system that estimates exposure to foods comprising the diet of the US population in general, also including estimates for many specific population subgroups. DEEM incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91.

The tolerance for naled is stated in terms of combined residues of naled and dichlorvos, expressed as naled equivalents. The acute and chronic anticipated residues are based on that portion of the tolerance level attributed to naled residues (that is to say the contribution of dichlorvos residues to the tolerance expression has been removed). All naled anticipated residues used in the acute and chronic dietary exposure analyses are based on tolerance levels or field trials.

Anticipated residues (ARs) for the chronic dietary analysis are based on average residues of naled and dichlorvos obtained from field trials, corrected by cooking factors where applicable. One half the limit of detection was assumed in calculating ARs if residues were not detectable and the detection limit for the RAC (Raw Agricultural Commodity) was available. If no AR and no detection limits were available, total residues expressed in naled equivalents were apportioned between naled and dichlorvos by extrapolating from data from another RAC. Anticipated residues for cucumbers, melons, pumpkins, peppers, and eggplants were generated by extrapolating from tomato data. Anticipated residues for collards, kale, and Swiss chard were generated by extrapolating from spinach data. Reduction factors for celery, collards, oranges, strawberries, and grapes were available for naled. Where naled reduction factors were not available, reduction factors for dichlorvos were assumed. A reduction factor of 0.1X was applied to all cooked forms of naled for the chronic analysis. There are no PDP (USDA pesticide data program) data for naled because naled breaks down to dichlorvos during the analytical process.

High-end ARs were used in the acute dietary exposure analysis. Field trial residues or the tolerance is generally the high-end residue estimate used in acute risk assessment. Acute ARs were calculated by using the ratios of naled residues and dichlorvos residues to total residues in naled equivalents. This ratio was used to determine an AR for naled *per se*, based on the tolerance level. As field trial data were used in generating the chronic ARs, it is reasonable to assume that the ratios between naled and dichlorvos residues observed in chronic ARs would also be appropriate for use in generating acute ARs. Residues on food items from the mosquitocide (widespread) use of naled were not considered in the naled acute analysis.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. The naled acute dietary risk from food is well below the

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Agency's level of concern; that is, less than 100% of the acute PAD is utilized. The acute dietary exposure and risk estimates do not exceed the Agency's levels of concern. A refined probabilistic (Monte Carlo) acute dietary risk analysis was performed. The acute ARs used in the exposure analysis are based on that portion of the tolerance level attributed to naled residues (i.e., the contribution of dichlorvos residues to the tolerance expression have been removed). At the 99.9th percentile exposure level, the percent of the acute PAD occupied ranged from 18% for the US Population to 39% for children 1-6 years old, the highest exposed subgroup.

Chronic dietary (food) exposure and risk estimates do not exceed the Agency's level of concern. The percent of the chronic PAD occupied ranged from 1.6% for the US Population to 3.2% for children 1-6 years old.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. In the absence of monitoring data for naled the Agency used the screening models SCI-GROW (for ground water) and GENEEC and PRZM/EXAMS (for surface water) to estimate surface water and groundwater concentrations of naled and dichlorvos.

Naled and its degradates are transformed by abiotic hydrolysis, indirect photolysis in water and biodegradation. Volatilization from soils and/or water is the major mode of transport for naled and its bioactive degradate dichlorvos. Under terrestrial, aquatic, and forestry field conditions naled dissipated rapidly with half-lives of less than 2 days. While naled and dichlorvos are potentially mobile in soil, their degradation is rapid and thus residues of naled, dichlorvos, and naled's other degradates should be available for runoff for surface waters for only one or two days post-application. Rapid hydrolysis and even faster biodegradation of these chemicals help decrease the concentration of naled and its degradates available for runoff.

a. Surface Water

The Tier II PRZM-EXAMS screening model is used to estimate the upper-bound concentrations in drinking water derived from surface water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. The acute and chronic estimated surface water concentrations do not exceed the Agency's level of concern for any potentially exposed population subgroup.

b. Ground Water

The SCI-GROW screening model was used to estimate ground water concentrations of naled. Groundwater concentrations do not exceed the Agency's levels of concern for either acute or chronic exposure.

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c. Drinking Water Levels of Comparison (DWLOCs)

A human health DWLOC (Drinking Water Level of Comparison) is the concentration of a pesticide in drinking water which would result in an unacceptable aggregate risk, after having already factored-in all food exposures and other non-occupational exposures for which EPA has reliable data. The Agency's drinking water analysis is summarized here in tables 3 and 4. See the Agency's Human Health Risk Assessment (October 12, 1999) for further details. For both acute and chronic risks, the potential drinking water exposure derived from either ground or surface water is not of concern for all populations. The tables below present the calculations for the acute and chronic drinking water assessments.

Table 3. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	**DWLOC (ppb)**	Ground Water (ppb) (SCI-GROW)	Surface Water (ppb) (PRZM-EXAMS)
U.S. Population	0.01	0.001844	.008156	**285**	0.005	13
Non-nursing infants (< 1 yr)	0.01	0.0022	0.0078	**78**	.005	13
Children 1-6	0.01	0.00382	0.00618	**61**	0.005	13

Acute DWLOC = (acute allowable water exposure x body wt) ÷ (consumption x 10^{-3} mg/μg); where allowable water exposure = acute PAD - acute food exposure (99.9 percentile). Average body weight is assumed to be 70 kg for adult males and 10 kg for children. Average water consumption is 2 liters per day for adults and 1 liter per day for children.

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Table 4. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	**DWLOC (ppb)**	Ground Water (ppb)	Surface Water (ppb) (PRZM-EXAMS)
U.S. Population	0.002	0.000032	.001968	**69**	0.005	0.56
Non-nursing Infants (<1 yr)	0.002	0.000022	.001978	**20**	0.005	0.56
Children 1 - 6	0.002	0.000063	.001937	**19**	0.005	0.56

Chronic DWLOC = (chronic allowable water exposure x body wt) ÷ (consumption x 10^{-3} mg/*u*g); where allowable water exposure = chronic PAD - chronic food exposure (99.9 percentile). Average body weight is assumed to be 70 kg for adult males and 10 kg for children. Average water consumption is 2 liters per day for adults and 1 liter for children.

3. Occupational and Residential Risk

a. Toxicity

All risk estimates for occupational and residential exposures are based on the most current toxicity information available for naled, including a recent 28-day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for naled are listed below in tables 5 and 6. By the oral, dermal, and inhalation exposure routes, technical naled is classified in Toxicity Category II. For eye and dermal irritation, naled is classified in Toxicity Category I. Naled was weakly positive in a guinea pig dermal sensitization study.

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

Assessment	Dose	Endpoint	Study (MRID) *	Absorption factor
Short-and intermediate term dermal	NOAEL = 10 mg/kg/day	Plasma, RBC, and brain ChE inhibition	28-day dermal rat (MRID 45222001)	N/A
Long-term dermal	Oral NOAEL = 0.2 mg/kg/day	Brain ChE inhibition	Chronic oral rat (MRIDs 00141784, 0008887)	21%
Inhalation (all time periods)	NOAEL=0.053 mg/kg/day	Plasma and RBC ChE inhibition	13-week rat inhalation (MRID 0016422)	100%
Non-dietary ingestion - short term (children)	NOAEL = 1.0 mg/kg/day	cholinergic effects and plasma and brain ChE inhibition	28-day oral rat study (MRID 00088871)	100%

* EPA Master Record Identification Number

Table 6. Acute Toxicity Profile for Occupational Exposure for Naled

Route of Exposure	Toxicity Category	MRID
Acute Oral	II	142660
Acute Dermal	II	146493
Acute Inhalation	II	146494
Eye Irritation	I	74826
Dermal Irritation	I	24825
Dermal Sensitizer	N/A	74657

b. Exposure

The Agency has determined that mixers, loaders, applicators, and other handlers may be exposed to naled from the following nine use patterns identified on the naled labels:
(1) mixing/loading liquids, (2) applying with aerial equipment, (3) applying with groundboom equipment, (4) applying with air blast equipment, (5) applying with thermal fog generator, (6) applying with ULV (ultra low volume) cold fog generator, (7) applying by evaporating liquid using a hot plate and pan, (8) flagger (liquids), (9) aerial and ground based ULV mosquitocide application

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Chemical-specific exposure data were not available for naled. In the absence of such data, the Agency estimates exposure using the Pesticide Handlers Exposure Database (PHED). The database uses chemical-specific data (such as application rates) in combination with generic pesticide worker (i.e., applicator, mixer, loader, flagger) exposure estimates. PHED can be used to estimate potential total exposure for a variety of scenarios, including those involving different application techniques (e.g., air blast spraying) and different types of clothing or PPE (personal protective equipment.) The dermal and inhalation exposure estimates generated by the data base are based on actual field monitoring data, which are reported generically (i.e., not chemical-specific). The basic assumption underlying the database is that exposure to pesticide handlers is based on the physical characteristics associated with handling and applying pesticides rather than the chemical properties of the individual active ingredient. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for naled, which is available in the public docket.

Anticipated use pattern, application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on naled labels range from 0.7 to 2.8 pounds of active ingredient per acre in agricultural settings, and from 0.02 pounds to 0.25 pounds of active ingredient per acre (lbs ai/A) in nonagricultural settings (public health). The application rate for almonds was 7.2 lbs ai/A; however, Valent proposed to reduce this rate to 2.8 which was adopted by Amvac in its 1999 end-use label and is reflected in the risk assessment presented here. The Agency typically uses acres treated per day values that are thought to represent eight solid hours of application work for specific types of application equipment. For agricultural uses of naled, EPA assumes the maximum acres treated per day are 350 for aerial applications, 80 for ground boom, and 40 acres per day was used for air blast equipment. For mosquito/black fly uses, EPA estimated 3,000 acres per day were treated for ground applications and 7,500 acres per day for aerial equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection, if needed to reduce exposure. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (margin of exposure) (i.e., going from minimal to maximum levels of protection). An MOE of 100 is the target for naled. MOEs above 100 are considered protective of the health of the handler, reentry worker, or resident.

The lowest tier of PPE is a baseline. If the risk is a concern (i.e., MOEs are less than 100), then increasing levels of risk mitigation (personal protective equipment (PPE) are considered. If MOEs are still less than 100, engineering controls (EC) are applied. This risk assessment does not estimate risk for baseline PPE because the high toxicity of naled will in most cases require at least maximum PPE to have acceptable risks. Following are risk mitigation measures used in this risk assessment:

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Inhalation: Organic vapor respirator (10-fold protection factor)

Baseline PPE: Not used in risk assessment

- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.

Engineering controls: Engineering controls include a closed cab tractor or cockpit for application scenarios, and closed systems for mixing and loading of pesticides. PPE for workers using engineering controls includes long pants, long sleeved shirts and no gloves (except mixer/loaders who wear chemical resistant gloves).

The exposure scenarios for agricultural handlers are sub-chronic, either short-term or intermediate-term. Most crop applications are made 1 - 2 times per year. However the rate per application and number of applications can vary from year to year. Amvac's most recent label (1999) specifies an application range (pints of concentrate per acre) for each crop, and a maximum number of pints that can be applied in one season for each crop. As a result, the number of applications for a crop may vary depending on the rate for an individual application. Brassica crops have the highest potential number of applications and total pounds of active ingredient that could be applied in one season, up to 10 applications of 0.94 lbs ai/A or up to 5 applications of 1.9 lbs ai/A.

Exposure to workers from entering agricultural fields treated with naled were also considered. The only remaining sources of residential exposure are from pet collars impregnated with naled to control fleas, and from wide area applications in residential areas to control mosquitos and black flies for public health reasons.

c. Occupational & Residential Handler Risk Summary

Risks for handlers and residents are expressed as MOEs. MOEs are calculated using toxicity values and estimates of exposure to the individual. An MOE for a specific exposure scenario is then compared to a target MOE for a chemical, in this case 100, to assess the extent of the risk. For naled, an MOE of 100 provides a 100-fold margin of safety for the individual by accounting for the following uncertainties: potential differences among humans (intraspecies variability) in their sensitivity to a chemical; and differences between species, i.e., the test animals and humans (interspecies extrapolation). In the case of naled, both uncertainty factors are 10 resulting in a total uncertainty factor of 100. The MOEs are calculated by dividing the NOAEL by the uncertainty factors (100).

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Risks for handlers were assessed using separate toxicological endpoints for dermal and inhalation exposures and for different levels of protection. Risks are expressed for each exposure and a total is given for the combined dermal and inhalation exposures.

1) Agricultural Handler Risk

Agricultural handlers include those who mix the pesticide, load it into application equipment, and those who apply the pesticide. Table 7 lists the MOEs for various handler exposure scenarios and for different crop groupings. Exposure to an individual can occur dermally and through inhalation. Separate dermal and inhalation MOEs are provided along with a combined total. For purposes of this analysis, it is assumed that mixing and loading of naled are conducted by the same person, so one MOE is provided for both activities. Three mixer/loader exposure scenarios are examined: aerial, groundboom, and air blast. Applicator risk is estimated for aerial equipment, groundboom, air blast and use of hot plate/hot pan in greenhouses. Risk for flagging activities is also provided. MOEs are given for individuals wearing PPE and for individuals protected with engineering controls.

The dermal PPE represents coveralls over long pants, long sleeve shirt, and chemical resistant gloves when using an open mixing/loading system and chemical resistant head gear for air blast applicators. The PPE when using engineering controls represent long pants, long-sleeve shirt, shoes and socks and no gloves. Gloves are not required for applications in an enclosed cab, except when entering and exiting the cab. Chemical resistant gloves are used for closed mixing and enclosed cab air blast, and closed systems (i.e., closed mixing/loading or enclosed cockpit/cabs). Inhalation PPE exposure values are based on an O/V (organic/vapor) respirator with a 10 fold PF (protection factor). Engineering Control values for inhalation exposure are based on no respirators and using closed systems (i.e., closed mixing/loading and enclosed cabs/cockpits). Engineering controls provide greater protection over PPE and result in reduced exposure with corresponding higher MOEs.

EPA's confidence in the PHED exposure estimates vary from medium to high. Confidence in data is primarily based on the number of replicates (measurements) and the quality of the studies from which the measurements are derived. The maximum area treated or maximum volume of spray solution which can be used in a single day is used in exposure calculations. The naled estimates include the refinement of a NOAEL from a new dermal toxicity study, which means that the Agency is not translating from an oral study to estimate risk for short or intermediate term dermal exposure. (The NOAEL changed from 1.0 to 10 mg/kg/day based on a new dermal toxicity study submitted by the registrants.)

In most cases the MOEs are over 100 for agricultural handlers, which means that the Agency does not have a risk concern. However, there are some scenarios with MOEs under 100, even with the use of engineering controls, which require further refinement or characterization, and include: aerial handling (both mixing/loading and applying) for crop groupings B (MOEs of 42 and 56) and D (MOEs of 57 and 77). Crop grouping B includes: broccoli, cabbage, cauliflower, Brussels sprouts, kale, collards, eggplant, pepper, melon, squash, walnut applied at

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1.9 lb ai/acre; and D includes: beans, peas, celery, chard, spinach, seed alfalfa (ID, UT, WA) applied at 1.4 lb ai/acre. Also of concern are aerial mixers/loaders for the E crop grouping with an MOE of 85, and air blast applicators for the A crop grouping with an MOE of 72.

Handlers are exposed to naled in greenhouses through use of hot plates. Handlers pour the recommended amount of naled into a metal pan and then heat it on a hot plate until the liquid vaporizes. The hot plate can be turned on manually or by automatic timer. Handlers would experience both dermal and inhalation exposures. Some naled labels specify that the hot plate must be activated by an automatic timer after all workers have vacated the greenhouse and the greenhouse is locked. However, other labels do not have this requirement. When the hot plate is turned on manually by the handlers, rather than with a timer, the handlers could experience inhalation exposure during the time they remain in the greenhouse. This potential exposure could be quite significant depending on the time involved in filling additional pans with naled and turning on the hot plates.

EPA does not have chemical-specific data to estimate greenhouse handler exposure. Data from PHED for handlers mixing/loading a pesticide in an open system is used. However, the Agency does not have other use-specific information such as the air concentration of naled in the greenhouse over time, after the hot plate is turned on. EPA does not have a concern for the automatic timer scenario because the MOE is estimated to be 800 for combined dermal and inhalation exposures, treating seven greenhouses in one day. This estimate is based on the use of a single layer of clothing, chemical resistant gloves and no respirator. Manual application is a concern for the agency. Even with the use of a 10 fold protection O/V respirator, the inhalation MOE is less than 1 for ½ hour.

In addition to the above uses, a variety of hand-held application methods were discussed in the Agency's 1995 risk assessment, including: greenhouse heat/steam pipe painting use, ready-to-use pump sprayer formulations, wet bait formulations, backpack sprayer, low pressure hand wand, sewage system injection, hand-held sprinkler can and high volume\low pressure lawn sprayer. EPA had concerns for all of these uses at that time with the exception of the low pressure hand wand. These concerns were based on dermal exposure alone. These uses were deleted from Valent and later Amvac labels. Because these have been deleted from labels, the 1999 risk assessment did not include them. EPA has concerns for the risks from these applications, however Amvac is deleting these uses so no further discussion of risk is needed.

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Table 7. Summary of MOE Values for Agricultural Uses of Naled

Exposure Scenario	Maximum acres treated in a day	Crop[1] Grouping/ App rate lbs ai/A	Dermal MOE[2]		Inhalation MOE[2]		Total MOE[2]		Confidence in PHED Estimates
			PPE	Engineering Control	PPE	Engineering Control	PPE	Engineering Control	
Mixer/Loader Exposure									
Mixing All Liquids for Aerial	350	(B) 1.9	43	119	53	66	24	42	High
		(D) 1.4	57	158	66	88	31	57	
		(E) 0.94	85	232	88	133	43	85	
		(G) 0.7	112	322	133	177	61	114	
Mixing All Liquids for Groundboom	80	(B) 1.9	185	500	177	265	90	173	High
		(D) 1.4	250	714	265	530	129	304	
		(E) 0.94	370	1,000	530	589	218	370	
		(G) 0.7	500	1,428	530	883	257	545	
Mixing of Liquids for Air blast	40	(A) 2.8	250	714	265	530	129	304	High
		(C) 1.9	370	1,000	530	589	218	370	
		(F) 0.7	769	2,500	757	1,325	381	866	
Applicator Exposure									
Aerial equipment (liquids)	350	(B) 1.9	No open cockpit uses	210	No open cockpit uses	76	NA	56	Medium
		(D) 1.4		280		106	NA	77	
		(E) 0.94		440		177	NA	126	
		(G) 0.7		580		265	NA	183	
Groundboom (liquids)	80	(B) 1.9	470	640	265	589	170	303	Medium
		(D) 1.4	640	890	530	883	287	447	
		(E) 0.94	930	1,300	757	1,325	413	643	
		(G) 0.7	1200	1,800	883	1,767	517	857	

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Exposure Scenario	Maximum acres treated in a day	Crop[1] Grouping/ App rate lbs ai/A	Dermal MOE[2]		Inhalation MOE[2]		Total MOE[2]		Confidence in PHED Estimates
			PPE	Engineering Control	PPE	Engineering Control	PPE	Engineering Control	
Air blast equipment	40	(A) 2.8	48	385	66	88	28	72	High
		(C) 1.9	71	588	106	133	43	108	
		(F) 0.94	143	1,111	177	265	79	213	
Hot plate/pan (greenhouse)		See text for assessment							
Flagger Exposure									
Liquids	350	(B) 1.9	270	5,400	177	883	107	756	High
		(D) 1.4	350	7,000	265	1,325	150	1,118	
		(E) 0.94	540	10,000	530	1,767	264	1,502	
		(G) 0.7	700	14,000	530	5,300	304	3,851	

[1] Crop groupings are: (A) almond, peach 2.8 lb ai/acre; (B) broccoli, cabbage, cauliflower, Brussels sprouts, kale, collards, eggplant, pepper, melon, squash, walnuts 1.9 lb ai/acre; ©) citrus 1.9 lb ai/acre; (D) beans, peas, celery, chard, spinach, seed alfalfa (ID, UT, WA) 1.4 lb ai/acre; (E) cotton, strawberry, Sugar beets, hops, seed alfalfa (OR), rangeland 0.94 lb ai/acre; (F) grape, walnut 0.94 lb ai/acre; and (G) safflower 0.7 lb ai/acre.

[2] Inhalation PPE exposure values based on an O/V respirator (10 fold PF). Engineering Control values are based on no respirators and using closed systems (i.e., closed mixing/loading and enclosed cabs/cockpits). The dermal PPE represents coveralls over long pants, long sleeve shirt, and chemical resistant gloves using open systems and chemical resistant head gear for air blast applicators. The engineering controls represent long pants, long-sleeve shirt, and no gloves (chemical resistant gloves used for closed mixing and enclosed cab air blast--no data are available for no glove scenarios), and closed systems (i.e., closed mixing/loading or enclosed cockpit/cabs).

2) Mosquito and Blackfly Application

In addition to the agricultural uses of naled, the Agency also assessed the risks associated with the public health use of naled on mosquitos and the use on blackflies. There are four exposure scenarios for this use. These include: 1) mixing/loading liquids for aerial (ULV) applications; 2) mixing/loading liquids for ground-based (ULV) applications; 3) applying aerial ULV sprays; and 4) applying using ULV ground-based foggers.

No data were submitted in support of the naled mosquito/blackfly applications. Additionally, scenario-specific data for these unique types of application are not available in PHED. However, as a range finding assessment, exposure information for the use of agricultural equipment available in PHED were used as a surrogate. The mixing/loading scenarios from the agricultural scenarios are assumed to be representative of the mosquito/blackfly uses (e.g., closed mixing/loading systems). Aerial application data from PHED were used to estimate exposure to pilots making mosquito/black fly applications. However, the Agency has insufficient data to determine if exposures to pilots from agricultural aerial applications are similar to the exposures to pilots applying mosquito control agents. Furthermore, PHED has no data for fogging techniques. In the absence of exposure data for fogging operations, air blast data were substituted. The representativeness of this scenario and pilot exposure must be characterized as very uncertain. Additional data must be collected to better define the potential exposure that the ground-based fogger operator may receive. EPA is developing methodology for conducting these exposure studies and will call in any needed data on a generic basis for all mosquitocide

Risk estimates for handlers of the mosquito/blackfly control uses are presented in Table 8. The quality of the data in the PHED database used in estimating exposure for these uses ranges from medium to high. The Agency has a risk concern for the mosquito/black fly handlers since total MOEs for most of the exposure scenarios are less than 100. In addition, for some scenarios the dermal or inhalation MOE individually is of concern. As for the agricultural handlers, these estimates include the refinement of a NOAEL from a new toxicity study.

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Table 8. Summary of Exposure/Risk for Mosquito/Blackfly Control Uses of Naled

Exposure Scenario	Maximum acres treated in one day	Application Rate (lb ai/A)	Dermal MOE[1]	Inhalation MOE[2]	Total MOE
Mixer/Loader					
Mixing/loading Liquids for Aerial (ULV) for Blackfly and Mosquito Control	7500	0.05	217	120	78
		0.10	109	60	38
		0.25	43	24	15
Mixing/loading Liquids for Ground-based Fogged (ULV) for Blackfly and Mosquito Control	3000	0.05	555	294	192
		0.10	270	147	95
		0.25	109	60	38
Applicator Exposure					
Aerial (ULV) for Blackfly and Mosquito Control	7500	0.05	370	147	105
		0.10	185	73	52
		0.25	77	29	21
Ground-based Fogged (ULV) for Blackfly and Mosquito Control using an air blast sprayer as a surrogate	3000	0.05	244	55	45
		0.10	123	28	23
		0.25	50	11	9

Note: Dermal exposure for mixers/loaders and applicators is based on use of closed mixing/loading and closed cabs/cockpits while wearing long pants, long sleeved shirts, and chemical resistant gloves, except gloves are not used for aerial applicators. Inhalation values are based on a 10 fold protection factor organic/vapor respirator to simulate the scenario.

[1]MOE = NOAEL/Daily Dose (mg/kg/day). Where: dermal NOAEL = 10 mg/kg/day, and inhalation NOAEL = 0.053 mg/kg/day.

[2]Total MOE = 1/((1/dermal MOE) + (1/inhalation MOE)).

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3) Post-Application Occupational Risk

EPA has determined that there is potential exposure to persons entering treated sites (e.g., harvesters) after application is complete. Four post-application studies (i.e., naled residue dissipation) have been submitted, and registrants have participated in the development of data as part of the Agricultural Reentry Task Force (ARTF). The four crop-specific residue studies are used in EPA's risk assessment as surrogates to represent other registered crops that were not monitored. Activity-specific transfer coefficients, developed by the Agricultural Reentry Task Force (ARTF), are used to assess postapplication exposures and risks. Transfer coefficients (Tc) are used to relate the leaf residue values to activity patterns (e.g., harvesting) to estimate potential human exposure.

Transfer coefficients were selected to represent the activities associated with 18 distinct crop/agronomic groupings based on different types of vegetables, trees, berries, vine/trellis crops, field crops, and bunch/bundle crops. Naled uses were identified in 12 of the 18 groupings. The following 12 crop groupings are used to assess the post-application exposures to naled. Within each of the crop groupings several levels of exposure activities have been identified ranging from "low" activities such as weeding and scouting in immature plants to very high activities such as hand harvesting. Only the foliar application rates were used to quantify postapplication exposures. The dormant sprays for peaches and walnuts are not assessed and postapplication exposures are expected to be minimal. The greenhouse vapor treatment was assessed separately.

(1) Low berry;
(2) Bunch/Bundle;
(3) Field row crop, low/medium;
(4) Outdoor grown ornamentals;
(5) Evergreen tree fruit;
(6) Deciduous tree fruit;
(7) Nut trees;
(8) Cucurbit vegetables;
(9) Fruiting vegetables;
(10) Brassica vegetables;
(11) Leafy vegetables; and
(12) Vine & trellis crops.

The post-application monitoring studies submitted provide DFR (dislodgeable foliar residue) data for grapes, oranges, broccoli, and cotton. Because of the absence of additional DFR data for the various other crops treated with naled, the available DFR data are used as surrogate residue values for other crops using best scientific judgement. Uncertainties are introduced into the assessment when crop-specific residues are used to estimate residues from other types of crops, however, it is believed to be more realistic than assuming a default initial residue value based on the application rate and an assumed dissipation rate per day.

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Table 9 summarizes the calculated REIs (restricted entry intervals) that would be needed after application to reach the target MOE of 100 for hand harvesting for the short- and intermediate-term durations. In summary, the potential REIs range from 0 to 2 days based on the short- and intermediate-term dermal toxicity. Because naled is classified in the Tox Category I for primary eye irritation, a minimum REI of 48 hours is needed for all agricultural crops and activities. A 48 hour REI is currently required on Amvac's naled product number 5481-479 label, and EPA's calculations confirm that the 48-hour REI would result in adequate MOEs. Although dichlorvos dislodgeable foliar residues were reported, because naled degrades to dichlorvos, the appropriateness of this REI will be reexamined during the reregistration of dichlorvos. Occupational post-application risk from greenhouse vapor treatment is discussed in a separate section below.

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Table 9. Summary of the Potential Naled REIs for Hand Harvesting[a]

Crop Grouping	Naled Specific Crops [b]	Max Foliar Rate (lb ai/acre)	Potential REIs [c]	MOEs [d]	PHI[e] (days)
Low berry	Strawberries	0.9375	0	340	1
Bunch/Bundle	Hops	0.9375	0	270	7
Field row crops, low/med	Beans, peas, seed alfalfa	1.406	0	120	1
	Cotton	0.9375	0	180	NA
	Safflower	0.703	0	240	30
Outdoor grown ornamentals	Conifers (e.g., Arborvitae), Broadleaf Trees (e.g., Elms), Flowers (e..g, Carnations)	0.9375	1	490	NA
Evergreen tree fruit	Citrus	1.875	1	150	7
Deciduous tree fruit	Peaches	Dormant spray only			
Tree nuts	Almonds	Dormant spray only			
	Walnuts	1.875	0	110	10
Cucurbit vegetables	Squash, melons	1.875	0	100	1
Fruiting vegetables	Eggplant, peppers	1.875	0	250	1
Brassica vegetables	Broccoli, cabbage, cauliflower, Brussels sprouts	1.875	1	340	1
Leafy vegetables	Kale, collards	1.875	0	100	Max 2
	Chard, spinach, celery	1.406	0	140	
Vine & trellis crops	Grapes	0.9375	1 (Cane turning 1)	370 (180 cane)	3

a Results are for the high exposure activity of hand harvesting.

b Surrogate DFR data used for each crop grouping is as follows: Broccoli (CA site) - Low Berry, Ornamentals, and all Vegetable groups; Orange (CA site) - Bunch/Bundle (hops), Evergreen tree fruit, and Walnuts; Cotton (CA site) - Field row crops; and Grape (CA) - Vine & trellis crops. See Table 1 for details on DFR levels and half-life data along with Table 2 for details on transfer coefficients.

c Although the potential REI for some crop groupings is listed as “0" day, naled is a Tox Cat I for eye irritation and a minimum REI of 48 hours will be established. The calculated REI is the number of days needed to reach an MOE of 100, before worker reentry can occur.

d Short- and Intermediate-term dermal NOAEL = 10 mg/kg/day (28-day rat dermal study with a 100 target MOE).

e PHI = Pre harvest interval

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Greenhouse Post-Application Exposures

A potential for both dermal and inhalation post-application exposure exists for greenhouse use scenarios. Workers may initially be exposed when entering the greenhouse to activate ventilation systems and remove the hot pan/ hot plate. After ventilation, workers routinely enter greenhouses to perform a variety of cultural tasks. Handlers in this scenario would experience possible inhalation exposure from the time they enter the greenhouse, while they activate the ventilation system, and until they exit the greenhouse. They would also experience possible dermal exposure, since the vapor may have condensed onto surfaces in the greenhouse, including the ventilation system.

The label specifies that the pan used for the application must be removed from the greenhouse before workers are allowed to enter. Persons removing the pan are defined as handlers under WPS (Worker Protection Standard). Handlers in this scenario would experience possible dermal exposure while handling and disposing of the pans. They would experience possible inhalation exposure, unless the entry to retrieve the pans is delayed until there is adequate ventilation. The WPS establishes ventilation criteria.

EPA expects that the PPE would protect the worker in this scenario provided there is adequate ventilation. The exposure discussion in the above scenario for the ventilation system would also apply to this scenario. Without any other data, this task (removal of the hot plates) should wait until the ventilation is complete, although it is unknown exactly how much protection this would provide for the worker.

Workers reentering treated greenhouses must wait until the building has been adequately ventilated. In the 1999 risk assessment EPA estimated that the dermal MOE would not reach 100 until 32 hours had elapsed following ventilation. EPA has revised its risk estimates for postapplication exposure based on a new dermal toxicity study and new dislodgeable foliar residue data. As a result, the dermal MOEs based on cholinesterase inhibition for greenhouse workers are protective following adequate ventilation. See table 10. However, because naled is classified in Toxicity Category I for dermal and eye irritation, the Agency is concerned about exposure to workers after ventilation has occurred.

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Table 10. Estimates of Exposures of Workers Reentering Greenhouses Treated with Naled

Start Work Period (hrs post aeration)	End Work Period (hrs post aeration)	DFR_{Avg}[a] ($\mu g/cm^2$)	Dermal Exposure[b] (mg/kg/day)	MOE
0	8	0.056	0.045	224
1	9	0.053	0.042	238
2	10	0.050	0.040	252
3	11	0.047	0.037	267
4	12	0.044	0.035	284
5	13	0.042	0.033	301
6	14	0.039	0.031	319
7	15	0.037	0.030	339
8	16	0.035	0.028	359
9	17	0.033	0.026	381
10	18	0.031	0.025	404
11	19	0.029	0.023	429
12	20	0.027	0.022	455

[a] Dislodgeable Foliar Residue (DFR) estimation is based on a study in which naled was applied at 0.9 lb/acre to grapes. Dislodgeable residues declined rapidly over the first three days with apparent first order kinetics described by the equation $DFR = DFR_0e^{-kT}$ where $DFR_0 = 0.17\ \mu g/cm^2$. k = 0.059/hour and T is in hours. In greenhouses, naled is applied at a rate of 1 oz of a 7.5 lb/gal formulation per 10,000 ft^3, or 0.059 lb/10,000ft^3. For a typical greenhouse with a volume of 85,000 ft^3 and floor dimensions of 120 ft x 48 ft, this is equivalent to 0.5 lb/0.13 acre or 3.8 lb/acre. If deposition of naled at 0.9 lb/acre on grapes were normalized to deposition on greenhouse foliage at 3.8 lb/acre, DFR_0 in the decline curve would be 0.7 $\mu g/cm^2$. However, because naled in the greenhouse is generated as a vapor rather than a spray, we assume that deposition on greenhouse foliage will be much less than on grapes. HED has assumed that 90% of naled generated in the greenhouse will be off gassed via the ventilation system and that DFR_0 in the decay curve = 0.07 $\mu g/cm^2$.

[b] Exposures were derived from the equation $T_C x CF x DFR_{Avg}/BW$ where T_C (Transfer Coefficient) = 7,000 cm^2/hr, BW (Body Wt.) = 70 kg and CF (conversion factor) = 0.001 mg/µg. DFR_{Avg}, the average DFR over the exposure period = $(DFR_T - DFR_{T+8})/8k$ where k=0.059/hr. The NOAEL is 10 mg/kg/day from a 28 day dermal study.

4) Residential Post-Application Risk

There are two remaining sources of exposure to residents: pet flea collars; and wide area application for mosquito and black fly control. The only use currently available to consumers is the pet collar; however, all four remaining pet collar product registrations are being voluntarily canceled.

To assess residential (bystander) exposures from the mosquitocide and blackfly uses of naled, EPA considered dermal exposures and incidental oral exposures (hand-to-mouth, object-to-mouth, and ingestion of soil) that could result from deposition of naled on turf. The Agency estimated risks at three different application rates: 0.02, 0.05, and 0.1. EPA did not estimate exposure and risk in residential areas at the highest application rate of 0.25 lbs ai/A because that maximum rate is only used in densely vegetated areas. Dermal MOEs for post-application

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exposure for all aerial mosquito and blackfly application scenarios do not exceed EPA's level of concern. Table 11 summarizes the scenarios and MOEs.

Table 11. Naled Residential Post-application Estimated Risks Resulting from ULV Aerial and Ground-based Fogged Mosquito and Blackfly Applications

Scenario	Individual	Application Rate Per Treatment (lbs ai/A)	MOE[1]
Dermal exposure	Adult	0.02 (Ground)	38,930
		0.05 (Aerial mosquito)	2,870
		0.1 (Aerial blackfly)	1,420
Dermal exposure	Toddler	0.02 (Ground)	23,263
		0.05 (Aerial mosquito)	1,717
		0.1 (Aerial blackfly)	848
Hand-to-Mouth	Toddler	0.02 (Ground)	8,523
		0.05 (Aerial mosquito)	551
		0.1 (Aerial blackfly)	280
Object-to-mouth	Toddler	0.02 (Ground)	2.7×10^5
		0.05 (Aerial mosquito)	18,000
		0.1 (Aerial blackfly)	8,900
Incidental soil ingestion	Toddler	0.02 (Ground)	2×10^7
		0.05 (Aerial mosquito)	1.3×10^6
		0.1 (Aerial blackfly)	6.7×10^5

[1]MOE based on short-term and intermediate dermal NOAEL= 10 mg/kg/day and 1 mg/kg/day subchronic oral rat study. Uncertainty factors for oral and dermal routes are both 100.

Children are exposed to naled from handling pets wearing flea and tick collars. When a flea collar becomes ineffective it is assumed that they are replaced by the owner, so the children in some areas could exposed on a daily basis year round. EPA had concerns about this exposure in its 1999 risk assessment. The four registrations for these collars are being voluntarily canceled by the Sergeant's company addressing any potential risks for this use.

4. Aggregate Risk

The Food Quality Protection Act of 1996 requires EPA to consider all non-occupational sources of exposure, including food and drinking water routes, and residential exposure. For naled, residents are exposed as bystanders to wide area application for mosquito and black fly

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control. There will no longer be an exposure from pet collars after the registrations have been canceled and all remaining collars no longer used by consumers. Generally, combined risks from these exposures must have MOEs greater than 100 to not be of concern to the Agency.

Acute Aggregate Risk Estimates (food and water)

The acute aggregate risk assessment considers acute (single day) food and water exposures. The individual acute dietary (food) risk estimates do not exceed EPA's level of concern. Tier 1 groundwater and tier 2 (PRZM-EXAMS) surface water EEC's do not exceed EPA's acute DWLOCs. Therefore, aggregate acute risk estimates for naled do not exceed EPA's level of concern.

Chronic Aggregate Risk Estimates (food, water and pet uses)

The chronic aggregate risk assessment considers chronic (lifetime) food and water exposures. The chronic dietary (food) risk estimates do not exceed EPA's chronic level of concern. Tier 1 groundwater and Tier 2 (PRZM-EXAMS) surface water EECs (Estimated Environmental Concentration) do not exceed EPA's chronic DWLOCs. Thus, chronic aggregate risk from food and drinking water is not of concern.

The risk from pet collars could be considered a chronic risk. However, because all remaining pet collar products are being canceled this risk has not been aggregated.

Short- and Intermediate-term Aggregate Risk Estimates (food, water, and non-occupational)

The short- and intermediate-term risk assessments consider residential exposures along with average food and water exposure. Short- and intermediate-term residential bystander exposures resulting from wide area mosquito and black fly applications do not exceed EPA's level of concern.

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 chapter, dated November 14, 1997, and an addendum dated March 18, 1999, available in the public docket.

The Agency estimated potential ecological risk to non-target organisms from the use of naled products using information about the toxicity of naled, how pesticide products are used and how naled behaves in the environment. The Agency's ecological risk assessment uses ecological toxicity studies to determine how toxic a pesticide is to certain aquatic animals, birds, mammals, plants for various durations of exposure. EPA then estimates environmental concentrations of the pesticide based on labeled application rates, monitoring data and

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environmental fate characteristics. Exposure is calculated by combining application rates, and chemical specific data such as degradation rates. EPA uses a risk quotient method to estimate risk that compares the toxicity of the compound to the estimated exposure. The risk quotient is then compared to levels of concern for general populations and endangered species to determine whether there is a risk concern and the extent of the concern. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

1) Birds

Based on acute toxicity data, naled is moderately to highly toxic to birds. Avian acute oral studies resulted in LD_{50} values of 36.9 to 64.9 mg/kg. On a subacute dietary basis, naled is slightly toxic to birds. Four studies produced LC_{50} values ranging from 1327 to 2724 ppm. Since naled has uses which involve repeat applications during breeding season, there is potential for repeated exposure to birds. To determine chronic toxicity, EPA used an avian reproduction study in the Mallard duck. The NOAEC is 260 ppm based on reductions in egg production, including: reductions in eggs laid, eggs set, viable embryos, live three week embryos, normal hatchlings, and 14-day old survivors.

Table 12. Avian Acute Toxicity

Species	% A.I.	LD_{50}	Toxicity Category
Mallard duck	93%	52.2 mg/kg	moderately toxic
Canada goose	93%	36.9 mg/kg	highly toxic
Sharp-tailed grouse	93%	64.9 mg/kg	moderately toxic

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Table 13. Avian Subacute Toxicity

Species	% A.I.	LD_{50}	Toxicity Category
Mallard duck	95%	2724 ppm	slightly toxic
Bobwhite quail	95%	2117 ppm	slightly toxic
Ring-necked pheasant	95%	2538 ppm	slightly toxic
Japanese quail	95%	1327 ppm	slightly toxic

2) Mammals

The mammalian data available to the Agency indicate that naled is moderately toxic to mammals on an acute basis, with rat LD_{50} values ranging from 92 to 371 mg/kg. On a chronic basis, a two-generation reproduction study with rats produced parental and progeny NOELs of 90 ppm (6 mg/kg/day).

3) Non-target Insects

Naled is highly toxic to honey bees, based on an acute contact LD_{50} of 0.48 µg ai/bee on *Apis mellifera*. Two additional studies were conducted. Using a 4 lb EC formulation applied at 1 lb ai/A, naled was highly toxic from 1-hour residues while 1-day residues were practically non-toxic to honey bees. The study using the 8 lb EC formulation applied at 0.5 lb ai/A showed that 3-hour residues were low to moderately toxic to the honey bees. These studies show a significant decrease in residual toxicity from 3 to 24 hours post-treatment.

b. Toxicity to Aquatic Animals (Fish and Invertebrate)

Naled is moderately to very highly toxic to freshwater fish on an acute basis, with LC50 values ranging from 87 ppb to 3.3 ppm (See table 14). In addition, an early life stage study shows that growth is impaired in the fathead minnow at concentrations greater than 6.9 ppb. The MATC (Maximum Allowable Toxicant Concentration) based on length and weight is 10 ppb, and the LOEC is 15.0 ppb.

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Table 14. Acute Toxicity for Freshwater Fish

Species	% A.I.	LC_{50}	Toxicity Category
Rainbow trout	90%	195 ppb	Highly toxic
Rainbow trout	90%	345 ppb	Highly toxic
Rainbow trout	Tech.	160 ppb	Highly toxic
Bluegill sunfish	90%	2.2 ppm	Moderately toxic
Cutthroat trout	90%	127 ppb	Highly toxic
Lake trout	90%	87 ppb	Very highly toxic
Fathead minnow	90%	3.3 ppm	Moderately toxic
Channel catfish	90%	710 ppb	Highly toxic
Largemouth bass	90%	1.9 ppm	Moderately toxic

Naled is very highly toxic to freshwater aquatic invertebrates. With LD50s ranging from 18 ppb to 0.3 ppb). A life-cycle study performed with *Daphnia magna* (97.3% ai) shows that length is affected at concentrations of greater than 0.098 ppb. The NOEC is 0.098 ppb, the MATC is 0.13 ppb, and the LOEC (Lowest Observable Effect Concentration) is 0.18 ppb.

Table 15. Acute Toxicity for Freshwater Invertebrates

Species	% A.I.	LC_{50}	Toxicity Category
Daphnia pulex	90%	0.4 ppb	Very highly toxic
Daphnia magna	91.6%	0.3 ppb	Very highly toxic
Simocephalus serrulatus	90%	1.1 ppb	Very highly toxic
Stonefly *(Pteronarycys californica)*	90%	8.0 ppb	Very highly toxic
Scud *(Gammarus fasciatus)*	90%	18 ppb	Very highly toxic

The use of naled on agricultural crops and in mosquito control may result in exposure to the estuarine environment. These studies characterize naled as very highly toxic to estuarine fish and invertebrates. EPA cannot estimate chronic risks to estuarine/marine organisms because of the lack of data, therefore an estuarine/marine fish early life stage study and an estuarine/marine invertebrate life cycle study using naled are being required.

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Table 16. Acute Toxicity for Estuarine/Marine Animals

Species	% A.I.	LC_{50}	Toxicity Category
Sheepshead minnow	90%	1.2 ppm	Moderately toxic
Grass shrimp	90%	92 ppb	Very highly toxic
Grass shrimp	90%	9.3 ppb	Very highly toxic
Eastern oyster	90%	0.19 ppm	Highly toxic
Eastern oyster	59.6%	170 ppb	Very highly toxic
Sheepshead minnow	59.5%	1.2 ppm	Moderately toxic
Mysid shrimp	59.6%	8.8 ppb	Very highly toxic

c. Toxicity to Plants

Table 17 summarizes the toxicity of naled to aquatic plants.

Table 17. Aquatic Plant Toxicity Studies

Species	% AI	EC_{50} ppb
Anabaena flos-aquae	94.4	5-day EC_{50} = 640
Skeletonema costatum	94.4	5-day EC_{50} = 15
Navicula pelliculosa	94.4	5-day EC_{50} = 12
Lemna gibba	94.4	> 1.8
Selenastrum capricornutum	94.4	5-day EC_{50} = 20

2. Environmental Fate and Transport

The naled environmental fate data base is adequate to support reregistration eligibility. Since no ground or surface water monitoring data for naled and limited data on its degradates were available to EPA, screening models were used to determine estimated concentrations of naled and dichlorvos in ground and surface water.

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Degradation

Naled and its degradates, dichlorvos and dichloroacetic acid (DCAA), are transformed largely by chemical hydrolysis and biodegradation. Under terrestrial, aquatic and forestry field conditions naled dissipated rapidly with half-lives of less than two days for all three cases. The dissipation of dichlorvos is also rapid.

Mobility

Naled, dichlorvos and DCAA are potentially mobile, however their degradation is rapid and they are not likely to leach into ground water. Substantial amounts of naled are available for runoff to surface waters for only one or two days following application. Rapid hydrolysis and biodegradation help decrease the concentration of naled available for runoff. Both naled and dichlorvos are less mobile in clay-rich soils.

Accumulation

In addition to rapid degradation, naled and its degradates do not persist long, and they have a low bioaccumulation potential.

Transport

Volatilization from soils and/or water is the major mode of transport for naled and its bioactive degradates. There is no evidence of movement by naled or dichlorvos through soil. Major routes of contamination of surface waters by naled are spray drift and direct application for mosquito abatement.

3. Risk to Birds and Mammals

EPA uses a risk quotient method to estimate risk that compares the toxicity of the compound to the estimated exposure. For example, an RQ of 1 for a species means that the environmental concentration of naled is equivalent to a lethal dose for 50% of animals tested. The risk quotient is then compared to levels of concern for general populations and endangered species to determine whether there is a risk concern.

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Table 18. Levels of Concern for Terrestrial Animals (birds and mammals)

Risk	Risk Quotient Calculation	Level of Concern
Acute risk	EEC/LC50 or LD50/day	0.5
Acute restricted use risk	EEC/LC50 or LD50/day	0.2
Acute endangered species	EEC/LC50 or LD50/day	0.1
Chronic	EEC/NOEC	1.0

Birds and mammals will be exposed to naled through the consumption of insect and plant food material containing naled residues and from direct exposure during application. The level of concern (LOC) for acute risk to avian species is exceeded for use on almonds, grapes, cotton, cole crops and seed alfalfa. The chronic avian LOCs are exceeded for almonds, cole, citrus, and seed alfalfa. (See Table 19.)

The LOC for acute and chronic risks to mammals is exceeded for naled use on safflower, grapes, seed alfalfa, citrus, cole crops, and almonds. (See Table 20.) The LOC for the mosquito use is only exceeded for acute risk to mammals. There is potential for chronic risk to mammals because naled may be applied repeatedly and because some of the use sites (citrus, grapes, and seed alfalfa) are high exposure sites for mammals.

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Table 19. Avian Acute and Chronic Risk Quotients for Various Crops

Site/App. Method	App.Rate (lbs.ai/A)	Food Items	Maximum EEC (ppm)	LC50 (ppm)	NOAEC (ppm)	Acute RQ	Chronic RQ
Almonds, aerial	2.8	Short Grass	672	2117	260	0.32[b]	2.58 [d]
		Tall Grass	308	2117	260	0.15[c]	1.18 [d]
		Large Insects	378	2117	260	0.18[c]	1.45 [d]
		Seeds	42	2117	260	0.02	0.16
Grapes/ Cotton, aerial	0.938	Short Grass	225	2117	260	0.11[c]	0.87
		Tall Grass	103	2117	260	0.05	0.40
		Large Insects	127	2117	260	0.06	0.49
		Seeds	14	2117	260	0.01	0.05
Cole Crops /citrus	1.875	Short Grass	450	2117	260	0.21[b]	1.73[d]
		Tall Grass	206	2117	260	0.09	0.80
		Large insects	253	2117	260	0.12[c]	0.97
		Seeds	28	2117	260	0.01	0.10
Safflower	0.70	Short Grass	168	2117	260	0.08	0.65
		Tall Grass	77	2117	260	0.04	0.30
		Large Insects	95	2117	260	0.04	0.36
		Seeds	11	2117	260	0.00	0.04
Seed Alfalfa .	1.40	Short Grass	336	2117	260	0.15[c]	1.30[d]
		Tall Grass	154	2117	260	0.07	0.60
		Large Insects	189	2117	260	0.09	0.73
		Seeds	21	2117	260	0.01	0.08
Mosquito	0.10	Short Grass	24	2117	260	0.01	0.09
		Tall Grass	11	2117	260	0.01	0.04

[a] Exceeds acute high, acute restricted, and acute endangered species LOCs.
[b] Exceeds acute restricted and acute endangered species LOCs.
[c] Exceeds acute endangered species LOCs.
[d] Exceeds chronic LOCs.

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Table 20. Acute and Chronic Risk to Mammals

CROP	App. Rate lb ai/A	Short Grass EEC	Short Grass RQ		Long Grass EEC	Long Grass RQ		Large insect EEC	Large insect RQ		Seed EEC	Seed RQ	
			Acute	Chr.		Acute	Chr.		Acute	Chr.		Acute	Chr.
Safflower	0.7	168	1.73[a]	1.87[b]	77	0.8[a]	0.86	94.5	0.98[a]	1.05[b]	10.5	0.02	0.12
Grapes	0.9	225.12	2.3[a]	2.50[b]	103	1.07[a]	1.15	126	1.3[a]	1.41[b]	14.0	0.03	0.16
Seed Alfalfa	1.4	336	3.47[a]	3.73[b]	154	1.59[a]	1.7[b]	189	1.95[a]	2.1[b]	21.0	0.05	0.23
Citrus/ Cole	1.9	456	4.7[a]	5.07[b]	209	2.16[a]	2.32[b]	256	2.65[a]	2.85[b]	28	0.07	0.23
Almonds	2.8	672	6.94[a]	7.47[b]	308	3.18[a]	3.42[b]	378	3.9[a]	4.20[b]	42	0.10	0.47
Mosquito	0.10	24	0.25[a]	0.27	11	.11	0.12[a]	13.50	.14[a]	0.15	1.50	0.00	0.02

[a] LOC is exceeded for acute risk to mammals
[b] LOC is exceeded for chronic risk to mammals
Acute RQ = EEC/LC50 (EEC/92mg/kg * %body weight)
Chronic RQ = EEC/NOEC (EEC/90 ppm)

4. Risk to Aquatic Species

Fish and aquatic invertebrates will be exposed to naled through drift and runoff from treated areas (from aerial and ground application) and through direct exposure of wetlands and aquatic habitats from mosquito/black fly control applications.

The acute and chronic LOC's for freshwater fish were not exceeded for any application rate. However, acute and chronic LOC's were exceeded for freshwater invertebrates (See Table 22 and 23).

There are also potential risks to marine fish and invertebrates; however they are not of major concern. The acute RQ for marine invertebrates applying 0.94 lb ai/A on cotton is 0.8. The acute RQ for marine fish is 0.006 (not an LOC exceedance). The EPA does not have sufficient data to estimate chronic risks, so the Agency is calling in additional data. The Agency has determined that crops such as non-Florida citrus, almonds, and cole crops with higher application rates are not generally located adjacent to marine or estuarine environments. Therefore exposures based on use on cotton is the most appropriate scenario for determining, marine and estuarine organisms risk from naled use.

Table 21. Levels of Concern for Freshwater Fish and Invertebrates

Risk	Risk Quotient Calculation	Level of Concern
Acute high risk	EEC/LC50 or EC50	0.5
Acute restricted use risk	EEC/LC50 or EC50	0.2
Acute endangered species	EEC/LC50 or EC50	0.1
Chronic	EEC/MATC or NOEC	1.0

MATC = Maximum Acceptable Toxicant Concentration

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Table 22. Estimated Acute Risk Quotients for Freshwater Organisms

Crop	Appl. Rate lb ai/A (# appls.)	Initial EEC (ppb)	Fish Risk Quotient	Invertebrate Risk Quotient
Safflower	0.7 (6)	1.9	0.01[a]	6.3[b]
Seed Alfalfa	1.4 (3)	3.9	0.02[a]	13.00[b]
Mosquitoes Direct	0.1 (3) 0.25 (5)	0.4 0.9	0.003[a] 0.006[a]	1.3[b] 3.0[b]
Hornflies Direct	0.1 (5)	1.1	0.007[a]	3.7[b]
Grapes	0.9 (6)	5.9	0.04[a]	19.7[b]
Cole Crops	1.9 (5)	12.7	0.08[a]	42.3[b]
Cotton	0.94 (5)	7.0	0.04[a]	23.3[b]
Almonds	2.8 (1)	12.6	0.08[a]	42[b]
Citrus	1.9 (3) 1.9 (7)	11.1	0.07[a]	37.00[b]

[a] The level of concern is **not exceeded** for acute risk to freshwater fish including endangered species
[b] The level of concern is exceeded for acute risk to freshwater invertebrates including endangered species

Table 23. Estimated Chronic Risk Quotients (RQ) for Freshwater Organisms

Crop	Appl. Rate lb ai/A (# appls.)	60-Day EEC (ppb)	21-Day EEC (ppb)	60-day Fish RQ	21-Day Invert RQ
Safflower	0.7 (6)	0.1	0.3	0.006[a]	3.1[b]
Seed Alfalfa	1.4(3)	0.3	0.5	0.02[a]	5.1[b]
Mosquitoes Direct	0.1 (3)	-- --	0.04 0.09	-- --	0.4[a] 0.9[a]
Grapes	0.9 (6)	0.5	0.5	0.03[a]	5.1[b]
Cole Crops	1.9 (5)	0.8	1.1	0.05[a]	11.2[b]
Cotton	0.9 (5)	0.5	0.6	0.03[a]	6.1[b]
Almonds	2.8 (1)	0.6	1	0.04[a]	10.2[b]
Citrus	1.9 (3) 1.9 (7)	0.5	0.9	0.03[a]	9.2[b]

[a] The level of concern is **not exceeded** for chronic risk to freshwater fish
[b] The level of concern is exceeded for chronic risk to freshwater invertebrates

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It should be noted that although multiple applications are allowed under current labeling, usage data indicate that the average number of applications of naled for most agricultural crops is 1-3. Therefore, calculations in the above tables with greater than 3 applications are likely overestimates.

5. Risk to Aquatic Plants

Aquatic plants will be exposed to naled through drift and runoff from treated areas (from aerial and ground application) and through direct exposure of wetlands and aquatic habitats from mosquito/black fly control applications. However, the level of concern for risk to aquatic plants were exceeded only for cole crops and almonds (See Table 24). The RQ's are a function of the estimated environmental concentrations and the most sensitive aquatic plant toxicity endpoint (EC_{50} 12 ppb for *skeletonema costatum*; See Table 17).

Table 24. Estimated Chronic Risk Quotients (RQ) for Aquatic plants

Crop	Appl. Rate lb ai/A (# appls.)	Initial EEC (ppb)	Aquatic Plant RQ[a] EEC/EC_{50}
Safflower	0.7 (6)	1.9	0.16
Seed Alfalfa	1.4 (3)	3.9	0.32
Mosquitoes Direct	0.1 (3) 0.25 (5)	0.4 0.9	0.03 0.07
Hornflies Direct	0.1 (5)	1.1	0.09
Grapes	0.9 (6)	5.9	0.50
Cole Crops	1.9 (5)	12.7	1.05[a]
Cotton	0.94 (5)	7.0	0.58
Almonds	2.8 (1)	12.6	1.05[a]

[a] Exceeds level of concern for risk to aquatic plants.

6. Insects

Data from an acute study shows naled to be highly toxic to honey bees. Data from foliar residue studies showed a significant decrease in residual toxicity from 3 to 24 hours post treatment. Acute risk to bees is anticipated from the use of naled on blooming crops. The extent of the hazard will vary with the application rate, weather conditions and the formulation of the specific product.

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7. Risks to Endangered Species

Endangered species LOCs for naled are exceeded for birds as follows: acute risks to herbivorous birds from all uses except for mosquito control; acute risks to insectivorous birds from the applications on almonds, cole crops and citrus; chronic risks to herbivorous birds from the uses on almonds, cole crops, citrus and seed alfalfa; and chronic risks to insectivorous birds from the use on almonds. Endangered species LOCs for mammals are exceeded as follows: acute risks to herbivorous and insectivorous mammals from all uses, including mosquito control. In addition, seed-eating mammals are at risk from the almond use. Chronic risks are also a concern for herbivorous and insectivorous mammals from all uses except for mosquito control. The chronic risk exceedance for birds and mammals are based on maximum residues following one application and do not include degradation or dissipation of naled in the environment. In addition, endangered terrestrial invertebrates are expected to be at risk from all uses of naled.

There are also risk concerns for endangered aquatic species. Endangered species acute and chronic LOCs are exceeded for freshwater invertebrates from all uses. Naled's use for mosquito control is only an acute risk to freshwater invertebrates. The acute LOC for endangered freshwater fish is only exceeded for the uses on cole crops, citrus, and almonds and to control hornflies. The acute LOC for endangered estuarine invertebrates is only exceeded for the use on cotton; however, there are currently no federally listed endangered/threatened species for this group of animals.

Naled was included in the formal Section 7 consultation with the US Fish and Wildlife Service (USFWS) for the rangeland cluster review in 1984. The Biological Opinion stated that this use of naled would jeopardize the continued existence of 40 species of freshwater fish, 22 species of freshwater mussels, four species of amphibians, one aquatic crustacean and three terrestrial insect species.

Naled was also included in the reinitiated Biological Opinion of 1989 from the USFWS. In this opinion, the Service found jeopardy to six species of amphibians, 32 species of freshwater fish, two species of mussels and five species of freshwater invertebrates from the uses on crops, pasture and rangeland and as a mosquito larvicide. Terrestrial insects were not considered in this opinion. Reasonable and Prudent Alternatives were given for each jeopardized species. Reasonable and Prudent Measures were also given for 55 non-jeopardized species to minimize incidental take of these species. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures and an older approach to consultation which is currently being revised through interagency collaboration.

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

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

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient naled, as well as a naled-specific dietary risk assessment that has not considered the aggregate risk of the naled metabolite, DDVP, which is also a registered pesticide, nor has it considered the cumulative effects of OPs as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient naled, EPA has sufficient information on the human health and ecological effects of naled 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 naled 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) cumulative risk considered for the OPs supports a final reregistration eligibility decision for naled. Label changes are described in Section V. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of naled, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet completed its consideration of cumulative risks for all of the OPs, the Agency is issuing this interim assessment now to identify risk reduction measures that are necessary to support the continued use of naled. Based on its current evaluation of naled alone, the Agency has determined that naled products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant

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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 naled.

At the time that cumulative risks are considered for all OPs, the Agency will address any outstanding risk concerns. For naled, 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 RED for naled after assessing the cumulative risk of the OP 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 OP in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the OPs in as timely a manner as possible.

Because the Agency has not yet considered cumulative risks for all the OPs, this interim RED does not fully satisfy the reassessment of the existing naled food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered cumulative risks, naled tolerances will be reassessed in that light. At that time, the Agency will reassess naled along with the other OP pesticides, including DDVP, 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 naled, 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 at this time do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the RED, that any of the determinations described in this interim RED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this interim RED. Additional risk mitigation might be identified in the future when EPA makes its reregistration eligibility decision for dichlorvos (DDVP).

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket. Some comments were naled specific while others were not-chemical specific. These non-chemical specific comments generally applied to science policy issues affecting the class of OP pesticides. EPA incorporated changes in its risk assessment where appropriate, however they did not significantly change the original risk assessments. EPA's responses to comments are summarized in the docket.

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C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the dietary risks associated with this OP. The assessment was for this individual OP, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the OPs through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of OPs once the methodology is developed and the policy concerning cumulative assessments is resolved. EPA's cumulative methodology is currently available for public comment until March 8, 2002.

EPA has determined that risk from exposure to naled is within its own "risk cup." In other words, if naled did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for naled meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to naled "fit" within the individual risk cup. Therefore, the naled tolerances remain in effect and unchanged except as noted below in Table 25, until a full reassessment of the cumulative risk from all OPs is considered.

b. Tolerance Summary

In the individual assessment for naled, tolerances for residues of naled in/on plant commodities [40 CFR §180.215] are presently expressed in terms of the residues of naled and its conversion product dichlorvos (2,2-dichlorovinyl dimethyl phosphate), expressed as naled. A summary of naled tolerance recommendations is presented in Table 25.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.215 for the following commodities: almonds, hulls; almonds, nutmeat; beans, dry; beans, succulent; broccoli; Brussels sprouts; celery; cottonseed; eggplant; grapefruit; grapes; grass forage; lemons; melons; oranges; peaches; peas, succulent; peppers; spinach (and chard); squash, summer; strawberries; sugar beet roots; sugar beet tops; tangerines; and walnuts.

Sufficient data are also available to support the established tolerances for eggs, milk, and tissues of animals resulting from dietary sources or through exposure via animal premise treatment. However, based on a 1999 reassessment of several pesticides, including naled, EPA

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has determined that there is no reasonable expectation of finite residues of naled on meat, milk, poultry or eggs. (64 *FR* 41933, August 2, 1999.) The Agency published the final revocation for all tolerances related to these commodities on October 5, 2001 (66 *FR* 50829). These uses fall under Category (3) of 40 CFR §180.6 (a), no reasonable expectation of finite residues. Since these tolerances are revoked they are not included in the Tolerance Summary below.

EPA proposed revocation of the following tolerances for naled on February 5, 1998 (63 *FR* 5907) because the food uses associated with those tolerances were no longer supported: rice; mushrooms; cucumbers; legumes, forage; lettuce; pumpkins; squash, winter; tomatoes; and turnip tops. The final revocation for rice and mushroom tolerances was published on October 26, 1998 (63 *FR* 57067). Since these two tolerances are revoked they are not included in the Tolerance Summary below. EPA did not revoke the remaining tolerances because the Agency received comments that they were needed for import purposes, or, in the case of legumes, forage, was needed in the state of Washington. These tolerances will be revoked unless the Agency receives a commitment to submit the necessary data, as required in: "Pesticides; Guidance on Pesticide Import Tolerances and Residue Data for Imported food; Request for Comment" (65 *FR* 35069, June 1, 2000). See http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-01/p13708.htm.

To make sure that the necessary data are submitted, EPA is requiring data for these tolerances without U.S. registrations in its data call in notice in Appendix E. At the same time, EPA is contacting the Canadian and Mexican governments who have expressed interest in retaining these tolerances for import purposes. If no entity supports these tolerances then they will be revoked.

Based on available data, the established tolerances for the following commodities are too high and the tolerance levels may be reduced: beans, dry; beans, succulent; beets, sugar, roots; broccoli; Brussels sprouts; celery; cottonseed; grapes; and peas, succulent.

Additional field residue data are required for the following commodities to determine the appropriate tolerance level: cabbage; cauliflower; collards; and hops. The required data for collards will be translated to kale.

The established 10 ppm crop group tolerance for "legumes, forage" is inappropriate since the registrant does not intend to support naled uses on soybeans, which is the third representative crop of the foliage of legume vegetables group. Therefore, this crop group tolerance should be revoked concomitant with the establishment of individual tolerances for cowpeas, hay; cowpeas, forage; pea, field, vine; and pea, field, hay. The 1999 human health risk assessment for naled stated that a tolerance should be established for "beans, forage" since it was covered by the legumes, forage tolerance. Since then "beans, forage" are no longer considered to be a significant feed item, and as a result no tolerance need be established. If field trial data are not provided for cowpeas, hay; and peas, field, hay, then all naled labels for beans and peas must restrict use to beans and peas for human consumption only.

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The available data for grapefruit, lemons, and oranges suggest that a crop group tolerance of 3.0 ppm for the citrus fruits group is appropriate. The individual tolerances for grapefruit, lemons, oranges, and tangerines should be reassigned concomitant with the establishment of a crop group tolerance for citrus fruits.

The Agency classifies the registered section 24(c) use of naled on alfalfa grown for seed to be a non-food use as long as there is appropriate label language for disposal and record keeping of seed screenings, prohibitions for feeding any portion of the treated plant for food or feed purposes, and the tagging of conditioned seeds which forbids the use of the seeds for human consumption or animal feed. Additionally, the Agency must have evidence that the respective states to which the special local need (SLN) use is registered have adequate regulatory mechanisms in place to enforce these limitations. If there is no evidence of adequate enforcement mechanisms, the alfalfa use will be considered a food use requiring tolerances and supporting residue data.

The established 0.5 ppm tolerance from use of naled for area pest control is adequate. The current tolerance for area pest control should be revised to include residues of dichlorvos as follows:

"A tolerance of 0.5 part per million is established for the pesticide naled and its conversion product 2,2-dichlorovinyl dimethyl phosphate (dichlorvos), expressed as naled equivalents, in or on all RACs, except those otherwise listed in this section, from use of the pesticide for area pest (mosquito and blackfly) control."

EPA usually requires data for cotton gin byproducts as a livestock feed item. Cotton gin byproducts (commonly called gin trash) include the plant residues from ginning cotton and consists of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. A cottonseed processing study contains residue data on ginned cotton lint. The combined residues of naled and dichlorvos (expressed as naled) in/on ginned cottonseed and cotton lint were nondetectable in a foliar application study. In consideration of the nondetectable residues obtained in ginned cotton lint following an exaggerated application rate and a 4-day PHI, EPA is not requiring data for cotton gin byproducts. The registrant should propose a tolerance for cotton gin byproducts.

Adequate processing studies have been submitted for cottonseed, grapes, oranges, and soybeans. The combined residues of naled and dichlorvos are not expected to concentrate in the processed commodities of grapes, oranges, and soybeans, except for orange oil. However, the available orange processing study indicates that residues of dichlorvos concentrated in oil 13X during processing of oil treated with naled; residues of dichlorvos did not concentrate in the citrus processed commodities wet pulp, dried pulp, molasses, and juice. Residues of naled were non-detectable both before and after processing of orange commodities. The Agency previously concluded that for the purposes of establishing tolerances, if appropriate, the combined residues of naled and dichlorvos will be assumed to concentrate 13X during processing of citrus treated with naled. A tolerance should be established at 30 ppm.

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Table 25 Tolerance Summary for Naled

Commodity	Current Tolerance (ppm)	Tolerance Recommendation (ppm)	[*Correct Commodity Definition*]/ Comment
Tolerances Listed Under 40 CFR §180.215			
Almonds (hulls)	0.5	0.5	[*Almond, hulls*]
Almonds (nuts)	0.5	0.5	[*Almond*]
Beans (dry)	0.5	0.05	[*Bean, dry]*
Beans (succulent)	0.5	0.05	[*Bean, succulent]*
Beets, sugar, roots	0.5	0.05	[Beet, *sugar, roots*]
Beets, sugar, tops	0.5	0.5	[Beet, sugar, tops]
Broccoli	1	TBD[1]	
Brussels sprouts	1	TBD[1]	
Cabbage	1	TBD[1]	
Cauliflower	1	TBD[1]	
Celery	3	2	
Collards	3	TBD[1]	
Cottonseed	0.5	0.05	[*Cotton, undelinted seed*]
Cucumbers	0.5	Revoke	The tolerance should be revoked unless registrants or other parties intend to support the use of naled on cucumbers and submit additional data.
Eggplant	0.5	0.5	
Grapefruit	3	Reassign	The tolerance should be reassigned into the crop group tolerance *fruit, citrus, group.*
Grapes	0.5	0.05	[Grape]
Grasses, forage	10	10	[*Grass, forage*]
Hops	0.5	TBD[1]	[*Hop, dried cones]*
Kale	3	TBD[1]	
Legumes, forage	10	Revoke	This crop group tolerance should be revoked concomitant with the establishment of individual tolerances for; beans, hay; peas, field, vines; and peas, field, hay.
Lemons	3	Reassign	The tolerance should be reassigned into the crop group tolerance *fruit, citrus, group.*
Lettuce	1	Revoke	The tolerance should be revoked unless registrants or other parties intend to support the use of naled on lettuce and submit additional data.
Melons	0.5	0.5	[*Melon*]
Oranges	3	Reassign	The tolerance should be reassigned into the crop group tolerance *fruit, citrus, group.*

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Commodity	Current Tolerance (ppm)	Tolerance Recommendation (ppm)	[*Correct Commodity Definition*]/ Comment
Peaches	0.5	0.5	[*Peach*]
Peas (succulent)	0.5	0.05	[*Pea, succulent*]
Peppers	0.5	0.5	[Pepper]
Pumpkins	0.5	TBD[1]	[*Pumpkin*]
Safflower, seed	0.5	0.5	
Spinach	3	3	
Squash, summer	0.5	0.5	
Squash, winter	0.5	TBD[1]	
Strawberries	1	1	[Strawberry]
Swiss chard	3	3	
Tangerines	3	Reassign	The tolerance should be reassigned into the crop group tolerance *fruit, citrus, group.*
Tomatoes	0.5	Revoke	The tolerance should be revoked unless registrants or other parties intend to support the use of naled on tomatoes and submit additional data.
Turnips, tops	3	Revoke	The tolerance should be revoked unless registrants or other parties intend to support the use of naled on turnips and submit additional data.
Walnuts	0.5	0.5	[Walnut]
Tolerances That Need To Be Established Under 40 CFR §180.215			
Cowpea, forage	None	TBD[1]	
Cowpea, hay	None	TBD[1]	
Fruit, citrus, group	None	3	Covers existing grapefruit, lemon, orange, and tangerine tolerances and allows use on other members of the fruit, citrus, group.
Cotton, gin byproducts	None	0.05	
Grass, hay	None	TBD[1]	
Peas, hay	None	1	pea, field, hay
Peas, vines	None	TBD[1]	pea, field, vine
Citrus, oil	None	30	

[1]TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required. AMVAC plans to propose a crop group tolerance for brassica leafy vegetables.

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CODEX Harmonization

There are no Codex (MRLs) Maximum Residue Limits established or proposed for residues of naled. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

Import Tolerances

It is EPA's policy to propose revocation of a tolerance following deletion of a related food use from a registration, or following the cancellation of a related food-use registration. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance on the grounds that the Agency cannot conclude that the tolerance is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy can be found in EPA's guidance on Import Tolerances in the *Federal Register* (65 FR 35069, June 1, 2000).

Parties interested in supporting an existing naled tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

2. Endocrine Disruptor Effects

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

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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, naled may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Risk Mitigation

Sergeant's Pet Products has requested the voluntary cancellation of its four flea collars containing naled, under section 6(f) of FIFRA, in a letter to the Agency dated September 28, 2001. EPA published a notice in the *Federal Register* on January 10, 2002 (67 FR 1348) announcing receipt of the voluntary cancellation of these pet collar products. These were the only remaining naled pet collar products.

In a letter to the Agency dated November 16, 2001, Amvac Chemical Corporation agreed to a number of risk mitigation measures for its naled products. The following is a summary:

1. Require engineering controls (closed mixing/loading and enclosed cabs/cockpits) for all agricultural uses and mosquito/blackfly control. This would not affect greenhouses or handheld applications.

2. Applications and ventilation in greenhouses must be activated automatically.

3. Prohibit human flaggers.

4. Reduce maximum application rate for mosquito and black fly use from 0.25 lbs ai/A to 0.1 lbs ai/A.

5. Prohibit hand-held foggers and backpack sprayers

6. Prohibit the following uses:

   - Greenhouse heat/steam pipe painting
   - Use in apartments, motels, hotels, and drive-in theaters
   - Wet and dry bait uses
   - Ready-to-use formulations

7. Prohibit aerial application on almonds and peaches and reduce the application rate for these crops from 2.8 lbs ai/A to 1.875 lbs ai/A.

8. Prohibit all uses in and around the home by residents/homeowners and by professional applicators.

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4. Labels

Label amendments, in addition to the existing label requirements, are necessary for naled products to be eligible for reregistration. Provided the following risk mitigation measures are incorporated in their entirety into labels for naled-containing products, the Agency finds that all currently registered uses of naled, with the exceptions noted in this document, would be eligible for reregistration, pending a cumulative assessment of the OPs. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of mitigation measures.

a. Dietary Risk Mitigation

No label modifications are needed to mitigate dietary risks for naled. However, certain crops, as discussed in the tolerance summary section above, should be deleted from the label and tolerances revoked unless the registrant or other interested parties commit to support use on those crops. These crops include tomatoes, cucumbers, lettuce and turnip tops. In addition, the following crops need new tolerances supported by data - cowpeas, hay; cowpeas, forage; grass, hay; pea, field, hay; pea, field, vines. EPA is concerned about possible residues on food from misapplication in and around food processing establishments. As a result, the following language is needed on labels permitting use in and around food processing establishments:

> "Use in areas where food is processed or prepared is prohibited. For use in non-food areas of food processing establishments including garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas where canned or bottled food is stored."

b. Occupational Risk Mitigation

To mitigate occupational risks from the use of naled, the following measures are necessary and have been agreed to by the registrant:

1. Require closed mixing/loading systems for all agricultural uses (except greenhouses and hand-held application) and public health uses involving control of mosquitos and black flies.

2. Require enclosed cabs for ground application or enclosed cockpits for aerial application, for all agricultural uses and public health uses involving control of mosquitos and black flies.

3. Prohibit manual activation of hotplates.

4. Prohibit manual activation of ventilation equipment in greenhouses.

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5. Delete backpack sprayers and hand-held foggers.

6. Delete the greenhouse heat/steam pipe painting use.

7. Delete use in apartments, motels, hotels and drive-in theaters.

8. Reduce the maximum application rate for use on almonds and peaches to 1.875 lbs ai/A and prohibit aerial use on almonds and peaches.

9. Prohibit ready to use formulation.

10. Delete wet and dry bait uses.

11. Delete spot treatment for cockroach control.

12. Prohibit human flaggers.

13. Establish 48 hour reentry intervals after application to field crops.

14. Establish 24 hour reentry intervals after application in greenhouses.

c. Residential Risk Mitigation

To mitigate risk to residents and children, the following measures are needed:

1. The sole manufacturer of pet collars (Sergeant's) has requested voluntary cancellation of these uses.

2. Prohibit all residential uses either by resident or professional applicator. Use in residential areas by mosquito control districts would still be allowed.

d. Ecological Risk Mitigation

1. Reduce application rates for control of black fly from 0.25 to 0.1 lbs/ai/A, and reduce rates on peaches and almonds from 2.8 to 1.875 lbs/ai/A.

2. Require buffer zones around permanent bodies of water to reduce runoff.

3. Establish spray setbacks to reduce spray drift for agricultural uses.

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e. Other Labeling

To remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing naled. For the specific labeling statements, refer to Section V of this document.

1) Endangered Species Statement

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

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register in the near future.

2) Spray Drift Management

The Agency is in the process of developing more appropriate label statements for spray, and dust drift control to ensure that public health, and the environment is protected from unreasonable adverse effects. In August 2001, EPA published draft guidance for label statements in a Pesticide Registration (PR) notice ("Draft PR Notice 2001-X") http://www.epa.gov/opppmsd1/PR_Notices/. A *Federal Register* notice was published on August 22, 2001 (http://www.epa.gov/fedrgstr) announcing the availability of this draft guidance for a 90-day public comment period. After receipt, and review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

Until EPA decides upon, and publishes the final label guidance for spray, and dust drift, registrants (and applicants) may choose to use the statements proposed in the draft PR notice.

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

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

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

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

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

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

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

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

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

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

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

For hand-applied products to be applied as sprays:

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

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

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

"Do not allow this product to drift."

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

D. Benefits Assessment

Naled is one of the principal OP insecticides used for adult mosquito control in the United States. It is effective against almost all species of *Aedes, Anopheles, Coquillettidia, Culex, Culiseta, Mansonia*, and *Psorophora*, which comprise the major nuisance and vector mosquito species in the U.S. and elsewhere in the world. In the U.S., naled is an essential pesticide for suppression of the mosquito born encephalitis viruses. It is also used in the U.S. and internationally for mosquito control in emergencies following hurricanes and floods, and in refugee camps for control of mosquito vectors of malaria and dengue and nuisance mosquitos and flies. A new pest, the Asian tiger mosquito, may be a vector for dengue and other diseases. Also a new disease in the U.S., the West Nile Virus, is vectored by mosquito species. Naled is also sold and used in public health vector control programs in Costa Rica, Guatemala, Taiwan, Thailand, and the United Arab Emirates.

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Naled has the advantages of being fast acting, dissipates and degrades very rapidly, and is effective in controlling mosquitoes where resistance to other OPs and synthetic pyrethroids occurs. Mosquitos in some areas have shown resistance to malathion, fenthion, and chlorpyrifos. When such resistance occurs, naled and other chemicals are an effective alternative. The disadvantage of naled is that it is corrosive to application equipment, which limits its use to aerial ultra low volume (ULV) applications with specialized corrosion resistant equipment. Naled can be irritating to humans, either from inhalation of the droplet mist at close range from the output of ground ULV equipment or from eye exposure to ULV droplets. The probability of this irritation occurring is reduced when the application output point is elevated or by mechanical introduction of air by turbine or fan to dilute the ULV output. Thus, aerial application of naled diminishes the irritability caused by this material. Local mosquito control districts tailor ground and aerial spraying to the locality to be sprayed based on documented resistence and the other factor noted above.

Considering that mosquito vectored diseases are prevalent and increasing throughout the tropics and subtropics, and that parts of the U.S. are subtropical (i.e. Florida), there is a probability that large outbreaks of these diseases could occur in the absence of adequate mosquito control. Naled has been described by the CDC (Center for Disease Control) as one of the principal pesticides used for adult mosquito control in the U.S. The Agency concludes that the current uses of naled in controlling mosquitos have a significant health benefit.

E. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

1) Acute Dietary (Food)

No mitigation is necessary for acute dietary exposure. The acute dietary risk (food) of naled is below the Agency's level of concern for the general U.S. population and all subgroups, including infants and children at the 99.9 percentile. The most highly exposed subgroup is children 1 - 6 years old at 39% of the acute population adjusted dose.

2) Chronic Dietary (Food)

No mitigation is necessary for chronic dietary exposure. The chronic dietary risk (food) of naled is below the Agency's level of concern for the general U.S. population and all

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subgroups, including infants and children at the 99.9 percentile. The most highly exposed subgroup is children 1 - 6 years old at 3.2% of the chronic Population Adjusted Dose (cPAD).

3) Drinking Water

No mitigation is necessary for drinking water exposure. The potential combined drinking water exposure from ground and surface water is not of concern for all populations. The DWLOC (61 ppb) for the most highly exposed subgroup (children 1 - 6) was not exceeded by the maximum anticipated acute exposure of 13 ppb. Also the DWLOC (19 ppb) for children 1 - 6 was not exceeded by calculated maximum anticipated chronic exposure of 0.56 ppb. In addition, the estimated concentration in groundwater is 0.005 for both acute and chronic exposures, well below the DWLOCs.

b. Occupational Risk Mitigation - Agricultural

Table 26 revises the MOEs presented in Table 7, based on several factors: 1) lower application rates for almonds and peaches (from 2.8 lbs ai/acre to 1.9 lbs ai/acre); 2) a 10 percent reduction in dermal exposure because the body weight to surface area ratio is not physiologically matched in that the surface area is for an average male while the body weight is the median for both male/female. The reduction factor would increase the dermal MOEs. 3) EPA has agreed to use the NAFTA (North American Free Trade Agreement) recommended values for breathing rate rather than the existing rates used by EPA, because these NAFTA rates take into account the fact that some worker activities are more strenuous than others. These new rates result in increases in the inhalation MOEs in Table 7 and are reflected in Table 26. Inhalation MOEs were increased by the following factors: 3.5 for tractor drivers and pilots, and 1.7 for mixer/loaders.

1) Mixer/Loaders

EPA has concerns for mixers/loaders for aerial applications. In Table 7, risks for mixers/loaders with double layers of clothing and a respirator exceed the Agency's level of concern for all crops, with MOEs of 24, 31, 43, and 61 for four crop groupings. As a result, the Agency has determined that closed mixing and loading systems are needed to mitigate these risks. Amvac and the Agency have agreed to limit all mixing/loading to closed systems after July 30, 2003. With this mitigation, and the new NAFTA breathing rates MOEs for these crop groupings increase to: 61, 81, 120 and 163.

Even with the above refinements and risk mitigation, two of the higher rate crop groups still exceed the Agency's level of concern, at 61 and 81. These MOEs reflect mixing and loading for aerial application to cole crops and beans, peas, chard, spinach and alfalfa seed. These are all minor uses with low percent crop treated. Furthermore, aerial is not the most common method of application for these crops. Hence, it is unlikely that a worker would be mixing and loading for 350 acres a day, or that he would be handling naled every day for 7 or more days at these rates.

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Until closed systems are required current PPE including double layers of clothing and a respirator should be retained.

Although the Agency does not have a concern for mixer/loader exposure for airblast and groundboom application, closed mixing/loading systems are still warranted for all aerial and ground application equipment for the following reasons: 1) naled is in toxicity category I for dermal and eye irritation and toxicity category II for acute oral, dermal, and inhalation exposure; (Any accidents in handling this highly toxic chemical could result in serious injury to the handler); and 2) because of the potential confusion to mixer/loaders resulting from requiring closed systems in some cases and not in others. If the manufacturer only produces naled in closed system compatible packaging, then there will be no confusion for distributors and handlers and there will be no need for users to maintain a supply of two different types of containers.

2) Applicators

EPA has concerns over risks to agricultural applicators using air blast equipment. As indicated in Table 7, all three crop groupings exceed the Agency's level of concern with double layers of clothing and a respirator (MOEs are 28, 43, and 79). Even with the inclusion of two correction factors explained earlier, two crop grouping still have MOEs of 59 and 65. Only with the use of enclosed cabs on application equipment will adequate protection for the applicator be achieved. The new MOEs with mitigation and correction factors are 210, 271, and 530. Until closed cab application methods are required, current PPE including double layers of clothing and a respirator should be retained.

Because of naled's high toxicity and to eliminate confusion over the need for closed cabs in different situations, the Agency has determined that closed cabs are necessary to reduce exposure to the applicator. The registrant, Amvac, and EPA have agreed to limit all agricultural and mosquito/black fly applications to closed cab/closed cockpit equipment starting with the 2004 application season, with the appropriate label language included on all naled products produced after December 31, 2003. For agricultural uses the enclosed cab must meet standards only for dermal protection.

EPA also has concerns over application with aerial equipment with MOEs of 56, 77, and 126 with closed cockpits. However, after incorporating the correction factors for body weight/surface area ratio and NAFTA breathing rates, these risks are no longer of concern. Closed cockpits are necessary for agricultural uses because the MOEs would be much lower with open cockpits. This requirement is on Amvac's current label and should remain.

Naled is applied in a greenhouse by evaporating the pesticide in a pan over a hot plate. Although EPA does not have data to estimate applicator exposure, the resulting inhalation exposure from turning on hot plates manually results in unnecessary exposure to the applicator. In addition, entering the greenhouse to activate the ventilation system after application is also an unnecessary source of exposure. The Agency believes that automatic activation of the hot plate

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after all individuals have left the greenhouse is protective. Amvac has incorporated this requirement in its registered product (EPA registration 5481-479).

EPA is very concerned about hand-held application, because of naled's high toxicity. There is potential for high exposure from open mixing/loading and applying naled in a manner close to the body. Some scenarios such as the hand held fogger and backpack sprayer have very low MOEs, and Amvac has requested deletion of these methods. However, the Agency is still concerned about other hand-held uses. Maximum PPE will be needed for any remaining hand-held application methods.

3) Flaggers

Amvac has agreed to prohibit the use of human flaggers.

c. Occupational Risk Mitigation - Mosquito and Blackfly Control

Some risks for mixing/loading and applying naled for mosquito/blackfly control exceed the agency's level of concern even with the assumption that closed/mixing loading, and closed cabs or cockpits are used for application. The Agency continues to have concerns over these risks, however there are high public health benefits from the use of naled for mosquito control. The Agency and Amvac have agreed to limit all mixing/loading to closed systems and applications by motorized equipment to closed cabs or cockpits. Because the mosquito application is made with a ULV or fine mist which stays suspended in the air longer than for agricultural applications, the closed cabs and cockpits must meet the standards for the 10 fold protection organic vapor respirator.

Based on comments from stakeholders indicating their belief that exposure from open cockpit mosquito applications is minimal and that current practices are adequate to protect applicators, EPA will reconsider the closed cockpit requirement if appropriate data are submitted demonstrating that exposure is not of concern. EPA's current estimates are based on data derived from agricultural uses. Until specific data are available, double layers of clothing and a 10 fold protection O/V respirator for ground applications must be retained.

For further information on risk mitigation see PR Notice 2000-9, "Worker Risk Mitigation Measures for OP Pesticides" at the following site: http://www.epa.gov/opppmsd1/PR_Notices/.

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Table 26. Revised MOE Values for Agricultural Uses of Naled

Exposure Scenario	Maximum Acres Treated in One Day	Crop[1] Grouping	Dermal MOE		Inhalation MOE		Total MOE		Confidence in PHED Estimates
			PPE	Control	PPE	Control	PPE	Control	
Mixer/Loader Exposure									
Mixing All Liquids for Aerial	350	(B)	47	132	90	113	31	61	High
		(D)	63	176	113	150	40	81	
		(E)	95	258	150	225	58	120	
		(G)	125	358	225	300	80	163	
Mixing All Liquids for Groundboom	80	(B)	206	555	300	450	122	249	High
		(D)	278	794	451	901	172	422	
		(E)	412	1111	901	1001	283	527	
		(G)	555	1587	901	1502	344	772	
Mixing of Liquids for Air blast	40	(A)	412	1111	901	1001	283	527	High
		(C)	412	1111	901	1001	283	527	
		(F)	854	2778	1287	2253	514	1244	
Applicator Exposure									
Aerial equipment (liquids)	350	(B)	No open cockpit uses	236	No open cockpit uses	265	NA	125	Medium
		(D)		309		371	NA	168	
		(E)		483		618	NA	271	
		(G)		654		928	NA	383	
Groundboom (liquids)	80	(B)	529	694	928	2061	337	519	Medium
		(D)	694	1010	1855	3091	505	761	
		(E)	1010	1388	2650	4638	731	1069	
		(G)	1389	1851	3092	6183	958	1425	
Air blast equipment	40	(A)	79	654	232	309	59	210	High
		(C)	79	654	371	464	65	271	
		(F)	158	1234	618	928	126	530	

[1] Crop groupings are: (A) almond, peach 1.9 lb ai/acre; (B) broccoli, cabbage, cauliflower, Brussels sprouts, kale, collards, eggplant, pepper, melon, squash, walnuts 1.9 lb ai/acre; (C) citrus 1.9 lb ai/acre; (D) beans, peas, celery, chard, spinach, seed alfalfa (ID, UT, WA) 1.4 lb ai/acre; (E) cotton, strawberry, sugar beets, hops, seed alfalfa (OR), rangeland 0.94 lb ai/acre; (F) grape, walnut 0.94 lb ai/acre; and (G) safflower 0.7 lb ai/acre.

Table 27 Revised MOEs for Mosquito/Blackfly Control Uses of Naled

Exposure Scenario	Maximum Acres Treated in One Day	Application Rate (lb ai/A)	Dermal MOE	Inhalation MOE	Total MOE
Mixer/Loader					
Mixing/loading Liquids for Aerial (ULV) for Blackfly and Mosquito Control	7500	0.05	241	204	110
		0.10	121	102	55
Mixing/loading Liquids for Ground-based Fogged (ULV) for Blackfly and Mosquito Control	3000	0.05	617	500	276
		0.10	300	250	136
Applicator					
Aerial (ULV) for Blackfly and Mosquito Control	7500	0.05	411	515	228
		0.10	206	256	114
Ground-based Fogged (ULV) for Blackfly and Mosquito Control using an air blast sprayer as a surrogate	3000	0.05	271	193	113
		0.10	137	98	57

d. Occupational post-application risk

EPA estimated the potential restricted entry intervals REIs for hand-harvesting for outdoor crops the short- and intermediate-term durations, ranging from 0 to 1 days based on the short- and intermediate-term dermal toxicity due to cholinesterase inhibition. Naled is classified in the Tox Category I for primary eye and dermal irritation which can result in serious injury to the worker. The current 48 hour REI should be retained for all crops and activities. The 48 hour REI is based on the WPS guidance for Tox Category I eye-irritating pesticides.

For the post-application assessment, dichlorvos dislodgeable foliar residues were reported, because naled degrades to dichlorvos. Risks from these residues will be examined during the reregistration for dichlorvos.

Occupational risk due to greenhouse vapor treatment can occur from activating the ventilation system, and from a variety of post-application activities. Amvac's current end-use label 5481-479 requires the use of automatic activation of ventilation systems, which eliminates this source of exposure. This requirement must be retained. Although the MOEs for dermal

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exposure are not of concern immediately following ventilation, EPA is still concerned about eye and dermal irritation, and inhalation exposure from vapors remaining in the greenhouse. It is also possible that vapors could condense and revolatilize. EPA believes that retention of the current REI of 24 hours is needed to protect workers. EPA will reconsider this REI if data are submitted characterizing potential sources of exposure following vapor treatment in a greenhouse.

e. Residential Risk Mitigation

1) Handler Risk

Amvac's 1995 technical label allows use in homes, apartments, motels and hotels, although their end use labels are silent on this matter. Amvac has agreed to prohibit use by residents or professional applicators in and around homes and other residential areas such as motels, hotels and apartments.

2) Post-Application Risk

EPA does not have a concern with residential bystander exposure resulting from mosquito/blackfly applications. EPA did not estimate exposure and risk in residential areas at the highest application rate of 0.25 lbs ai/A because that maximum rate is only used in densely vegetated areas. Dermal MOEs for post-application exposure for all aerial mosquito and black-fly application scenarios do not exceed EPA's level of concern. Amvac has agreed to limit mosquito/black fly applications to a maximum of 0.1 lbs ai/A. This will eliminate any potential exposures at the 0.25 rate which could have occurred through accidental or intentional use.

Since Sergeant's is voluntarily canceling all pet collar products, children will not be exposed to naled during/following this use.

2. Environmental Risk Mitigation

The 1997 ecological risk assessment and the 1999 addendum pointed out several areas of environmental risk concerns. In response to these risk concerns, Valent, the previous registrant of naled, made several risk mitigation proposals to the Agency. Amvac has agreed with these measures. Some mitigation measures were included in Amvac's 1999 revision of its major end use label *Dibrom 8 Emulsive* (5481-479) and included:

--reduction in the application rate to almonds from 7.2 lbs ai/acre to 2.8 lbs ai/A (crop with the highest application rate);

-- elimination of aerial applications to almonds and peaches, decreasing the potential for drift;

-- reduction in the number of applications from seven for citrus and six for safflower to three for each crop; and

--reduction in rates on citrus and cole crops in Florida to 0.938 lbs ai/acre.

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These changes reduced risks to birds and mammals and also reduced the amount of naled available for surface water exposure affecting aquatic invertebrates.

In addition Amvac has also agreed with Valent and the Agency to implement additional mitigation measures. These measures include spray drift setbacks, and uncultivated buffer zone of 10 feet. These risk mitigation measures were not taken into consideration in the 1999 revised risk assessment.

The spray drift risk mitigation was based on the recommendations of the Spray Drift Task Force, and includes establishing spray setbacks from surface water of 25 feet for ground applications, 50 - 100 feet for air blast applications, and 150 feet for aerial applications. Air assisted applications (air blast) to tree and vine crops also require nozzle direction restrictions for the outside two rows in orchards and vineyards to limit drift. In addition, a 10-foot uncultivated buffer strip between the cultivated area and aquatic area is required for all agricultural applications to reduce drift and runoff.

Amvac also agreed to make the follow risk mitigation to reduce ecological exposure. These include reducing the maximum mosquito/blackfly rate from 0.25 lbs ai/A to 0.1 lbs ai/A, and reducing the application rate for almonds and peaches by ground application from 2.8 lbs ai/A to 1.875 lbs ai/A. With this reduction, almonds will have the same chronic avian RQs as cole crops and citrus (1.73). This RQ is mitigated to some extent by spray drift measures outlined above and the uncultivated buffer zone, although the reductions are not quantified. Other crops with the same application rate have lower chronic RQs because there are fewer applications per season. Further reductions in this chronic RQ and others would result from one or more of the following: further reducing application rates and number of applications, and increasing the interval between applications.

Acute and chronic risks for aquatic invertebrates still exceed the Agency's level of concern at the application rate of 2.8 lbs ai/acre for almonds. Acute and chronic RQs for this lower rate are still of concern at 42 and 10.2 respectively. Citrus is also a concern with RQs of 37 for acute and 9.2 for chronic. Amvac's proposed rate reduction to 1.875 lbs ai/A will further reduce these RQs.

Aquatic invertebrate risks are not likely to be mitigated further (reduced below the Agency's level of concern) for freshwater and estuarine/marine species on an acute basis and freshwater invertebrate species on a chronic basis. Chronic estuarine/marine invertebrate risks cannot be determined because testing remains unfulfilled. EPA is requiring data to address this data gap (72-4(b) Life cycle-aquatic invertebrates using *Mysid* shrimp). Spray drift management practices outlined on the current label, will reduce estimated concentrations in surface water, thus reducing the degree to which the risk is exceeded. The only recommendation that would further reduce the Agency's concern for aquatic invertebrates, other than reduction in use rates, is to alter the spray drift "setbacks" to include the designation of "properly maintained vegetative buffer strips" and direct the user to USDA's guide titled, "Conservation Buffers to Reduce Pesticide Losses," Natural Resources Conservation Service, March 2000 for further information

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on their design, operation and maintenance. A 10-foot "uncultivated buffer" as indicated on the label will reduce the estimated RQs, further risk reduction could be obtained from a larger buffer adhering to the USDA's buffer practices.

V. What Registrants Need to Do

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

A. Manufacturing-Use Products

1. Basic requirements

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

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

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

b. submit any time extension and/or waiver requests with a full written justification

Within the time limit specified in the generic DCI:

c. cite any existing generic data which address data requirements or submit new generic data responding to the DCI. Please contact Tom Myers at 703-308-8589 with questions regarding reregistration and/or the generic DCI. All materials submitted in response to the generic DCI should be addressed as follows:

By US mail:
Document Processing Desk (DCI/SRRD)
Tom Myers
Chemical Review Manager
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

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2. Additional Generic Data Requirements

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

72-4 (b) Life-cycle Aquatic Invertebrate (Estuarine/Marine, Mysid Shrimp)

72-5 Early life stage-- Fish (Sheepshead Minnow)

171-4 (k) Magnitude of Residue in Plants

Cabbage
Cauliflower
Collards
Cucumbers
Grass Forage and hay (pasture and range)
Lettuce
Pea
Pumpkins
Soybeans
Squash, Winter
tobacco
Tomatoes
Turnip, tops

171-4(l) Magnitude of Residue in Processed Food/Feed
Soybeans
Tomatoes

Also, a DCI was recently sent to registrants of OP pesticides currently registered under FIFRA (August 6, 1999 64 FR 42945-42947, August 18, 1999 64 FR 44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies.

3. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the language contained in Table 28 at the end of this section.

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B. End-Use Products

1. Required submissions

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

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

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

b. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

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

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

c. five copies of the draft label incorporating all label amendments outlined in Table 28 of this document;

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

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

f. the product-specific data responding to the PDCI.

Please contact Karen Jones at 703-308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

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

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

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2. Additional Product-Specific Data Requirements

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

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

3. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 28 at the end of this section.

C. Existing Stocks

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

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

D. Labeling Changes Summary Table

To be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV. The following Table 28 describes how language on the labels should be amended.

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Table 28: Summary of Labeling Changes for Naled		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	This pesticide is toxic to fish, aquatic invertebrates, 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."	Directions for Use

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

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Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the RED (liquid formulations)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers using engineering controls must wear: – long-sleeved shirt and long pants, – socks and shoes, – chemical resistant gloves and apron when mixing or loading." "See engineering controls for additional requirements" "Mixers, loaders, applicators and other handlers using handheld equipment, participating in applications to greenhouses, or engaged in those other handler activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves, -- chemical-resistant footwear plus socks, -- chemical-resistant apron if exposed to the concentrate, -- chemical-resistant headgear for overhead exposure, and -- A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N*, R or P prefilter."	Precautionary Statements Following Hazards to Humans and Domestic Animals.

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Description	Amended Labeling Language	Placement on Label
PPE Requirements continued	**"Exception**: handlers who enter into hot-plate-treated greenhouses to operate ventilation systems or to respond to an emergency and remain in the treated greenhouse for more than **10 consecutive minutes** at any time from when the hot plate is activated and until the required ventilation criterial has been met, must wear a NIOSH-approved respirator that is one of the following types: - a supplied-air respirator (MSHA/NIOSH approval number prefix TC-19C) or - a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F). "*Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation for the respirator filter must be dropped..*	
User Safety Requirements	"Any handler who, due to an emergency or to operate ventilation equipment, enters a greenhouse anytime after the hot plate is activated and before the ventilation criteria have been met must maintain continuous visual or voice contact with another handler. That other handler must have immediate access to the PPE required on this labeling for handlers for which engineering controls are not feasible in the event entry into the treated greenhouse becomes necessary for rescue." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. "Keep and wash PPE separately from other laundry.""Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Immediately following the PPE requirements

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

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Description	Amended Labeling Language	Placement on Label
Engineering Controls (continued)	"Applicators using motorized ground-equipment for ULV mosquito and/or black fly control must use an enclosed cab with a nonporous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. The cab must either have a properly functioning ventilation system that is used and maintained according to the manufacturer's written operating instructions and is declared in writing by the manufacturer or by a governmental agency to provide at least as much protection as the type of respirator listed in the PPE section above **or** the occupant must wear a respirator as specified in the PPE section above. In addition, applicators must: -- wear the personal protective equipment required in the PPE section of this labeling for applicators, -- be provided and have immediately available for use in case of an emergency when they must exit the cab, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible. -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "Handlers performing applications to greenhouses using hotplate fumigation equipment must use a remote control or timing device located outside the treated greenhouse to turn the hotplate equipment on and off. After the start of application and until the ventilation criteria have been met, handlers may enter treated greenhouses only to operate ventilation systems or to respond to an emergency, and must wear the PPE specified in this label for such handlers."	Precautionary Statements: (Immediately following PPE and 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 Engineering Controls (Must be placed in a box.)

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Description	Amended Labeling Language	Placement on Label
Environmental Hazards	"Environmental Hazards:" "This pesticide is toxic to fish, aquatic invertebrates, and wildlife. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply within 24 hours following rainfall or irrigation, or in areas where intense or sustained rainfall is forecasted to occur within 24 hours following application. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow to drift to blooming crops or weeds while bees are actively visiting the treatment area."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval All REI statements currently on labels must be removed and replaced with the requirements specified in the RED.	"**For all applications, except greenhouse hot-plate applications**: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours." "**For greenhouse hot-plate applications:"** "**Entry prohibition period:** Entry (including early entry that would otherwise be permitted under the WPS) by any person -- other than a correctly trained and PPE-equipped applicator who is operating ventilation equipment or responding to an emergency is PROHIBITED in the entire greenhouse (entire enclosed structure/building) from the start of application until the greenhouse is ventilated as follows: (1) 10 air exchanges; (2) 2 hour of mechanical ventilation (fans); or (3) 4 hours of passive (vents) ventilation. Note: the PPE requirements for handlers entering during the entry prohibition period are listed in the label precautionary statements." **"Restricted-entry interval and early-entry restrictions:** Do not enter or allow worker entry into a treated greenhouse following hot-plate applications during the restricted entry interval (REI) of 24 hours. After the initial ventilation criteria have been met, workers who enter the treated greenhouse to perform WPS-permitted early-entry tasks (1) must wear the following early entry PPE: coveralls, waterproof gloves, and protective eyewear AND (2) must work in the naled-treated area for no more than 4 hours in the first 24 hours following application. In addition, when any worker is present in the greenhouse during the 24-hour REI, the greenhouse must be ventilated -- continuously or intermittently -- so that within each hour at least one of the following ventilation criteria has been met: 2 air exchanges or 5 minutes of mechanical (fans) ventilation, or 10 minutes of passive (vents, windows)."	Directions for Use, Agricultural Use Requirements Box

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Description	Amended Labeling Language	Placement on Label
Early Re-entry Personal Protective Equipment established by the RED.	"**For all applications, except greenhouse hot-plate applications**: PPE 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 over long-sleeved shirt and long pants, Chemical-resistant gloves made out of any waterproof material Chemical resistant footwear plus socks Protective eyewear Chemical-resistant headgear (if overhead exposure)"	
Double Notification Statement	"**For all applications, except greenhouse hot-plate applications**: Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." "**For greenhouse hot-plate applications:** Notify workers of the application by warning them orally and by posting fumigant warning signs at all entrances to the greenhouse. The signs must bear the skull and crossbones symbol and state: (1) "Danger/Pellagra"., (2) "Greenhouse under fumigation, DO NOT ENTER/NO ENTRE", (3) the date and time of fumigation. (4) (insert name of product) in use, and (5) name, address and phone number of the applicator. Post the fumigant warning sign instead of the WPS sign for this application, but follow all WPS requirements pertaining to location, legibility, size, and timing of the posting and removal. Once the initial ventilation criteria specified for greenhouse hot-plate applications have been met, then remove all the fumigant warning signs and post WPS warning signs at entrances to the greenhouse for the remainder of the restricted-entry interval."	Directions for Use, Agricultural Use Requirements Box

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Description	Amended Labeling Language	Placement on Label
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." **Application Rate Restrictions *(revise label to reflect the following)*:** The maximum application rate for mosquito/black fly applications is 0.1 lbs ai/A The maximum application rate on almonds is 1.875 lbs. a.i./A The maximum application rate on peaches is 1.875 lbs. a.i./A The maximum application rate on citrus in Florida is .938 lbs. a.i./A The maximum application rate on cole crops in Florida is .938 lab. A.i./A **Aerial Application restrictions:** "Aerial applications to almonds and peaches is prohibited." **Greenhouse Restrictions:** "Manual activation of hotplates and ventilation is prohibited." "Application by heat/steam pipe painting is prohibited" "For use in commercial greenhouses only. Use in residential greenhouses or other indoor plant sites is prohibited." "Do not apply this product to a greenhouse that is attached to another structure, including another greenhouse, unless the greenhouse to be treated is entirely sealed off from the other structures." "Do not apply this product in any greenhouse that is located within 100 feet in any direction of a residential area (e.g., homes, apartments, schools, playgrounds, recreation areas)."	Directions for Use Application Restrictions

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Description	Amended Labeling Language	Placement on Label
Application Restrictions (continued)	**Food Processing Area Prohibitions (replaces current statements)** "Use in areas where food is processed or prepared is prohibited. For use in non-food areas of food processing establishments including garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas where canned or bottled food is stored." **Other Restrictions/Prohibitions (below uses are not eligible and must be removed from the label):** Wet and dry bait uses are prohibited; Spot treatments for cockroach control are prohibited All residential uses either by resident or professional applicator are prohibited (does not apply to wide area mosquito/black fly control) Prohibit use in apartments, motels, hotels, and drive-in theaters;	Directions for Use Application Restrictions
End Use Products Intended for Occupational Use (Non-WPS Mosquito/Black Fly Control Sole Use Products Only)		
Environmental Hazards	"Environmental Hazards:" "This pesticide is toxic to fish, aquatic invertebrates, and wildlife. Before making the first application in a season, consult with the primary State agency responsible for regulating the use of pesticides to determine if permits are required or regulatory mandates exist. Do not apply over water (e.g., lakes, swamps, rivers, permanent streams, natural ponds, marshes or estuaries), except to target areas where mosquitos may rest. Do not contaminate water when disposing of equipment washwaters or rinsate. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. To minimize hazard to bees, avoid applying more than two hours after sunrise or two hours before sunset, limiting application to times when bees are least active.	Precautionary Statements immediately following the User Safety Recommendations
Handler PPE considerations	Same as handler PPE consideration for WPS products (See above table)	Handler PPE

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Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the RED	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "Mixers, loaders and applicators using engineering controls must wear: – long-sleeved shirt and long pants, – socks and shoes, – chemical resistant gloves and apron when mixing or loading. See engineering controls for additional requirements" "Mixers, loaders, applicators and other handlers engaged in those handler activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves, -- chemical-resistant footwear plus socks, -- chemical-resistant apron if exposed to the concentrate, -- chemical-resistant headgear for overhead exposure, and -- A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N*, R or P prefilter." *Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation for the respirator filter must be dropped..*	Precautionary Statements: Immediately following Hazards to Humans and Domestic Animals

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Description	Amended Labeling Language	Placement on Label
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. "Keep and wash PPE separately from other laundry.""Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements.
Engineering Controls	**Engineering Controls"** "Mixers and loaders supporting aerial or ground applications must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people *AND* the system must be functioning properly and must be used and maintained in accordance with the manufacturer's written operating instructions. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 mL. per disconnect point." In addition, mixers and loaders must: -- wear the personal protective equipment required above for mixers/loaders, and -- have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the PPE specified above for handlers engaged in those activities for which use of an engineering control is not possible – if the system operates under pressure, protective eyewear must be worn. "Pilots must use an enclosed cockpit and must wear the PPE specified above for applicators using engineering controls. When entering or leaving an aircraft, handlers must wear chemical resistant gloves of the type specified in the PPE section of this label when entering or leaving an aircraft contaminated by pesticide residues and must store used gloves in a closed, chemical resistant container inside the cockpit. "Applicators using motorized ground-equipment must use an enclosed cab with a nonporous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. The cab must either have a properly functioning ventilation system that is used and maintained according to the manufacturer's written operating instructions and is declared in writing by the manufacturer or by a governmental mental agency to provide at least a as much protection as the type of respirator listed in the PPE above **or** the occupant must wear a respirator as specified in the PPE above.	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

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Description	Amended Labeling Language	Placement on Label
Engineering Controls (continued)	In addition, applicators must: -- wear the personal protective equipment required in the PPE section of this labeling for applicators, -- be provided and have immediately available for use in case of an emergency when they must exit the cab, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible. -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
General Application Restrictions	The maximum application rate for mosquito/black fly applications is 0.1 lbs ai/A. For ground application: - Specify the blower pressure for gas units and rotation speed of sprayer head for electric units. - Restriction against spraying when it is raining. - State the temperature range for effective application (based on efficacy studies and/or physical chemical properties of the formulation. For aerial application: - Specify flow rate (in fl ox and ml/min) at operational pump speed and pump pressure. For electrical atomizing nozzles/units rotation speed of the nozzle sprayer had must be stated. - Sleeves and filters must be changes according to the sprayers manufacturer's recommendations. - The type, composition and number of nozzles on aircraft should be specified. - Spraying over residential settings requires filing a flight plan with the FAA 24 hours before making the aerial application.	Place in the Direction for Use Box.

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Related Documents and How to Access Them

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

The docket initially contained preliminary risk assessments and related documents as of August 7, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on October 21, 1999.

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

VII. Appendices

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Appendix A. Table of Naled Use Patterns Eligible for Reregistration

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Naled Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Crop Uses						
Almonds						
Spray application Dormant/delayed dormant Ground equipment	7.5 lb/gal EC [5481-479]	1.875 lbs/A	1	Not Applicable (NA)	48	Apply during dormant period. Aerial application is prohibited.
Beans (dry and succulent)						
Spray applications Foliar Ground equipment	7.5 lb/gal EC [5481-479]	1.4 lb/A	4 ½ pts/A	7	48	Do not apply within one day of harvest.
Spray applications Foliar Aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A	4 ½ pts/A	7	48	Aerial use limited to CA. Do not apply within one day of harvest
Broccoli						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Brussels sprouts						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Cabbage						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.8 75 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Cauliflower						

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Celery						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.4 lb/A	7 ½ pts/A	7	48	Do not apply within one day of harvest
Collards						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Cotton						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A	5 pts/A	7	48	Do not apply after first bolls open. Do not graze livestock in treated fields.
Eggplant						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A (0.9375 lbs/A in FLA)	6 pts/A	7	48	Do not apply within one day of harvest.
Grapefruit						

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.8 75 lb/A (0.9375 lbs/A in FLA)	6 pts/A	7	48	Do not apply within 7 days of harvest.
Grapes						
Spray applications Foliar Ground equipment	7.5 lb/gal EC [5481-479]	0.61875 lb/A (2/3 pt)	6 pts/A	NS	48	Do not apply withing 10 days of harvest.
Spray applications Prebloom/postbloom Airblast equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A (1 pt)	6 pts	NS	48	Use limited to CA. Do not apply within 10 days of harvest.
Grasses (pasture and rangeland)						
Spray applications to control crop pests Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.1 lb/A	NS	7	48	Animals may be present during foliar applications. Grazing of lactating dairy cattle on treated areas is prohibited.
Hops						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lbs/A	5	14	48	Do not apply within 7 days of harvest.
Kale						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lb/A	10 pts/A	7	48	Apply no more than 1 pt/A in Florida. Do not apply within one day of harvest
Lemon						
Spray applications Foliar	7.5 lb/gal EC [5481-479]	1.875 lb/A (0.9375 lbs/A in	4	NS	48	Do not apply within 7 days of harvest.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Melons (including cantaloupe, honeydew, muskmelon, and watermelon)						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A	2 pts/A	7	48	Do not apply within one day of harvest.
Oranges						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.875 lbs/A (0.9375 lb/A in FLA)	6 pts	7	48	Do not apply within 7 days of harvest.
Peaches						
Spray application Dormant/delayed dormant Ground equipment	7.5 lb/gal EC [5481-479]	1.875 lbs/A	1	NA	N/A	Dormant application
Peppers						
Spray applications Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.8 lb/A (0.9375 lbs/A in FLA)	6 pts	7	48	Do not apply within one day of harvest.
Safflower						
Spray application Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	2.1 lbs/A	2.1 lbs/A	7	48	Do not apply within 30 days of harvest.
Spinach						

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Spray application Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.4 lbs/A	7 ½ pts	7	28	Do not apply within 2 days of harvest.
Squash, summer						
Spray application Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	1.8 lb/A (0.9375 lbs/A in FLA)	6 pts	7	48	Do not apply within one day of harvest.
Strawberries						
Spray application Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A	5 pts/A	7	48	Do not apply within one day of harvest.
Sugar beets						
Spray application Foliar Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.9375 lb/A	5 pts/A	7	48	Do not apply within 2 days of harvest.
Swiss Chard						
Spray application Foliar Ground equipment	7.5 lb/gal EC [5481-479]	1.4 lb/A	7 ½ pints	7	48	Do not apply within 2 days of harvest.
Tangerines						
Spray applications Foliar Ground or aerial equipment	7.2 lb/gal EC [5481-479]	1.8 lb/A (0.9375 lbs/A in FLA)	6 pts	7	48	Do not apply within 7 days of harvest.

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Walnuts						
Spray applications Foliar Ground equipment	7.2 lb/gal EC [5481-479]	1.875 lb/A	NS	7	48	Do not apply within 10 days of harvest. Grazing of livestock in treated groves is prohibited.
Spray applications Foliar Aerial equipment	7.2 lb/gal EC [5481-479]	1.8 lb/A	4 pts	7	48	Use limited to CA. Do not apply within 10 days of harvest. Grazing of livestock in treated groves is prohibited.
Wide Area and General Outdoor Treatments						
Mosquito Abatement and Fly Control						
Spray applications to control pests of humans and animals Cold fog generator, mist blower, or aerial equipment	78% [5481-481]	0.1 lb/A	NS	NS	NS	No PHI has been established. For use only by personnel trained in commercial pest control, public health or pest abatement programs.
Animal Uses						
Dairy barns, livestock barns, pig pens, poultry houses, feed lots, and cattle pens premise treatments						
Space spray application Ground equipment	3.6 lb/gal EC [5481-482]	5 teaspoons of AI	NS	NS	NS	Do not use inside homes or in milk processing rooms.
Feed lots, holding pens, or corral premise treatment						
Space spray application Ground or aerial equipment	7.5 lb/gal EC [5481-479]	0.1 lb/A	NS	NS	48	
Non-food uses						

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Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Restricted Entry Interval (Hours)	Use Limitations
Greenhouse ornamentals						
Vapor treatment with hot plate	7.5 lb/gal EC [5481-479]	1 fl oz per 10,000 cubic feet	Repeat as needed	3	24	
Forest and Shade Trees, Ornamental Shrubs, and flowering plants						
By ground only	7.5 lb/gal EC [5481-479]	1 pt in 100 gals water	Repeat as needed	NS	48	
Food processing plants						
Ground only	7.5 lb/gal EC [5481-479]	2 oz in 2 ½ gals water or 5 pts in 100 gals water	Repeat as needed	5 - 7 days as needed	?	Do not apply in food areas.

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Naled

REQUIREMENT			USE PATT.	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	Old Guid. Number			
830.1550	61-1	Product Identity and Composition	All	43606201
830.1600	61-2a	Start. Mat. & Mnfg. Process	All	00138602, 00138846
830.1670	61-2b	Formation of Impurities	All	43606201
830.1700	62-1	Preliminary Analysis	All	43606201
830.1750	62-2	Certification of limits	All	43606201
830.1800	62-3	Analytical Method	All	43606201
830.6302	63-2	Color	All	00074790
830.6303	63-3	Physical State	All	00074790
830.6304	63-4	Odor	All	00074790
830.7050	None	UV/Visible Absorption	All	data gap
830.7220	63-6	Boiling Point	All	00074653, 00074724, 00074790
830.7300	63-7	Density	All	00138602
830.7840 830.7860	63-8	Solubility	All	00074653, 00074790
830.7950	63-9	Vapor Pressure	All	00074653, 00074790, 45088901, 45088902
830.7370	63-10	Dissociation Constant	All	43753401
830.7550	63-11	Octanol/Water Partition Coefficient	All	00138602
830.7000	63-12	pH	All	00138602
830.6313	63-13	Stability	All	00074653, 00074724, 00074790
830.6314	63-14	Oxidizing/Reducing Action	All	00074790
830.6315	63-15	Flammability	All	43753401
830.6316	63-16	Explodability	All	00074790
830.6317	63-17	Storage Stability	All	00074653
830.7100	63-18	Viscosity	All	00074790
830.6319	63-19	Miscibility	All	00074790
830.6320	63-20	Corrosion characteristics	All	00074790, 00144887

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Data Supporting Guideline Requirements for the Reregistration of Naled				
REQUIREMENT			USE PATT.	**CITATION(S)**
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	A, B	00160000
850.2200	71-2a	Avian Dietary Toxicity - Quail	A, B	00022923
850.2200	71-2b	Avian Dietary Toxicity - Duck	A, B	00022923
850.2400	71-3	Wild Mammal Toxicity	A, B	00142660, 00146498
850.2300	71-4a	Avian Reproduction - Quail	A, B	44517901
850.2300	71-4b	Avian Reproduction - Duck	A, B	44517902
850.1075	72-1a	Fish Toxicity Bluegill	A, B	00160741, 40098001
850.1075	72-1c	Fish Toxicity Rainbow Trout	A, B	00160740, 40098001
850.1010	72-2a	Invertebrate Toxicity	A, B	00097572, 00263578, 40098001
850.1075	72-3a	Estuarine/Marine Toxicity - Fish	A, B	00160746, 42637201
850.1025	72-3b	Estuarine/Marine Toxicity - Mollusk	A, B	00160748, 42751101
850.1035	72-3c	Toxicity - Shrimp	A, B	40098001, 00160747, 42637202
850.1400	72-4a	Fish- Early Life Stage	A, B	42602201
850.1350	72-4b	Aquatic Invertebrate Life Cycle	A, B	42908801 (freshwater) Data Gap for Estuarine/Marine
850.1500	72-5	Estuarine/Marine Life Cycle Fish	A, B	Data Gap
850.3020	141-1	Honey Bee Acute Contact	A, B	00036935, 00060628, 05000837
850.4400	123-2	Aquatic Plant Growth	A, B	42529601, 42529602, 42529603, 42529604, 42529605
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A, B	00142660, 00142665
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A, B	00146493
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B	00146494
870.2400	81-4	Primary Eye Irritation-Rabbit	A, B	00074826
870.2500	81-5	Primary Skin Irritation	A, B	00074825
870.2600	81-6	Dermal Sensitization	A, B	00074657
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A, B	41630701
870.6200	81-8	Acute Neurotoxicity - Rat	A, B	42861301, 43189601
870.3100	82-1a	90-Day Feeding - Rodent	A, B	00088871, 00246496
		90-Day Neurotoxicity-rodent	A, B	43223901
870.3200	82-2	28-Day Dermal - Rabbit/Rat	A, B	00160750, 45222001

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Data Supporting Guideline Requirements for the Reregistration of Naled				
REQUIREMENT			USE PATT.	**CITATION(S)**
870.3465	82-4	90-Day Inhalation-Rat	A, B	00164224, 00265678, 265680
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	A, B	00141784
870.4100	83-1b	Chronic Feeding Toxicity - Non-Rodent (Dog)	A, B	00160751
870.4200	83-2a	Oncogenicity - Rat	A, B	00128701, 00088871, 00141784, 40418901
870.4200	83-2b	Oncogenicity - Mouse	A, B	00141785, 00148569
870.3700	83-3a	Developmental Toxicity - Rat	A, B	00138682, 00144026
870.3700	83-3b	Developmental Toxicity - Rabbit	A, B	00146496
870.3800	83-4	2-Generation Reproduction - Rat	A, B	00146498
870.5140	84-2 (a,b) 84-4	Mutagenicity Studies	A, B	00141571, 00142662, 00142662, 00146497, 00142665
870.7485	85-1	General Metabolism	A, B	00013546, 00074857
870.7600	85-3	Dermal Penetration	A, B	45099301, 45099302
		Domestic Animal Safety		00060430, 00079549
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1a	Foliar Residue Dissipation	A, B	43223901, 43223904, 45276801, 45276802, 45276803
875.2400	133-3	Dermal Passive Dosimetry Exposure	A, B	43223905, 43223906, 43223907
		Tank mixing Data	A, B	42778101
ENVIRONMENTAL FATE				
None	160-5	Chemical Identity	A, B	43606201
835.2120	161-1	Hydrolysis	A, B	40034902, 41354101
835.2240	161-2	Photodegradation - Water	A, B	41310702, 42445103
835.2410	161-3	Photodegradation - Soil	A, B	41310701, 42445104
835.2370	161-4	Photodegradation - Air	A, B	41310703, 42445102
835.4100	162-1	Aerobic Soil Metabolism	A, B	00085408
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	40618201, 41354102, 42445101
835.1240	163-1	Leaching/Adsorption/Desorption	A, B	00161100, 40279200, 40394904, 41354104, 41354105, 41354106
835.6100	164-1	Terrestrial Field Dissipation	A, B	00160040, 40304301, 40494101, 40976401, 40976402, 41354107,
835.1850	165-1	Confined Rotational Crop	A, B	40034905, 40304301, 41354109, 43065101

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Data Supporting Guideline Requirements for the Reregistration of Naled				
REQUIREMENT			USE PATT.	**CITATION(S)**
None	165-4	Bioaccumulation in Fish	A, B	00074643
RESIDUE CHEMISTRY				
None	171-2	Chemical Identity	A, B	43606201
860.1300	171-4a	Nature of Residue - Plants	A, B	00074647, 00074654, 00074836, GS092090, 00154126
860.1300	171-4b	Nature of Residue - Livestock	A, B	00059386, 00074844, GS092091, GS092092, 00126462, 00126463
860.1340	171-4c, d	Residue Analytical Method - Plants and animals	A, B	00073820, 00073821, 00074647, 00074721, 00074725, 00074806, GS092026, 00160765, 40506401, 43189602
860.1380	171-4e	Storage Stability	A, B	00160765,43223908, 43223909
860.1480	171-4j	Magnitude of Residues - Meat/Milk/Poultry /Egg	A, B	GS092026, GS092092, GS092094, GS092095, 00073821 GS092096, 00074692
860.1500	171-4k	Crop Field Trials (Sugar beet tops)	A, B	00073815, 00073819, 00073821, 00074836
860.1500	171-4k	Crop Field Trials (Turnip Tops)	A, B	00073820, data gap
860.1500	171-4k	Crop Field Trials (Celery)	A, B	00073821, 00074722, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Lettuce)	A, B	00073820, 00074807, data gap
860.1500	171-4k	Crop Field Trials (Spinach)	A, B	00073820, 00074722, 43223910
860.1500	171-4k	Crop Field Trials (Swiss Chard)	A, B	00074836
860.1500	171-4k	Crop Field Trials (Broccoli)	A, B	00073820, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Brussels Sprouts)	A, B	00073820, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Cabbage)	A, B	00074836, 00160765, data gap
860.1500	171-4k	Crop Field Trials (Cauliflower)	A, B	00074836, 00160765, data gap
860.1500	171-4k	Crop Field Trials (Collards)	A, B	00073821, 00160765, data gap
860.1500	171-4k	Crop Field Trials (Kale)	A, B	00073821
860.1500	171-4k	Crop Field Trials (Beans)	A, B	00073820, 00073821, 00073846, 00074699, 00074729, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Peas)	A, B	00073846, 00160765, data gap

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Data Supporting Guideline Requirements for the Reregistration of Naled				
REQUIREMENT			USE PATT.	**CITATION(S)**
860.1500	171-4k	Crop Field Trials (Soybeans)	A, B	00073821, 00073846
860.1500	171-4k	Crop Field Trials (Bean vines and hay)	A, B	00073820, 00073821, 00073846, 00074699, 00074729, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Pea vines and hay)	A, B	00073846, 00160765
860.1500	171-4k	Crop Field Trials (Soybean forage and hay)	A, B	00073821, 00073846, data gap
860.1500	171-4k	Crop Field Trials (Eggplant)	A, B	00073820, 00074836, 00075668
860.1500	171-4k	Crop Field Trials (Peppers)	A, B	00073820, 00074836
860.1500	171-4k	Crop Field Trials (Tomatoes)	A, B	00073820, 00074836, 00075668, data gap
860.1500	171-4k	Crop Field Trials (Cucumbers)	A, B	00073820, 00075668, data gap
860.1500	171-4k	Crop Field Trials (Melons)	A, B	00073820
860.1500	171-4k	Crop Field Trials (pumpkins)	A, B	data gap
860.1500	171-4k	Crop Field Trials (Squash, summer)	A, B	00073820
860.1500	171-4k	Crop Field Trials (Squash, winter)	A, B	data gap
860.1500	171-4k	Crop Field Trials (Grapefruit)	A, B	00160765, 40376601
860.1500	171-4k	Crop Field Trials (Lemons)	A, B	00073820, 00160765, 40376601
860.1500	171-4k	Crop Field Trials (Oranges)	A, B	00073820, 00074807, 00160765, 40376601
860.1500	171-4k	Crop Field Trials (Tangerines)	A, B	00160765, 40376601
860.1500	171-4k	Crop Field Trials (Peaches)	A, B	00074836, 00073821
860.1500	171-4k	Crop Field Trials (Grapes)	A, B	00073817, 00073821, 00074728, 00074836, 00160765
860.1500	171-4k	Crop Field Trials (Strawberries)	A, B	00073820, 00160765
860.1500	171-4k	Crop Field Trials (Almonds)	A, B	00073830
860.1500	171-4k	Crop Field Trials (Walnuts)	A, B	00073821
860.1500	171-4k	Crop Field Trials (Rice)	A, B	00074723, 00073820
860.1500	171-4k	Crop Field Trials (Rice Forage and straw)	A, B	00074723, 00073820
860.1500	171-4k	Crop Field Trials (Grass Forage and hay)(Pasture and Range)	A, B	00073816, 00160765, 43536701, data gap
860.1500	171-4k	Crop Field Trials (Alfalfa forage and hay)	A, B	00073816, 00073818, 00073821, 00074836, 40605201

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Data Supporting Guideline Requirements for the Reregistration of Naled				
REQUIREMENT			USE PATT.	**CITATION(S)**
860.1500	171-4k	Crop Field Trials (Cottonseed)	A, B	00073821, 00074700, 00074845, 00160765
860.1500	171-4k	Crop Field Trials (Hops)	A, B	00073846, 43493101
860.1500	171-4k	Crop Field Trials (Mushrooms)	A, B	GS092093
860.1500	171-4k	Crop Field Trials (Safflower seed)	A, B	00073846, 00074845
860.1500	171-4k	Crop Field Trials (Tobacco)	A, B	data gap
860.1500	171-4k	Crop Field Trials (Sugar Beet Roots)	A, B	00073815, 00073819, 00073821, 00074836
860.1520	171-4l	Processed Food (Cottonseed)	A, B	43189606
860.1520	171-4l	Processed Food (Grapes)	A, B	43189603, 43189604, 43189605
860.1520	171-4l	Processed Food (Oranges)	A, B	42262801
860.1520	171-4l	Processed Food (Safflower)	A, B	00073846, 00074845
860.1520	171-4l	Processed Food (Soybeans)	A, B	data gap
860.1520	171-4l	Processed Food (Sugar Beets)	A, B	00073815, 00073819, 00073821, 00074836
860.1520	171-4l	Processed Food (Tomatoes)	A, B	data gap
	171-5	Reduction of Residues	A, B	42529606, 42529607, 42529608, 42529609
	201-1	Droplet Size Spectrum	A, B	43760606, 43760607, 43766502
	202-1	Drift Field Evaluation	A, B	41887501, 43786903

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Appendix C. Technical Support Documents

TECHNICAL SUPPORT DOCUMENTS

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

The docket initially contained preliminary risk assessments and related documents as of December 27, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on October 16, 2000.

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

http://www.epa.gov/pesticides/docket/

These documents include:

HED (Health Effects Division) Documents:

1. Leighton, Tim (USEPA/OPPTS/OPP/HED), Naled Postapplication Assessment Revision, September 19, 2001.

2. Khasawinah, Abdallah (USEPA/OPPTS/OPP/HED), Naled - Report of the Hazard Identification Assessment Review Committee, May 29, 2001.

3. Jaquith, David (USEPA/OPPTS/OPP/HED), Exposure Assessment for Hand Held Fogger Application of Naled, January 9, 2001.

4. Hummel, Susan (USEPA/OPPTS/OPP/HED), Human Health Risk Assessment: Naled. October 13, 1999.

5. Leighton, Tim (USEPA/OPPTS/OPP/HED), Revised Naled Mosquito Control Use Bystander Exposure Assessment for Ground-based and Aerial Applications, September 16, 1999.

6. Jaquith, David (USEPA/OPPTS/OPP/HED), Revised Risk Assessment for Naled: Greenhouse Uses and Further Refinement of Assessment for Pet Collar Uses, February 24, 1999.

7. Perreault, Peg (USEPA/OPPTS/OPP/HED), Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Document for Naled, May 19, 1995.

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EFED (Environmental Fate and Effects Division) Documents:

1. Jenkins, Fred (USEPA/OPPTS/OPP/EFED), Error Correction on Naled Ecological Risk Assessment Document, November 29, 2001.

2. Abel, Sid,(USEPA/OPPTS/OPP/EFED), Review of Naled Label (5481-479) to Assess Risk Management Benefits.

3. Peckenpaugh, Jon (USEPA/OPPTS/OPP/EFED) Naled: Addendum to EFED's Reregistration Chapter, March 18, 1999.

4. Peckenpaugh, Jon (USEPA/OPPTS/OPP/EFED) EFED's Reregistration Chapter for Naled, November 14, 1997.

Other related documents:

1. Myers, Tom (USEPA/OPPTS/OPP/SRRD) Response to Public Comments on the Preliminary Risk Assessment for the Organophosphate Naled, October 5, 1999.

2. Faulkner, John (USEPA/OPPTS/OPP/BEAD) Naled: EPA's Quantitative Usage Analysis, January 20, 1999.

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

GUIDE TO APPENDIX D

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

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

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

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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

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BIBLIOGRAPHY

MRID	CITATION
13546	Casida, J.E.; McBride, L.; Niedermeier, R.P. (1962) Metabolism of 2,2-Dichlorovinyl dimethyl phosphate in relation to residues in milk and mammalian tissues. Journal of Agricultural and Food Chemistry 10(5):370-377. (Also In unpublished submission received Apr 16, 1965 under 5H1748; submitted by Shell Chemical Co., Washington, D.C.; CDL:221616-D)
59386	Casida, J.E.; McBride, L.; Niedermeier, R.P. (1961) Metabolism of O,O-Dimethyl 2,2-dichlorovinyl phosphate (Vapona® or DDVP) in Relation to Residues in Milk and Mammalian Tissues. (Unpublished study received on unknown date under unknown administration number.; prepared by Univ. of Wisconsin, Departments. of Entomology and Dairy Husbandry, submitted by Shell Chemical Co., Washington, D.C.;CDL:120596-C)
60430	Goldenthal, E.I.; Wazeter, F.X.; Jessup, D.C.; et al. (1977) Toxicological Evaluation of Antiflea Collar in Dogs: IRDC No. 259-141. (Compilation; unpublished study received Sep 29, 1978 under 778-42; prepared by International Research and Development Corp., submitted by Miller-Morton Co., Richmond, Va.; CDL:235216-A)
73815	Chevron Chemical Company (1971) Bromide Ion Residues Resulting from the Use of Dibrom® (Naled) on Forage Crops. (Compilation; unpublished study, including test nos. T-2175 and T-2176, received Sep 21, 1972 under 0F0975; CDL:091678-A)
73816	Chevron Chemical Company (1972) Total Bromide Ion Levels in Alfalfa, Pasture and Range Grass. (Compilation; unpublished study received on unknown date under 0F0975; CDL:091678-B)
73817	Chevron Chemical Company (1972) Bromide Ion Concentrations of Grapes Treated with Naled. (Compilation; unpublished study received on unknown date under 0F0975; CDL:091678-C)
73818	Chevron Chemical Company (1971) Residue Data Sheets of Naled on Alfalfa: Test No. T-2177. (Compilation; unpublished study, including test no. T-2178, received Aug 20, 1973 under 0F0975; CDL:091679-E)
73819	Chevron Chemical Company (1971) Residue Data Sheets of Naled on Sugar Beets: Test No. T-2179. (Compilation; unpublished study received Aug 20, 1973 under 0F0975; CDL:091679-F)
73820	Chevron Chemical Company (1966) Dibrom® Naled: The Results of Tests on the Amount of Residue Remaining Including a Description of the Analytical Methods Used. Includes residue methods RM-3 dated Jul 28, 1966, RM-3A dated Aug 18, 1966, RM-3C dated Aug 22, 1966 and RM-3E dated Aug 16, 1966. (Compilation; unpublished study received Sep 20, 1966 under 7F0532; CDL:090647-A)

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73821 Chevron Chemical Company (1970) Dibrom® Naled: The Results of Tests on the Amount of Residue Remaining Including a Description of the Analytical Methods Used. Includes methods RM-3 dated Jul 28, 1966, RM-3A dated Aug 18, 1966 and RM-3G dated Oct 31, 1969.(Compilation; unpublished study received Mar 27, 1970 under 0F0975; CDL:091677-A)

73830 Chevron Chemical Company (1974) Summary of Almond Residue Trials. (Compilation; unpublished study received April 7, 1975 under 5F1614; CDL:094559-B)

73846 Chevron Chemical Company (1970) Dibrom® Naled: The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Methods Used. (Compilation; unpublished study received on unknown date under 1F1078; CDL:093389-B)

74647 Chevron Chemical Company (1966) Analysis of Dibrom® Naled Residues by Acetylcholinesterase Inhibition: File 740.10. Method RM-3 dated Jul 28, 1966. (Compilation; unpublished study received September12, 1966, under 7F0532; CDL:092821-A)

74654 Chevron Chemical Company (1966) Naled: The Degradation and Metabolic Fate in Biological Media. Rev. (Compilation; unpublished study received Sep 12, 1966 under 7F0532; CDL:092821-I)

74657 Rittenhouse, J.R. (1978) The Skin Sensitization Potential of Naled Technical in Guinea Pigs: SOCAL 1293/35:28 (S-1336). (Compilation; unpublished study received Dec 21, 1978 under 239-1633; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:236683-A)

74692 Chevron Chemical Company (1971?) Description of a Residue Test (T-2360) To Determine Bromide Ion Residues in Poultry Tissue and Eggs following the Application of Ortho Fly Killer D (36% Naled) in Poultry Houses and on Laying Hens: File No. 741.11. (Compilation; unpublished study received Mar 4, 1972 under 1F1111; CDL:090881-B)

74699 Kohn, G.K. (1959) Letter sent to G.S. Hensill dated Dec 16, 1959: Dibrom residues--pole beans. (Unpublished study received Jan 14, 1960 under 239-1281; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:119766-A)

74700 Chevron Chemical Company (1965) Dibrom Residues in Spinach, Grain Sorghum and Cotton. (Compilation; unpublished study, Jul 9, 1965 under unknown admin. no.; CDL:124538-A)

74721 Chevron Chemical Company (1957?) Analysis of Dibrom Residues. Undated method RM-III. (Compilation; unpublished study, Feb 19, 1958 under unknown admin. no.; CDL:119738-A)

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Appendix E. Generic Data Call-in

Generic Data Call-in

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

[The following printouts should be included behind this cover page. Use this list for reference only do not include it on the cover page:]

DCI Response

Requirements Status and Registrant's Response

Footnotes and Key Definitions for Guideline Requirements

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Appendix F. Product Specific Data Call-In

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

EPA'S BATCHING OF *NALED* PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing Naled 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.

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Nineteen products were found which contain ***Naled*** as the active ingredient. These products have been placed into **two** batches and a **"No Batch"** category in accordance with the active and inert ingredients and type of formulation.

* Registrants with product EPA Reg. No. 5481-481 may cite the acute toxicity data from Batch 1.

* Registrants with product EPA Reg. No. 2517-44 may cite the acute toxicity data from product EPA Reg. No. 2517-43.

* Registrants with product EPA Reg. No. 2517-46 may cite the acute toxicity data from product EPA Reg. No. 2517-45.

Batch 1	EPA Reg. No.	Percent Naled	Formulation Type
	5481-478	94.5%	Liquid
	5481-480	87.4%	Liquid

Batch 2	EPA Reg. No.	Percent Naled	Formulation Type
	5481-479	62%	Liquid
	2935-284	58%	Liquid
	10163-46	58%	Liquid
	34704-351	58%	Liquid
	34704-546	58%	Liquid
	51036-73	58%	Liquid

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No Batch	EPA Reg. No.	Percent Naled	Formulation Type
	5481-481	78.0	Liquid
	5481-482	36.0	Liquid
	5011-71	20.0	Liquid
	2517-43	15.0	Solid
	2517-45	15.0 Naled 4.2 Propoxur	Solid
	2517-52	15.0 Naled 4.2 Chlorpyrifos	Liquid
	6218-40	15.0	Liquid
	2517-44	10.0	Solid
	5011-60	10.0	Liquid
	2517-46	7.0 Naled 2.4 Propoxur	Solid
	34704-616	1.0	Liquid

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

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

LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

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

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

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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EPA Pesticide Registration Forms

EPA FORM	DESCRIPTION	INTERNET SITE
8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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:

US EPA ARCHIVE DOCUMENT

1. The Office of Pesticide Programs' website.

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

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

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

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

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

   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:

   a. Date of receipt;
   b. EPA identifying number; and
   c. Product Manager assignment.

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

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

Documents Associated with this RED

US EPA ARCHIVE DOCUMENT

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

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.

2. Detailed Label Usage Information System (LUIS) Report.

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